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ORIGINAL ARTICLE

Superior versus anteroinferior plating for mid-shaft clavicle fractures: a randomized clinical trial

Fracturas diafisarias de clavícula manejadas con placa superior versus anterior: ensayo clínico aleatorizado

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Abstract

Background: *Clavicle fractures represent 2.5-4% of all fractures observed in emergency services. 80% occurs in the middle third. Treatment by plating requires a higher level of evidence.* **Objective:** *To compare the functional outcomes of mid-shaft clavicle fractures managed with superior plating compared to anteroinferior plating.* **Trial Design:** *A randomized, double-blind, parallel, superiority clinical trial.* **Patients and methods:** *Patients with fractures of the clavicles AO15B1 and AO15B2 were studied. Patients were randomized to be treated with either 3.5 mm superior or anteroinferior plating. A rehabilitation program was designed for both groups. The primary outcome measure was the Disability of Arm, Shoulder, and Hand (DASH) score; secondary outcomes included pain, union rate, and complication rates.* **Results:** *Twenty-eight patients were studied and were eligible for analysis. Significant differences were found in the function assessed with the DASH score at 30 days for the superior plating compared with anteroinferior (43.74 vs. 29.26, respectively, p = 0.027), 60 days (23.97 vs. 11.18, p = 0.021), and 90 days (9.52 vs. 3.5, p = 0.016). One loosening with superficial infection was found with superior plating.* **Conclusions:** *Using an anteroinferior reconstruction plate in diaphyseal fractures offers better functional results than the upper plate in patients with fractures of the middle third of the clavicle.*

Keywords: *Clavicle. Bone fractures. Surgical technique. Bone plates. Treatment outcome.*

Resumen

Antecedentes: *Las fracturas de clavícula comprenden el 2.5-4% de todas las fracturas observadas en los servicios de emergencia. El 80% se presentan en el tercio medio. La posición de la placa como tratamiento requiere mayor nivel de evidencia.* **Objetivo:** *Comparar los resultados funcionales de las fracturas diafisarias de clavícula manejadas con placa superior versus placa anteroinferior.* **Método:** *Ensayo clínico aleatorizado, doble ciego, paralelo, de superioridad. Se estudiaron pacientes con fractura diafisaria de clavícula AO15B1 y AO15B2. Se manejaron con placa de reconstrucción de 3.5 mm colocada en forma superior o anteroinferior. Se diseñó un programa de rehabilitación para ambos grupos. El resultado primario fue medido con el cuestionario DASH y los resultados secundarios incluyeron dolor, presencia de consolidación y complicaciones.* **Resultados:** *Fueron elegibles para análisis 28 pacientes. Se encontraron diferencias significativas de la escala DASH a los 30 días para la maniobra superior comparada con la inferior (43.74 vs. 29.26, respectivamente; p = 0.027), a los 60 días (23.97 vs. 11.18; p = 0.021) y a los 90 días (9.52 vs. 3.5; p = 0.016).* **Conclusiones:** *El uso de placa de reconstrucción anteroinferior en las fracturas diafisarias ofrece mejores resultados funcionales en comparación con la placa superior en pacientes con fracturas de tercio medio de clavícula.*

Palabras clave: *Clavícula. Fracturas óseas. Técnica quirúrgica. Placas óseas. Resultados de tratamiento.*

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Introduction

Clavicle fractures involve approximately 2.4-4% of all body fractures and represent 44% of shoulder fractures. 80% of these fractures occur in the middle third of the clavicle[1]. This condition is more common in men and occurs most often between the ages of 30 and 70[2]. Clavicle fractures have been treated conservatively for decades, but the increase in pseudoarthrosis has forced to review other treatments[3]. In the '60s, percentages of 0.8-0.13% of pseudoarthrosis were described[4,5]. In the '90s, the frequency of pseudoarthrosis was described as around 13-15%[6,7]. Surgical management of displaced fractures with reconstruction plates, which have acceptable biomechanical resistance[8-10], is currently encouraged. Several publications analyze the advantages of superior and anteroinferior techniques of reconstruction plating for fractures of the mid-shaft of the clavicle, with results based on fracture union and some aspects related to surgical technique[11-13], without measuring clinical outcomes.

The clinical outcomes with superior and anteroinferior plating are very important for the return to daily living activities and the return to work. In countries with emerging economies, where social security services cover periods of paid incapacity, a rapid return to work without relapses or physical restrictions is a priority in terms of the effectiveness and efficiency of the treatment.

The main objective of the present study is to compare the functional outcomes of patients with mid-shaft clavicle fractures managed with 3.5 mm superior reconstruction plating compared to anteroinferior plating. Our research hypothesis is that the anteroinferior reconstruction plating has at least 10% better outcomes measured with the Disability of Arm, Shoulder, and Hand (DASH) score, pain, and complications associated compared with superior reconstruction plating in AO 15B1 and B2 mid-shaft clavicle fractures.

Patients and methods

Study design and ethical approval

Ethical approval for the study was granted by the Local Committee for Research and Research Ethics, registered number R-2017-2105-2, and ClinicalTrials.gov: NCT03533634. Ethical approval was granted for two treatment groups: superior reconstruction plating, considered the "control" or "conventional" surgical management, and anteroinferior reconstruction plating. This is a randomized, parallel, double-blinded clinical trial in patients with AO15B1 and AO15B2 clavicle fractures in a third-level trauma and orthopedics hospital conducted between 2018 and 2020. During the study period, 327 patients were received with clavicle fractures, and 77% had fractures of 15B1 and B2 (Fig. 1). The exclusions were mainly due to the presence of obesity and/or associated comorbidities. When the calculated sample size, the effect size of our research hypothesis, and a statistical power > 0.80 were reached, the Ethics Committee was informed to conclude with recruitment. Patients who met the criteria for inclusion were extensively explained the purpose of the study and its objectives and were invited to participate. Patients had the opportunity to assimilate this information and ask questions before consenting to the trial. Patients who agreed to participate in the study signed informed consent, and their demographic data were collected. A soft sling was placed on the affected side to prevent fracture displacement. The corresponding pre-surgical protocol was carried out (complete blood count, blood chemistry test, prothrombin time, activated partial thromboplastin time test, ABO group, Rh type test, electrocardiogram, and chest X-rays).

Inclusion criteria were patients with isolated mid-shaft clavicle fractures AO15B1 and B2, in the age range of 18-60 years with a closed fracture of traumatic origin with < 7 days of evolution. Patients had to be able to consent to the trial.

Exclusion criteria included poly-trauma, patients with associated systemic diseases, patients with a previously injured shoulder, patients with a body mass index (BMI) > 35, and the inability to give consent.

The primary outcome measure was clinical assessment using the DASH scale, and secondary measures included pain, mobility, loosening of metalwork, and infection.

Randomization

Once the patient met the criteria for inclusion, randomization was performed by using sealed and opaque envelopes containing a sequence of random even and odd numbers in a 1:1 ratio. Even numbers were assigned to anteroinferior management and odd numbers to superior plating. Patients were blinded to their surgical procedure. Randomization was performed

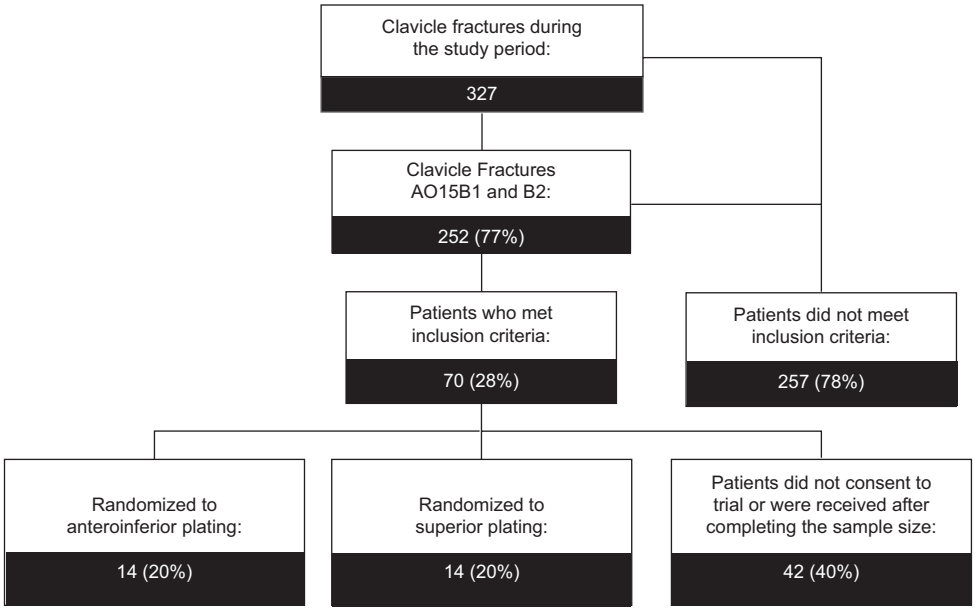

Figure 1. *Flow diagram demonstrating distribution of patients in the study.*

by traumatology and orthopedics residents blinded to the implementation of the present study.

Physicians who evaluated the clinical data during the follow-up were previously standardized for the application of the DASH scale and blinded to the surgical procedure performed. Statistical analysis was also performed without the information of the treatment applied.

Superior reconstruction plating method

Under general anesthetic and with antibiotic prophylaxis, the patients were placed in a beach chair position. The operating side was prepped and draped, and a longitudinal incision was made on the anterior edge of the clavicle over the area of the fracture site. The morphology of the fracture was corroborated. Open reduction was performed with reduction clamps. A malleable plate was then placed on the superior surface of the clavicle, molded anatomically, and used to measure the length of the implant. Reconstruction plates with seven or more holes were selected. The goal was to achieve three bi-cortical screws in both the proximal and distal fragments as a minimum. The selected implant was molded with the malleable plate as a template, and its correct position was verified. Cortical screws (3.5 mm) were inserted, and implant stability was verified (Fig. 2). Subcutaneous tissue was closed with an absorbable suture of 2-0 and the skin with a nylon suture of 3-0. The wound was covered with sterile gauze and a transparent adhesive dressing (Tegaderm).

Anteroinferior reconstruction plating method

Under general anesthetic and with antibiotic prophylaxis, the patients were placed in a beach chair position. The operating side was prepped and draped, and a longitudinal incision was made one centimeter below the anterior edge of the clavicle over the area of the fracture site. The morphology of the fracture was corroborated. Open and direct reduction was performed with reduction clamps. A malleable plate was then placed on the anteroinferior surface of the clavicle, molded anatomically, and used to measure the length of the implant. Reconstruction plates with seven or more holes were selected. The goal was to achieve three bi-cortical screws in both the proximal and distal fragments as a minimum. The selected implant was molded with the malleable plate as a template, and its correct position was verified. Cortical screws (3.5 mm) were inserted, and implant stability was verified (Fig. 3). Subcutaneous tissue was closed with an absorbable suture of 2-0 and the skin with a nylon suture 3-0. The wound was covered with sterile gauze and a transparent adhesive dressing (Tegaderm).

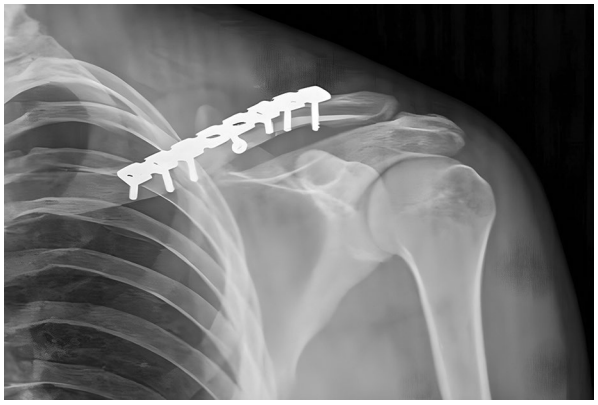

Figure 2. *Post-operative X-rays with superior reconstruction plating.*

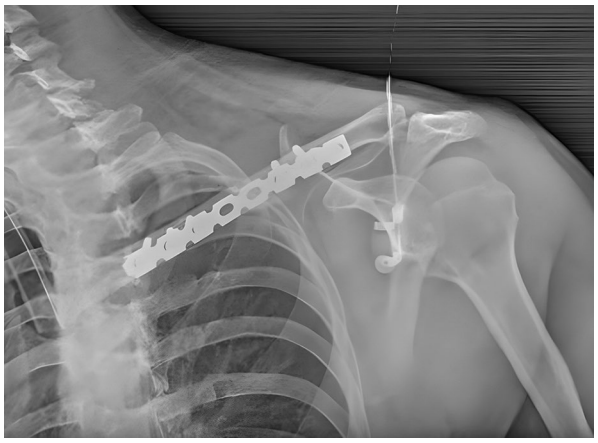

Figure 3. *Post-operative X rays with anteroinferior reconstruction plating.*

Post-op management

All patients received prophylactic antibiotics, proper analgesia, and a soft sling placed on the operated side. Patients were clinically reviewed within a post-operative week, surgical wound healing was evaluated, and they were referred to physiotherapy to begin with glenohumeral range of motion exercises. Patients received training to perform Codman's pendulum exercises, abduction, and flexion limited to 90 degrees from the first to the 4th week. From the fourth to the 8th week, isotonic and isometric strengthening exercises were performed. From the 6th week onwards, they were given full ranges of mobility.

Follow-up

Patients were observed in the consultation by the attending physicians and surgical team. Anteroposterior X-rays were performed at the second and 6th weeks, at 3 months, and at 6 months, 1 year, and 2 years, to assess consolidation. DASH score was conducted at every visit. Throughout the follow-up period, patients were monitored for wound or metalwork complications.

Outcome scoring

Outcome scoring was performed by a trained orthopedist, unaware of the type of surgery performed. The primary evaluation was the DASH score, which evaluates the abilities to perform activities of daily living, medium- and high-effort activities, the pain, and the social impact related to the injury of the affected extremity. The DASH scale is evaluated with a score from 0 to 100 points, with 0 points being the best possible rating (absence of disability). The secondary outcomes were evaluated with a visual analog scale (VAS) (0-10), a range of active and passive mobility, and metalwork complications (X-ray interfaces, screw loosening).

Calculation of the sample size

The sample size calculation was based on a prospective study of mid-shaft clavicle fractures. A statistical power of 0.80 and a statistical significance of 0.05 were assumed, with a standard deviation of 7.4[14], to detect a difference of 10% in the primary measurement (DASH scale; 2-tail test),[15] estimating 14 patients per group. Demographic data, functional outcome data, and complications were analyzed using the statistical program SPSS V21.0 (Demo).

Results

During the study period, 28 patients with clavicle fractures (AO 15B1 and 15B2) were recruited, randomly assigned to the treatment group, and distributed equally. Fourteen patients for anteroinferior plating and fourteen for superior plating. Superior plating was considered the "control" maneuver. Patient exclusions were mainly due to the presence of obesity and associated comorbidities.

We recruited 24 male and 4 female patients with a median age of 24.5 ± 9.87 years (range, 18-56). We had a male-to-female ratio of 6:1, but the gender distribution for both treatment arms had no statistically significant differences. The demographic data are shown in table 1.

Table 1. Demographics and results of patients with clavicle fracture AO 15B1 y 15B2 treated with reconstruction plate anteroinferior vs superior (n = 28)

Variable	Anteroinferior	Superior	p (U Mann-Whitney)
Number of patients	14	14	
Male: Female Ratio	12:2	12:2	
Mean Age (years)	27.71 ± 4.4	31.8 ± 12.1	0.310
Mean Weight (kg)	69.42 ± 11.7	74.28 ± 16.0	0.511
Mean Height (m)	1.55 ± 3.9	1.7 ± 9.4	0.085
Mean BMI	25.21 ± 3.7	25.04 ± 3.25	0.734
Mean time of fixation (days)	1.14 ± 1.35	1.07 ± 0.51	0.482
Mean DASH (90 days)	3.27 ± 5.8	9.7 ± 8.8	0.004
Mean VAS (90 days)	0.06 ± 0.24	0.45 ± 0.7	0.125
Number United	14 (100%)	14 (100%)	

BMI: body mass index kg/m^2.

Table 2. Distribution of the qualitative characteristics of the sample

(n = 28)	Frequency	%	Rate	Ratio (R/I)	95% IC
Gender					
Male	24	85.71	0.85	6.0	0.27|1.32
Female	4	14.28	0.14	0.16	
PPH					
Absent	26	92.85	0.928	13	−2.39|0.16
Endometriosis	1	3.57	0.035	0.07	
Asthma	1	3.57	0.035	0.07	
Affected side					
Right	14	50.0	0.5	1.0	0.68|31.4
Left	14	50.0	0.5	1.0	
Lateral dominancy					
Dominant	15	53.57	0.535	1.15	0.64|27.95
Non-dominant	13	46.42	0.464	0.86	
Loosening					
Absent	27	96.42	0.964	27	−3.3|0.1
Present	1	3.57	0.035	0.03	
Infection					
Absent	27	96.42	0.964	27	−3.3|0.1
Present	1	3.57	0.035	0.03	
BMI					
Normal	13	46.42	0.464	0.86	0.72|35.09
Overweight	13	46.42	0.464	0.86	
Obesity	2	7.14	0.071	0.07	

Rate per 1000 inhabitants, PPH: pathological personal history; BMI: body mass index; 95% CI: 95% confidence interval.

Most patients had no pathological personal history, and only one presented metalwork loosening and infection (Table 2). The patient was conventionally managed with reoperation, surgical debridement, and antibiotic management. The patient had radiographic evidence of union and no relapse of infection at 90 days.

The sample was evaluated by the DASH and VAS scales at 30, 60, and 90 days, 6 months, 1 year, and 2 years post-operatively. In both groups, the days of evolution (time from the fracture to surgical management) had a median of 1 day (range 0-4 days).

The homogeneity of the sample is shown in table 3.

The mean DASH score in the anteroinferior plating group was 3.5, and in the superior plating group was 9.52. The mean pain measured 0.06 in the anteroinferior plating group and 0.45 in the superior group, both measured at 90 days. Significant differences were found between groups in the DASH score at 30 days for the superior plating compared to the anteroinferior (43.74 vs. 29.26, respectively, p = 0.027; CI 95% 2.3|26.59) and the visual analog scale at 30 days for the superior plating compared to the anteroinferior (5.11 vs. 3.44, respectively, p = 0.003; CI 95% 0.39|2.94). Significant differences were also found in DASH scores at 60 and 90 days and VAS between groups at 60 days. No differences in VAS were found from day 90 between groups (Table 4). One patient underwent metalwork removal of the superior plating group due to soft tissue irritation. The metalwork removal was performed after 2 years of surgical management, and the patient achieved complete fracture union.

DASH scores at 30, 60, and 90 days were categorized at a 50% cut-off point to perform dichotomic adjustment and obtain the risks associated with the interventions performed. VAS was categorized into adverse pain (greater than or equal to 7) and non-adverse pain (< 7) for the creation of associated risks. The "control" was superior plating and was analyzed as the exposure factor (Table 5).

Discussion

In the present study, mid-third clavicle fractures AO 15B1 and B2, managed with superior and anteroinferior reconstruction plating, achieved a 100% union rate with no major complications and avoidance of persistent pain, weakness, or alterations in shoulder mobility. This patient was treated at a tertiary referral

Table 3. Homogeneity of the sample obtained from patients with clavicle fracture AO 15B1 and 15B2

Variable	SUP plate n (%)	AINF plate n (%)	χ^2	p*-value
Gender				
Male	12 (42.9)	12 (42.9)	0.00	1.00
Female	2 (7.1)	2 (7.1)		
PPH				
Absent	13 (46.4)	13 (46.4)	2.0	0.368
Endometriosis	0 (0.0)	1 (3.6)		
Asthma	1 (3.6)	0 (0.0)		
AO				
15B1.2	3 (10.7)	4 (14.3)	1.762	0.890
15B1.3	3 (10.7)	1 (3.6)		
15B2.1	3 (10.7)	4 (14.3)		
15B2.2	3 (10.7)	4 (14.3)		
15B2.3	2 (7.1)	1 (3.6)		
Lateral Dominance				
Right-handed	13 (46.4)	12 (42.9)	0.373	0.500
Left-handed	1 (3.6)	2 (7.1)		
Affected Side				
Right	10 (35.7)	4 (14.3)	5.143	0.023
Left	4 (14.3)	10 (35.7)		
Loosening	13 (46.4)			
Absent	1 (3.6)	14 (50.0)	1.307	1.000
Present		0 (0.0)		
Infection				
Absent	13 (46.4)	14 (50.0)	1.307	1.000
Present	1 (3.6)	0 (0.0)		
BMI				
Normal	7 (25.0)	6 (21.4)	2.769	0.250
Overweight	5 (17.9)	8 (28.6)		
Obesity	2 (7.1)	0 (0.0)		

SUP; Superior, AINF; Anteroinferior. * χ^2 de Pearson o Fisher's exact test, α =0.05; PPH: pathological personal history; BMI: body mass index.

center with a mean follow-up of 2 years. All fractures presented union 6 months after the surgical procedure. The last evaluations were performed via telephone secondary to the social distancing due to the SARS-CoV-2 pandemic.

Clavicle fractures represent 2-5% of injuries in adults and 10-15% of injuries in children. They represent 44-66% of shoulder girdle fractures. We found no bimodal distributions in the presentation of our cases and found a mean age of 27.7 years, not different from that found in the literature that marks a mean age of 29.3 years ($p < 0.05$), and the presentation between men and women in our sample was 6-1, contrasting with what was previously reported of a 3:1 ratio[16]. In the sample obtained, weight, height, and BMI showed independence with the results of the fracture and with the functional results. No reports in the literature make a causal relationship between these variables and the presence of fractures. However, in post-menopausal patients with decreased bone quality in a study conducted by Compston et al., the only factor that was associated with proximal humerus fractures and clavicle fractures was not the weight or BMI but height, where, for every 10 cm of height, the risk of suffering a clavicle fracture increased by 73%[17]. In the Gnudi et al. series, BMI was considered a risk factor for proximal humerus fractures (OR 1.077)[18]. Our patients managed normal or overweight BMIs, and only two were obese. We did not find a relationship between height, weight, BMI, and clavicle fractures or a relationship with the type or fracture complexity in our analysis. Our sample size was not calculated to this objective, and results finding no causality or risk should be interpreted carefully. Clavicle fractures are poorly characterized in terms of their relationship with other comorbidities. In our sample, we had two people with previous diseases that did not modify the result after surgery; one of the patients had endometriosis, and another patient was asthmatic. Our criteria excluded all chronic diseases to accomplish better control; further investigation of patients with associated comorbidities should be done.

Clavicle fractures are usually also associated with head injuries, chest injuries, or vascular injuries[19]. No patient in our study has these associations, so we treated isolated medium-energy mid-shaft clavicle fractures.

The complications associated with clavicular fractures range from damage to the subclavian vasculature to neuropraxia of the posterior branches of the brachial plexus, hemothorax, and pneumothorax. Complications related to the surgical procedure are the non-union, the migration of osteosynthesis material, paresthesia, and vascular or nerve lesions[20]. We had one patient with metalwork loosening and an infection. This patient was re-operated and managed conventionally for the infection, achieving an adequate evolution with consolidation and absence of infection at 3 months. A neat surgical technique and careful control of the post-operative period allow adequate control of complications. Although the follow-up was performed for 2 years, satisfactory results were obtained within 90 days of the post-operative period with complete recovery. Return to activities and reduction of pain were two variables found with no statistical difference after 90 days. Both surgical techniques

Table 4. Comparative analysis between the two assigned treatment groups (superior reconstruction plate vs. anteroinferior) for patients with clavicle fracture AO 15B1 and 2 (n = 28)

Variable	Group	Media	SD	p*-value	CI 95% of the difference	Power (1-β)
Days to fixation	Superior	0.5	0.51	0.161	−1.4|0.06	41.65
	AINF	1.21	1.31			
DASH 30	Superior	43.74	20.06	0.027	2.3|26.59	> 80
	AINF	29.26	9.16			
DASH 60	Superior	23.97	13.98	0.021	3.55|22.01	> 80
	AINF	11.18	9.3			
DASH 90	Superior	9.52	9.1	0.016	0.09|11.9	> 80
	AINF	3.5	5.7			
DASH 180	Superior	6.63	6.8	0.009	−0.29|8.72	78.26
	AINF	2.41	4.6			
DASH 360	Superior	5.11	5.58	0.016	−0.47|7.21	> 80
	AINF	1.75	4.2			
DASH 720	Superior	3.44	4.3	0.044	−0.95|5.01	> 80
	AINF	1.4	3.32			
VAS 30	Superior	5.11	1.97	0.003	0.39|2.94	> 80
	AINF	3.44	1.22			
VAS 60	Superior	2.67	1.65	0.006	0.67|2.99	> 80
	AINF	0.8357	1.30			
VAS 90	Superior	0.45	0.70	0.125	−0.02|0.79	> 80
	AINF	0.0643	0.24			
VAS 180	Superior	0.35	0.49	0.114	0.08|0.063	> 80
	AINF	0.0	0.0			
VAS 360	Superior	0.28	0.46	0.210	0.02|0.54	> 80
	AINF	0.0	0.0			
VAS 720	Superior	0.21	0.42	0.325	−0.01|0.44	> 80
	AINF	0.0	0.0			

AINF: anteroinferior; SD: standard deviation; *U de Mann-Whitney, CI95%: Confidence interval; DASH: The disabilities of the arm, shoulder and hand score; VAS: visual analogue scale.

presented good results after 3 months of follow-up; however, the anteroinferior plating showed better functional results after 6 months of treatment. We found among our colleagues the perception that anteroinferior plating technique is more complex than superior plating. The anteroinferior technique requires adequate molding of the plate and requires a stable instrumented reduction to obtain satisfactory results. Anatomically, the anteroposterior placement of the screws decreases the likelihood of injury to the subclavian vessels below the clavicle. Which are more exposed to injury when the screws are introduced cephalocaudally. By placing the superior reconstruction plate, the plate requires a slight pre-molding, and even in clavicles with a sufficient anteroposterior length (clavicular width, at least greater than one cm), the plate may not even require pre-molding. This makes the superior plating technique apparently simpler but more likely to cause inadvertent arterial injury, especially among surgeons with poor training placing screws in high-risk sites.

The functional outcomes assessed by the *DASH* scale showed significant differences throughout follow-up in both treatment groups. During the 1st year of the post-operative period, the anteroinferior plating technique had better functional outcomes for the performance of activities of daily living and work compared with superior plating. This result remained until the 2nd year of the post-operative period. The placement of anteroinferior pre-molded plates does not

Table 5. Risk measures for patients with clavicle fracture AO 15B1 and 15B2, treated with open reduction and reconstruction anteroinferior plate (factor group) versus superior (control) (n = 28)

Risk measure	DASH > 50	VAS adverse (> 7)
ER	−0.429	−0.214
CI 95%	2.44|−3.3	1.07|−1.5
ARR	0.429	0.214
CI 95%	4.74|−6.02	1.49|−1.07
NNT	2.333	4.667
CI 95%	3.29|−2.44	−1.67|−7.66
RR	0.17	0.33
CI 95%	1.58|4.77	1.46|3.53

DASH: the disabilities of the arm, shoulder and hand score; VAS: visual analogue scale; ARR: absolute risk reduction; ER: excess risk; NNT: number needed to treat; RR: relative risk; CI95%: confidence interval 95%.

interfere with the mobility of the clavicle; they are not placed subcutaneously, and the integral mobility of the shoulder girdle is not compromised[21]. Pain was controlled with both techniques from the 3rd month of treatment, showing no differences until the 2nd year of management, which is comparable with the literature previously analyzed. However, no study has performed long-term management up to 2 years postoperatively as the present one[12,21].

In the present study, we used molded reconstruction plates due to their low cost compared to other types of blocked anatomical plates. In emerging economies, this is a factor of great importance. The use of these reconstruction plates was a feasible option with adequate results in the short, medium, and long term. The use of reconstruction plates reduces costs compared to low-contact anatomical plates.

Due to social distancing related to the SARS-CoV-2 pandemic, follow-up in the 2nd year was necessary to be carried out strictly by telephone, which constitutes a source of bias for such evaluations.

Conclusions

Our results provide evidence that surgically managed AO 15B1 and B2 fractures present adequate clinical and functional outcomes. Anteroinferior reconstruction plating in mid-shaft clavicle fractures offers better outcome scores compared to superior plating. The pain was significantly less in anteroinferior plating in the first 3 months of follow-up. After this period, the differences were not statistically significant (2 years of follow-up). Functional results obtained by the *DASH* scale showed better results using anteroinferior plating compared to superior plating. Both methods achieved 100% union, and only the superior plating technique presented minor complications that did not affect the functionality after 90 days of the post-operative period. We recommend the use of anteroinferior plating for clavicle mid-shaft fractures as a safer and more stable method compared to superior plating, which maintains its outcomes 2 years after surgery.

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Conflicts of interest

The authors state that there are no conflicts of interest in this manuscript.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

References

1. Postacchini F, Gumina S, De Santis P, Albo F. Epidemiology of clavicle fractures. J Shoulder Elbow Surg. 2002;11:452-6.
2. Salipas A, Kimmel LA, Edwards ER, Rakhra S, Moaveni AK. Natural history of medial clavicle fractures. Injury. 2016;47:2235-39.
3. Frima H, van Heijl M, Michelitsch C, van der Meijden O, Beeres FJ, Houwert RM, et al. Clavicle fractures in adults; current concepts. Eur J Trauma Emerg Surg. 2020;46:519-29.
4. Neer CS 2nd. Nonunion of the clavicle. J Am Med Assoc. 1960;172:1006-11.
5. Rowe CR. An atlas of anatomy and treatment of midclavicular fractures. Clin Orthop. 1968;58:29-42.
6. White RR, Anson PS, Kristiansen T, Healy W. Adult clavicle fractures: relationship between mechanism of injury and healing. Orthop Trans. 1989;13:514-5.

7. Hill JM, McGuire MH, Crosby LA. Closed treatment of displaced middle-third fractures of the clavicle gives poor results. J Bone Joint Surg Br. 1997;79:537-9.
8. Robertson C, Celestre P, Mahar A, Schwartz A. Reconstruction plates for stabilization of mid-shaft clavicle fractures: differences between nonlocked and locked plates in two different positions. J Shoulder Elbow Surg. 2009;18:204-9.
9. Partal G, Meyers KN, Sama N, Pagenkopf E, Lewis PB, Goldman A, et al. Superior versus anteroinferior plating of the clavicle revisited: a mechanical study. J Orthop Trauma. 2010;24:420-5.
10. Favre P, Kloen P, Helfet DL, Werner CM. Superior versus anteroinferior plating of the clavicle: a finite element study. J Orthop Trauma. 2011;25:661-5.
11. Formaini N, Taylor BC, Backes J, Bramwell TJ. Superior versus anteroinferior plating of clavicle fractures. Orthopedics. 2013;36:898-904.
12. Ai J, Kan SL, Li HL, Xu H, Liu Y, Ning GZ, et al. Anterior inferior plating versus superior plating for clavicle fracture: a meta-analysis. BMC Musculoskelet Disord. 2017;18:159.
13. Nourian A, Dhaliwal S, Vangala S, Vezeridis PS. Midshaft fractures of the clavicle: a meta-analysis comparing surgical fixation using anteroinferior plating versus superior plating. J Orthop Trauma. 2017;31: 461-7.
14. Ferran NA, Hodgson P, Vannet N, Williams R, Evans RO. Locked intramedullary fixation vs plating for displaced and shortened mid-shaft clavicle fractures: a randomized clinical trial. J Shoulder Elbow Surg. 2010;19:783-9.
15. García-García JA, Reding-Bernal A, López-Alvarenga JC. Cálculo del tamaño de la muestra en investigación en educación médica. Invest Educ Med. 2013;2:217-24.
16. Paladini P, Pellegrini A, Merolla G, Campi F, Porcellini G. Treatment of clavicle fractures. Transl Med UniSa. 2012;2:47-58.
17. Compston JE. Relationship of weight, height, and body mass index with fracture risk at different sites in postmenopausal women: the global longitudinal study of osteoporosis in women (GLOW). J Bone Miner Res. 2014;29:487-93.
18. Gnudi S, Sitta E, Lisi L. Relationship of body mass index with main limb fragility fractures in postmenopausal women. J Bone Miner Metab. 2009;27:479-84.
19. Gottschalk H, Dumont G, Khanani S, Browne R, Starr A. Open clavicle fractures: patterns of trauma and associated injuries. J Orthop Trauma. 2012;26:107-9.
20. Mouzopoulos G, Morakis E, Stamatakos M, Tzurbakis M. Complications associated with clavicular fracture. Orthop Nurs. 2009;28:217-24.
21. Chen CE, Juhn RJ, Ko JY. Anterior-inferior plating of middle-third fractures of the clavicle. Arch Orthop Trauma Surg. 2010;130:507-11.

ORIGINAL ARTICLE

Malnutrition: muscle wasting, inflammation, RDW, and their relation with adverse outcomes

Desnutrición durante la estancia hospitalaria: desgaste muscular, inflamación, ancho de distribución eritrocitaria y su relación con resultados adversos

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Abstract

Objective: *The objective of the study was to explore red cell distribution width (RDW) as a surrogate marker of inflammation, alone and in conjunction with muscle wasting to predict malnutrition-related adverse outcomes.* **Methods:** *This was a single-center observational study including adult hospitalized patients. Demographic variables, malnutrition criteria, and RDW were captured within 24 hours of hospital admission. Correlation tests and regression models were performed between these variables (RDW and muscle wasting) and adverse outcomes (in-hospital mortality and unplanned transfer to critical care areas (CCA).* **Results:** *Five hundred and forty-five patients were included in the final analysis. Muscle wasting showed an independent association with adverse outcomes in every regression model tested. RDW alone showed fair predictive performance for both outcomes' significance and the adjusted model with muscle wasting showed association only for unplanned transfer to CCA.* **Conclusion:** *RDW did not improve the prediction of adverse outcomes compared to muscle wasting assessed by physical examination and simple indexes for acute and chronic inflammation. Malnourished patients presented higher RDW values showing a possible metabolic profile (higher inflammation and lower muscle). It is still unknown whether nutrition support can influence RDW value over time as a response marker or if RDW can predict who may benefit the most from nutritional support.*

Keywords: *Malnutrition. Inflammation. Muscle. Red cell distribution width. Adult*

Resumen

Objetivo: *Explorar el ancho de distribución eritrocitaria (ADE) como un marcador subrogado de inflamación, individualmente y en conjunto con el desgaste muscular, para predecir resultados adversos asociados a la desnutrición.* **Método:** *Estudio unicéntrico, observacional, incluyendo pacientes adultos hospitalizados. Se capturaron variables demográficas, criterios de desnutrición y el ADE en las primeras 24 horas de ingreso. Se realizaron pruebas de correlación y modelos de regresión entre dichas variables (ADE y desgaste) y resultados adversos (mortalidad hospitalaria y traslado no planeado a áreas críticas).* **Resultados:** *Se incluyeron 545 pacientes. El desgaste muscular mostró asociación independiente con los resultados adversos en cada modelo. El ADE individualmente mostró un desempeño aceptable para la predicción de ambos resultados, y en modelos ajustados con desgaste muscular mostró asociación únicamente con traslado no planeado a áreas críticas.*

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Conclusiones: *El ADE no mejoró la predicción de resultados adversos comparado con el desgaste muscular por exploración física e índices simples de inflamación. Los pacientes con desnutrición presentaron mayores valores de ADE, mostrando un posible perfil metabólico (mayor inflamación y menos músculo). Aún se desconoce si el soporte nutricional puede influenciar el ADE como un marcador de respuesta o si puede predecir una respuesta favorable al soporte nutricional.*

Palabras clave: *Desnutrición. Inflamación. Músculo. Ancho de distribución eritrocitaria. Adulto.*

Introduction

Malnutrition is known as a risk factor for a large number of adverse outcomes in hospitalized adult patients[1,2]. Malnutrition diagnosis has been recently proposed using the Global Leadership Initiative on Malnutrition (GLIM, core leadership: ASPEN: American Society for Parenteral and Enteral Nutrition, ESPEN: European Society for Parenteral and Enteral Nutrition, FELANPE; Federación Latino Americana de Terapia Nutricional, Nutrición Clínca y Metabolismo and PENSA: The Parenteral and Enteral Nutrition Society of Asia) criteria. The presence of at least one phenotypic criterion (unplanned weight loss, low body mass index [BMI], and decreased muscle mass) and one etiologic criterion (reduced nutrient intake, altered nutrient assimilation or absorption, acute and chronic inflammation) is required to diagnose malnutrition. Once diagnosed the severity of malnutrition will be determined by specific thresholds based on phenotypic criteria[3].

A previous study has shown a correlation between malnutrition and its severity, according to the GLIM criteria, with adverse outcomes such as mortality or worsening of the clinical condition requiring unplanned transfer to critical care areas (CCA). Muscle wasting and inflammation were found to be independent risk factors for such outcomes, as previously shown these are malnutrition characteristics. However, muscle wasting was assessed by physical examination and inflammation was determined using simple indexes related to chronic and acute illness inflammation such as the Charlson comorbidity index (CCI) and the NRS2002 illness severity accordingly (Fig. 1, upper panel)[1].

The inclusion of more objective markers related to muscle mass and inflammation in the nutritional assessment could improve its precision and performance to detect adverse outcomes in adult hospitalized patients.

Red cell distribution width (RDW) shows the discrepancy between red cell volume, represented as a percentage of dispersion or coefficient of variance, representing ineffective erythropoiesis. Previous studies have shown a correlation between higher RDW values and mortality in adult critically ill patients, mainly during sepsis[4-9]. One study showed a correlation between higher RDW and sarcopenia measured with dual-energy X-ray absorptiometry (DEXA), especially in patients with overweight and obesity[10]. It has been theorized that the RDW can be a marker of chronic inflammatory states, given red cells' life span (approximately 120 days) directly affecting erythropoiesis by chronic inflammation and concomitant oxidative stress[11,12].

RDW can be considered a routine test in hospitalized patients, and its use usually does not increase workload and costs of attention, highlighting the relevance of exploring this laboratory test as an inflammatory marker. Given the correlation of muscle wasting and inflammation with adverse outcomes in adult inpatients, we included RDW as a biomarker related to inflammation alone and adjusted for muscle wasting by physical exploration to explore its utility in predicting adverse outcomes (Fig. 1, lower panel).

Methods

Study design and center

This was a single-center observational study carried out in a private (78 beds) teaching hospital. This center has a wide span of capacity for attention to different medical and surgical specialties (orthopedic surgery, general surgery, neurology, neurosurgery, cardiology, geriatrics, internal medicine, gynecology, oncology, etc.).

Inclusion of patients started on the April 21 and ended on the July 31, 2021 (102 days), follow-up ended at hospital discharge.

Inclusion criteria

Every non-pregnant adult patient (≥18 years old) was admitted to regular hospital wards, with RDW processed at the hospital's laboratory within the first 24 h of admission to the ward.

Patients discharged from CCA to the regular ward were included; the assessment was performed at the moment they arrived in the regular ward. Patients admitted from other hospitals for continuity of care were included (as "Other hospital"). Programmed admission (elective) was considered for every patient coming from home to receive previously planned treatment. Previous hospitalization within 6 months before current admission was captured as a binary variable (yes/no).

Exclusion criteria

Patients admitted for bariatric and/or esthetic surgery, previous neuromuscular disease (because muscle mass physical assessment could be biased), admitted for palliative care, or with do not resuscitate order. Patients with hematological malignancies as a history or recent diagnosis (within actual hospitalization), patients admitted for chronic anemia, or with RDW processed after 24 h of admission or in another center were excluded from the study.

Elimination criteria

If information was not provided due to denial of the routine evaluation or inability to communicate and without any family or caregiver to provide the requested information. Patients transferred to another hospital for continuity of care were also eliminated.

Screening and assessment

Nutritional assessment was carried out by the nutrition department by direct interview with the patient or caregiver if communication with the patient was not possible. During the routine evaluation, the clinician searches for phenotypic criteria, such as unplanned weight loss, low BMI (according to age), and muscle wasting; along with etiologic criteria such as low intake and gastrointestinal conditions impairing nutritional intake[3]. Physical assessment was performed searching for reduced muscle mass (as one phenotypic criterion) following the recommendations of the Subjective Global Assessment and Fischer et al. (searching for signs of decreased muscle at the triceps, chest, quadriceps, deltoids, trapezius, temporalis, hands, mild axillary line, etc.). Decreased muscle mass was rated as 0: none, 1+: mild deficit, 2+: moderate deficit, 3+: severe deficit[13,14].

Chronic inflammation was determined by the CCI given that considers only chronic conditions (present if ≥ 1 point), and acute inflammation was determined by the injury score of the NRS 2002 (present if ≥ 1 point), both considered independent etiologic criteria.

Biochemical markers

Hemoglobin (g/dL) and RDW (%) as determined by the local laboratory. Hemoglobin normal value: 12.0-16.0g/dL, RDW normal value: 11.5-15.0%.

Finally, the diagnosis of malnutrition (at least one phenotypic and one etiologic criterion present) and its severity were determined according to the GLIM criteria (3), and a nutritional therapy plan was proposed.

Data collection

The study team collected the variables (including demographic ones) after every screening/assessment (or at the end of the shift).

Outcomes

Mortality and unplanned transfer to CCA were obtained using the information provided by the Rapid Response Team monthly report and the Clinical file service.

Statistical analysis

For the statistical analysis, the Shapiro–Wilk test was used to determine the type of distribution of the quantitative variables, presenting them as mean (standard deviation) or median (interquartile range) if presented normal or non-normal distribution, respectively. Qualitative variables are presented as frequency (percentage).

Receiver operating characteristics (ROC) curves were used to explore the performance of RDW to predict adverse outcomes, showing its Area Under the Curve (AUC).

Finally, binary logistic regression was modeled using different pre-planned models:

Model 1: Muscle wasting, acute inflammation (as NRS2002 injury score), and chronic inflammation (CCI) versus mortality.

Table 1. General characteristics

Variables	Malnutrition		
	No (n = 408)	Yes (n = 137)	Total
Age (years)	46 (35-66)[$]	70 (48-82)[$]	52 (36-71)
Gender			
Male	203 (49.8)[$]	54 (39.4)[$]	257 (47.2)
Female	205 (50.2)[$]	83 (60.6)[$]	288 (52.8)
CCI	0 (0-1)[$]	1 (0-3)[$]	0 (0-2)
BMI	26.63 (24.33-29.74)[$]	23.39 (20.82-26.37)[$]	26.03 (23.44-29.28)
Previous hospitalization*	49 (12.0)[$]	41 (29.9)[$]	90 (16.5)
Source of admission			
Emergency room	326 (79.9)	116 (84.7)	442 (81.1)
Programmed (elective)	58 (14.2)	10 (7.3)	68 (12.5)
Critical areas	18 (4.4)	9 (6.6)	27 (5.0)
Other hospital	6 (1.5)	2 (1.5)	8 (1.5)
Total NRS2002 (points)	1 (0-2)[$]	4 (3-5)[$]	1 (1-3)
Hemoglobin (g/dL)	14.7 (13.3)[$]	13.4 (11.5-14.7)[$]	14.4 (12.9-15.7)
RDW (%)[#]	13.0 (12.5-13.9)[$]	14.3 (13.0-15.8)[$]	13.1 (12.5-14.3)
Mortality	2 (0.5)[$]	11 (8.0)[$]	13 (2.4)
Unplanned transfer to CCA	5 (1.2)[$]	16 (11.7)[$]	21 (3.9)

RDW: red cell distribution width; CCA: Critical care area; CCI: Charlson comorbidity index; BMI: body mass index;
*within the last 6 months; [#]Red cell distribution width; [$]the difference between groups ($p < 0.05$).
Hemoglobin normal value: 12.0-16.0 g/dL; RDW normal value: 11.5-15.0%.

Model 2: Muscle wasting, acute inflammation (as NRS2002 injury score), and chronic inflammation (CCI) versus unplanned transfer to CCA.

Model 3: Muscle wasting and inflammation (RDW) versus mortality.

Model 4: Muscle wasting and inflammation (RDW) versus unplanned transfer to CCA.

Every model was adjusted for possible confounding variables observed during the initial analysis.

The Local Ethics Committee approval was obtained previously.

R studio cloud ® and SPSS 24.0 (BMI) were used for statistical analysis considered significant every $p < 0.05$.

Results

A total of 545 patients were included in the final analysis, with a malnutrition prevalence of 25.14%. General characteristics are presented in Table 1.

Malnourished patients showed a higher age, illness severity, CCI, and RDW, but lower hemoglobin and BMI. A higher proportion of malnourished patients was female and showed adverse events (mortality and unplanned transfer to CCA) and previous hospitalization (within 6 months).

Malnutrition using the GLIM criteria was correlated with mortality (Odds Ratio [OR] 17.72, 95% Confidence interval [95%CI] 3.88-81.02) and unplanned transfer to CCA (OR 10.66, 95%CI 3.83-26.69).

Given the differences in age and gender, every model was adjusted for such variables, showing no correlation with adverse events in all of them.

Models 1 and 2:

To compare and assess the correlation of RDW with adverse outcomes, these initial models do not include RDW. Instead, the inclusion of CCI and NRS2002 illness severity were used as inflammatory markers and the only variable that remained was muscle wasting.

Muscle wasting severity and acute inflammation (NRS2002 illness severity) correlated with adverse outcomes, but chronic inflammation (CCI) did not reach significance in both models (Fig. 2).

ROC curves are shown in Fig. 3 and their analysis is in Table 2.

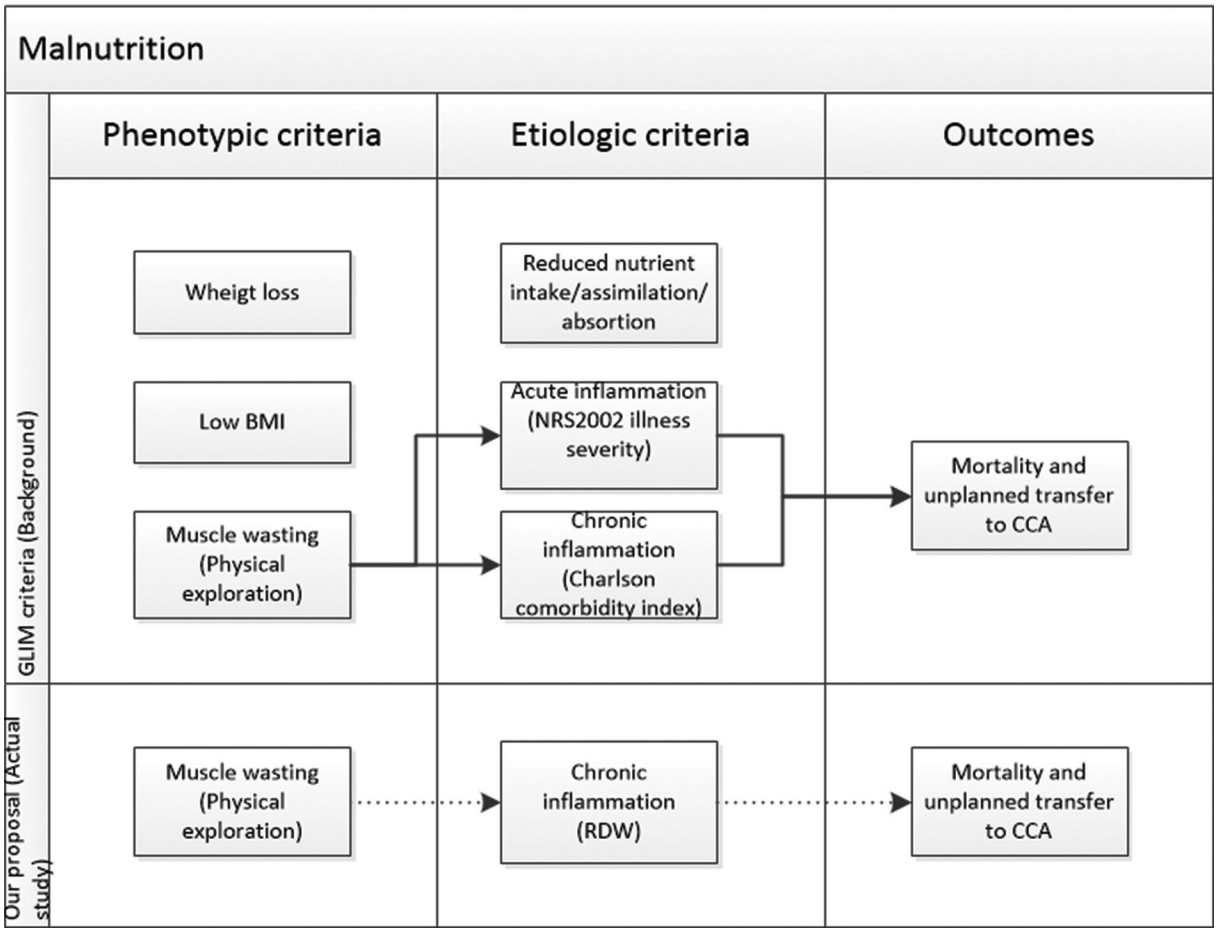

Figure 1. *Previous findings and actual hypothesis. RDW: red cell distribution width; CCA: critical care areas. Continuous line: findings of a previous study (1); Dotted line: actual study hypothesis.*

Table 2. ROC curve analysis

Variable	AUC	p	95% confidence interval	
			Inferior limit	Superior limit
Mortality				
RDW	0.76	0.002	0.67	0.86
Unplanned transfer to critical care areas				
RDW	0.79	< 0.001	0.72	0.87

ROC: receiver operating characteristics; RDW: red cell distribution width; AUC: area under the curve.

RDW alone showed fair performance to predict mortality and unplanned transfer to CCA.

Final models (3 and 4) were constructed as follows (Fig. 4).

Using RDW as an inflammatory marker showed significance in model 4 as an independent risk factor but did not increase the percentage of correct classification in both models compared with the initial models (Fig. 2). Again, muscle wasting was correlated with adverse outcomes in both models (3 and 4).

Discussion

In the present study, muscle wasting and inflammation showed to be independently correlated with adverse outcomes. Using RDW as an inflammatory biomarker showed statistical performance in the ROC curves predicting unplanned transfer to CCA and in-hospital mortality. RDW did not add classification performance in the regression analysis adjusted with muscle wasting, searching for correlations with adverse outcomes, and compared more simplistic models using the CCI and the NRS2002 illness severity score. However, RDW remained an independent risk factor for clinical deterioration requiring transfer to CCA.

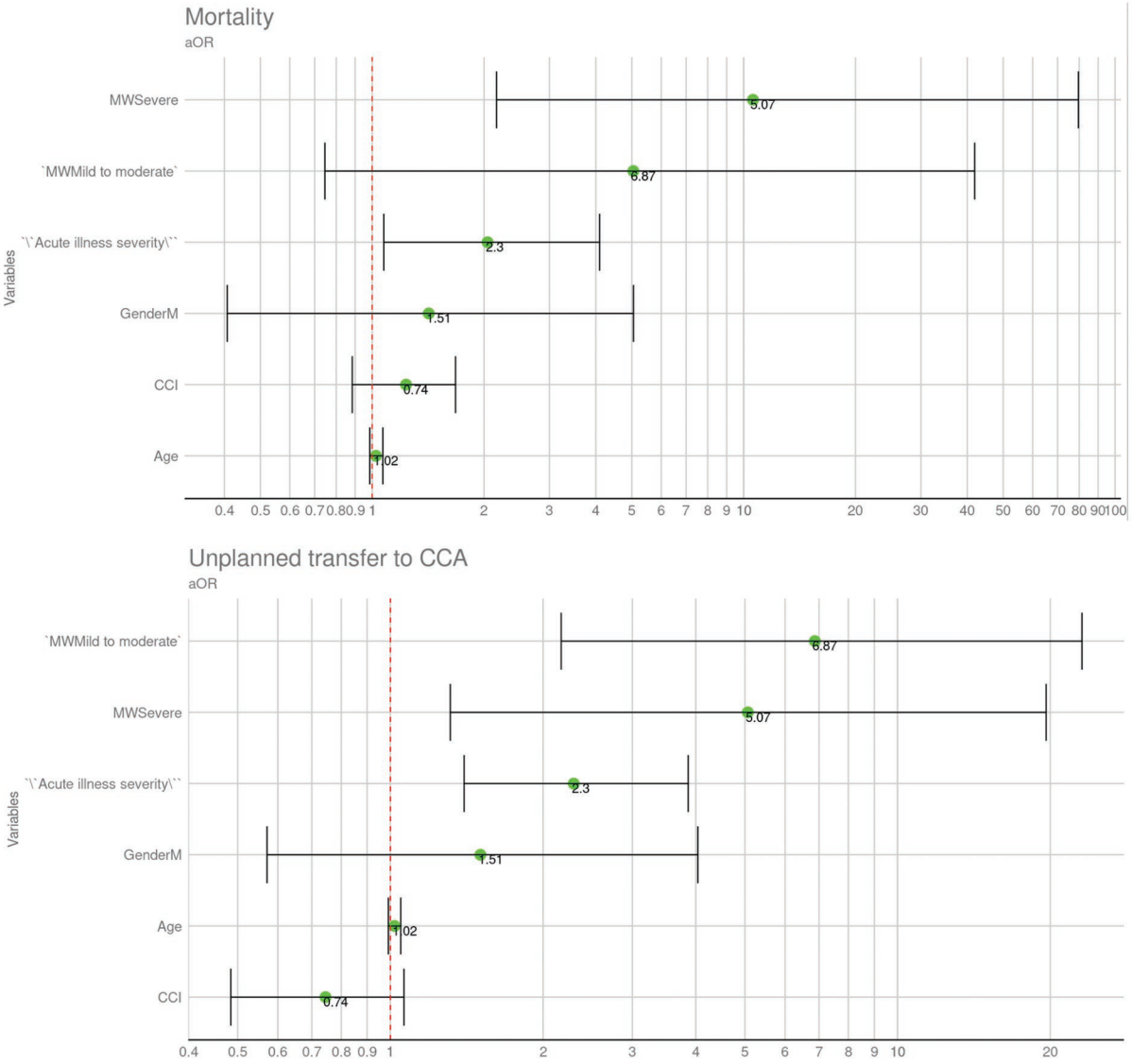

Figure 2. *Initial regression analysis. Mortality, Hosmer Lemeshow test p > 0.05, percentage of correct 97.6%. Unplanned transfer to critical care areas. Hosmer Lemeshow test p > 0.05, percentage of correct 96.0%. Acute inflammation according to NRS2002 illness severity (0-3 points), and chronic inflammation according to the Charlson comorbidity index. CCI: Charlson comorbidity index; MW: muscle wasting; GenderM: gender male; aOR: adjusted odds ratio; Error bars: 95% confidence interval.*

It is worth to mention the significant difference in RWD between both groups (well-nourished and malnourished), suggesting a profile in malnourished patients with a physiological association such as muscle wasting and inflammation. Being that those patients with malnutrition showed higher RDW values.

RDW has shown a correlation with mortality mainly in critically ill adult patients. Recently, Moreno–Torres et al. observed a group of 203 septic patients admitted to the intensive care unit, showing higher values of RDW in non-survivors, but also RDW remained elevated (during the first 7 days from admission) when compared with non-survivors. Using ROC curves adjusted for CCI, immunosuppression, nosocomial infection, National Early Warning Score 2, Sequential Organ Failure Assessment, Simplified Acute Physiology Score-II, and hemoglobin, RDW at admission presented an AUC of 0.812 for in-hospital mortality. RDW showed an AUC of 0.76 for mortality in our model, but when adjusting for muscle wasting resulted in a small (but significant) correlation with clinical deterioration requiring transfer to CCA and no correlation with mortality, this contrast remarks the importance of muscle mass during inflammatory conditions[8].

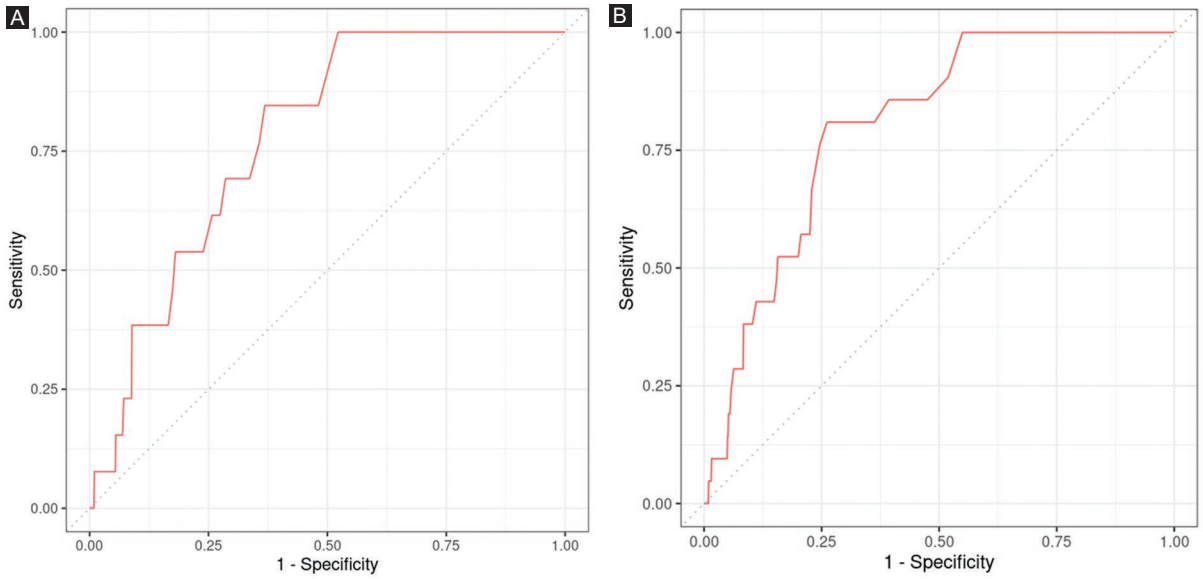

Figure 3. *Receiver operating characteristics curves.* **A:** *RDW versus mortality.* **B:** *RDW versus unplanned transfer to critical care areas. RDW: red cell distribution width.*

Zhang et al. conducted a meta-analysis to explore the role of RDW as a prognostic marker in critically ill patients with sepsis. Including 11 studies with a total of 17,961 patients a hazard ratio of 1.14 (1.09-1.20) for mortality was found for elevated RDW values[5].

Kim et al. evaluated the relation between RDW and muscle mass measured by DEXA in participants of the National Health and Nutrition Examination Survey (NHANES) 1999-2006. Low muscle mass was defined by skeletal muscle index or ASM (appendicular skeletal muscle [kg]/body weight [kg] × 100) using a cutoff point estimated from the mean ASM and its standard deviations (11,761 patients) and then adding low gait speed (< 0.8 m/s in a 20ft walk test) to define sarcopenia (2825 patients). Higher RDW was significantly associated with a higher risk for low muscle mass and sarcopenia, and when adjusting for BMI the relation was significant only in overweight and obese patients, showing the poor utility of BMI for nutritional status assessment[10]. The physiological explanation for these results remains to be elucidated, but if RDW really can be translated as a marker of inflammation (and perhaps as a chronic inflammation marker), and conditions such as obesity are considered proinflammatory[15], the loss of muscle mass, and function associated with inflammation could be the explanation for such results.

Inflammation has an influence in protein metabolism and muscle wasting, given that during the inflammatory process, gluconeogenesis and production of acute phase reactants as repair measures need amino acid mobilization from muscles, resulting in muscle wasting, a cardinal sign of malnutrition[16].

A recent secondary analysis of the study by Merker et al. was nutritional support in high nutritional risk patients (total NRS2002 ≥ 3 points) correlated with lower 30-day mortality, compared to standard of care. This correlation disappeared when analyzing the results between patients presenting high inflammation (C reactive protein > 100 mg/L) with patients with low-to-moderate inflammation (C reactive protein < 100 mg/L). Furthermore, nutritional support did not influence C reactive protein levels during the intervention[17]. These results underline the influence of inflammation with malnutrition, being that both conditions correlate with worse outcomes when they are present at the same time.

Limitations of the present study are its observational nature increasing the risk for residual confounders and being a single-center study reduces the external validity. Furthermore, there is a high risk for an impression when there is a low prevalence of the outcomes, 2.38% (13/545) for mortality and 3.85% (21/545) for unplanned transfer to CCA, showing that the population observed was at an overall lower risk for adverse events. The use of physical examination searching for muscle wasting introduced a wide confidence interval given the lack of precision. Finally, patient-centered outcomes were not considered.

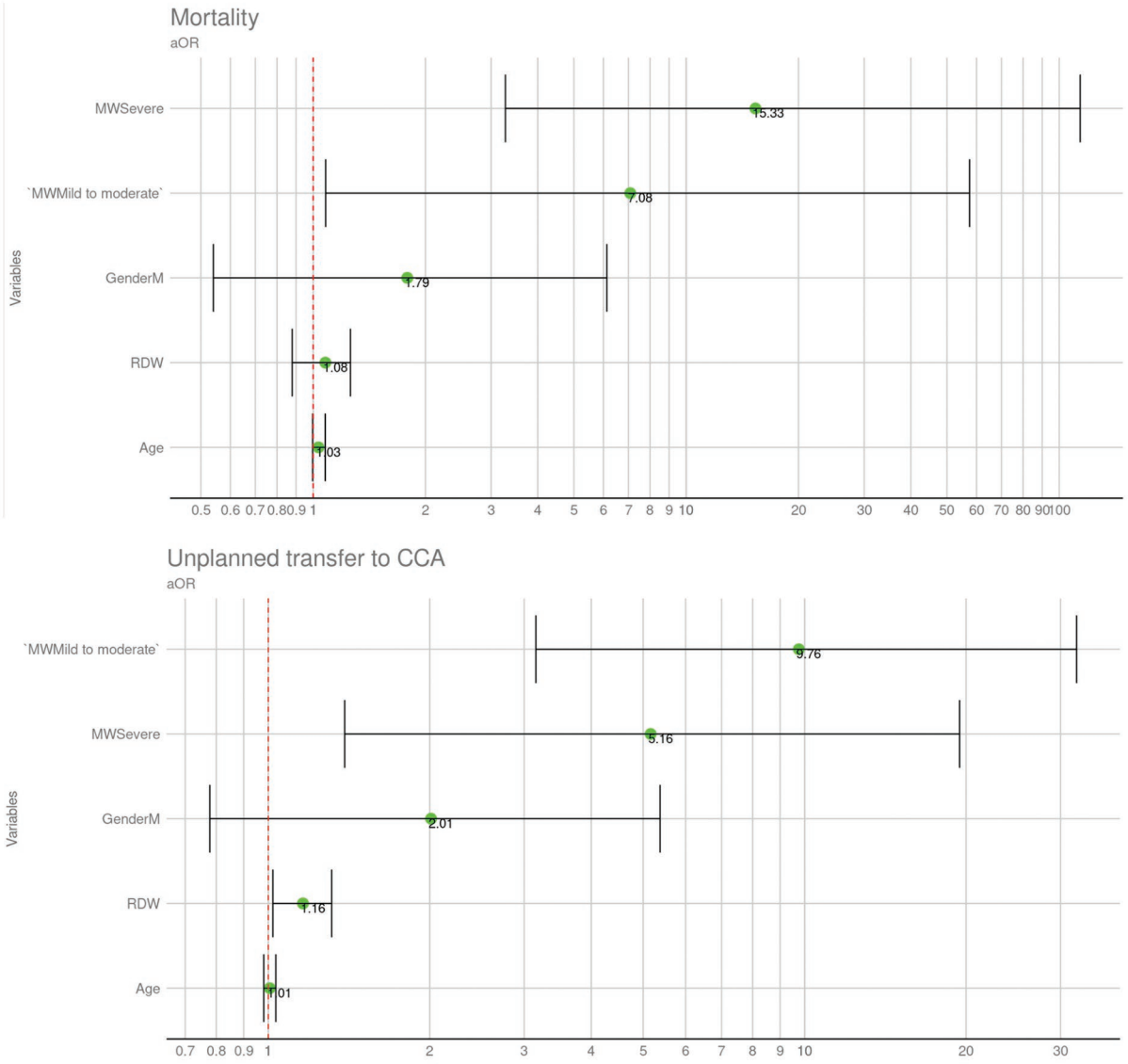

Figure 4. *Final regression analysis. Mortality, Hosmer Lemeshow test p > 0.05, percentage of correct 97.6%, 0% mortality was shown in muscle wasting 1+ subgroup. Unplanned transfer to critical care areas, Hosmer Lemeshow test p > 0.05, percentage of correct 96.0%. Inflammation according to red cell distribution width. RDW: red cell distribution width; MW: muscle wasting; GenderM: gender male; aOR: adjusted odds ratio. Error bars: 95% confidence interval.*

Strengths are the high number of patients observed and a preceding study in our center confirming the greater risk for adverse outcomes related to malnutrition. Furthermore, the observational nature shows a daily practice approach.

Conclusion

Physical examination searching for muscle wasting remains a valid tool to detect patients with malnutrition and the corresponding high risk for adverse outcomes. RDW in conjunction with muscle wasting remained as an independent risk factor for unplanned transfer to CCA (clinical deterioration) but not mortality. It is still unknown whether RDW can detect patients who benefit the most from nutritional support or if RDW changes can be used as a response marker for nutritional support. More studies in different centers, controlling for different nutritional approaches during malnutrition and using biomarker kinetics over time are needed to fully understand the association of RDW, muscle wasting, and clinical outcomes.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical disclosures

Protection of humans and animals. The authors declare that the procedures followed conformed to the ethical standards of the responsible human experimentation committee and in accordance with the World Medical Association and the Declaration of Helsinki.

Confidentiality of data. The authors declare that they have followed their center's protocols for the publication of patient data.

Right to privacy and informed consent. The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the corresponding author.

References

1. Galindo Martín CA, Aportela Vázquez VA, Becerril Hernández F, Aguilar Medina CR, Ayala Carrillo SL, Chávez Flores A, et al. The GLIM criteria for adult malnutrition and its relation with adverse outcomes, a prospective observational study. Clin Nutr ESPEN. 2020;38:67-73.
2. Meyer F, Valentini L. Disease-related malnutrition and sarcopenia as determinants of clinical outcome. Visc Med. 2019;35:282-90.
3. Jensen GL, Cederholm T, Correia MI, Gonzalez MC, Fukushima R, Higashiguchi T, et al. GLIM criteria for the diagnosis of malnutrition: a consensus report from the global clinical nutrition community. J Parenter Enter Nutr. 2019;43:32-40.
4. Li Y, She Y, Fu L, Zhou R, Xiang W, Luo L. Association between red cell distribution width and hospital mortality in patients with sepsis. J Int Med Res. 2021;49:(4)1-15:3000605211004221
5. Zhang L, Yu CH, Guo KP, Huang CZ, Mo LY. Prognostic role of red blood cell distribution width in patients with sepsis: a systematic review and meta-analysis. BMC Immunol. 2020;21:40.
6. Sadaka F, O'Brien J, Prakash S. Red cell distribution width and outcome in patients with septic shock. J Intensive Care Med. 2013;28:307-13.
7. Meynaar IA, Knook AH, Coolen S, Le H, Bos MM, Dijs F, et al. Red cell distribution width as predictor for mortality in critically ill patients. Neth J Med. 2013;71:488-93.
8. Moreno-Torres V, Royuela A, Múñez-Rubio E, Gutierrez-Rojas Á, Mills-Sánchez P, Ortega A, et al. Red blood cell distribution width as prognostic factor in sepsis: a new use for a classical parameter. J Crit Care. 2022;71:154069.
9. Zhang Z, Xu X, Ni H, Deng H. Red cell distribution width is associated with hospital mortality in unselected critically ill patients. J Thorac Dis. 2013;5:730-6.
10. Kim J, Im JS, Choi CH, Park CH, Lee JI, Son KH, et al. The association between red blood cell distribution width and sarcopenia in U.S. Adults. Sci Rep. 2018;8:11484.
11. Hu ZD, Lippi G, Montagnana M. Diagnostic and prognostic value of red blood cell distribution width in sepsis: a narrative review. Clin Biochem. 2020;77:1-6.
12. Salvagno GL, Sanchis-Gomar F, Picanza A, Lippi G. Red blood cell distribution width: a simple parameter with multiple clinical applications. Crit Rev Clin Lab Sci. 2015;52:86-105.
13. Fischer M, Jevenn A, Hipskind P. Evaluation of muscle and fat loss as diagnostic criteria for malnutrition. Nutr Clin Pract. 2015;30:239-48.
14. Detsky AS, McLaughlin JR, Baker JP, Johnston N, Whittaker S, Mendelson RA, et al. What is subjective global assessment of nutritional status? 1987. Classical article. Nutr Hosp. 2008;23:400-7.
15. Kawai T, Autieri MV, Scalia R. Adipose tissue inflammation and metabolic dysfunction in obesity. Am J Physiol Cell Physiol. 2021;320:C375-91.
16. Hartl WH, Jauch KW. Metabolic self-destruction in critically ill patients: origins, mechanisms and therapeutic principles. Nutrition. 2014;30:261-7.
17. Merker M, Felder M, Gueissaz L, Bolliger R, Tribolet P, Kägi-Braun N, et al. Association of baseline inflammation with effectiveness of nutritional support among patients with disease-related malnutrition: a secondary analysis of a randomized clinical trial. JAMA Netw Open. 2020;3:e200663.

ORIGINAL ARTICLE

Comparison of the two histological subtypes of ampullary adenocarcinoma: a retrospective study

Comparación de los dos subtipos histológicos del adenocarcinoma ampular: un estudio retrospectivo

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Abstract

Objectives: *This study aimed to compare the intestinal and pancreatobiliary subtypes of ampullary adenocarcinoma in a large patient group due to limited data on survival and risk factors.* **Methods:** *A retrospective analysis of the clinical and pathological findings and the survival of 184 patients with ampullary adenocarcinoma who underwent curative operation between 2007 and 2018 was performed.* **Results:** *Pancreatobiliary subtype had a higher prevalence of jaundice before operation than the intestinal subtype ($p < 0.05$). Pancreatobiliary subtype had a larger tumor size (> 2 mm) ($p < 0.01$) and poorer differentiation ($p < 0.05$) than the intestinal subtype. Perineural invasion more frequently occurred in pancreatobiliary subtype than the intestinal subtype ($p < 0.01$) and pancreatobiliary subtype had a higher prevalence of positive dissected lymph nodes ($p < 0.05$) with an advanced disease stage ($p < 0.01$) than the intestinal subtype. Patients of the pancreatobiliary subtype had poorer disease-free and overall survival than patients of the intestinal subtype. No survival benefit of adjuvant chemotherapy was found in either patients of the intestinal subtype or pancreatobiliary subtype. No significant difference was found in any subtypes regarding the recurrent regions.* **Conclusions:** *Pancreatobiliary subtype exhibited a higher recurrence rate and a poorer overall survival rate with more unfavorable pathological characteristics than the intestinal subtype.*

Keywords: *Ampullary adenocarcinoma. Histological subtype. Survival, prognosis.*

Resumen

Objetivos: *Los datos sobre la supervivencia y los factores de riesgo del adenocarcinoma ampular son limitados debido a su rareza. Este estudio buscó comparar el subtipo intestinal y el subtipo pancreático-biliar en pacientes con adenocarcinoma ampular.* **Métodos:** *Análisis retrospectivo de hallazgos clínicos y patológicos y la supervivencia de 184 pacientes con adenocarcinoma ampular tratados entre 2007 y 2018.* **Resultados:** *El subtipo pancreático-biliar tuvo una mayor prevalencia de ictericia antes de la operación y un tamaño de tumor mayor, y una peor diferenciación, que el subtipo intestinal. La invasión perineural fue más frecuente en el subtipo pancreático-biliar, con una mayor prevalencia de linfonodos disecados positivos y un estadio avanzado de la enfermedad. Los pacientes del subtipo pancreático-biliar tuvieron una supervivencia libre de enfermedad y una supervivencia general peores que los pacientes del subtipo intestinal. No se encontró ningún beneficio de la quimioterapia adyuvante en pacientes del subtipo intestinal o pancreático-biliar. No hubo diferencia significativa en las regiones recurrentes.* **Conclusión:** *El subtipo pancreático-biliar mostró una tasa de recurrencia y una tasa de supervivencia general peores, con características patológicas más desfavorables que el subtipo intestinal.*

Palabras clave: *Adenocarcinoma ampular. Subtipo histológico. Supervivencia. Pronóstico.*

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Introduction

The ampullary adenocarcinoma is a malignancy arising from the periampullary region[1]. It has been classified as intestinal and pancreatobiliary subtypes in histopathology[2]. The previous studies suggested that the prognosis was directly correlated with subtypes of ampullary adenocarcinoma[3,4]. Since the disease is rare, data on survival and the risk factors are limited. Most studies focusing on the histopathological predictors of ampullary adenocarcinoma have a small study population. The aim of this study is to compare the intestinal subtype and the pancreatobiliary subtype of ampullary adenocarcinoma in a large cohort of patients.

Methods

Patients

The findings on 184 consecutive patients who were operated on for ampullary adenocarcinoma from January 2007 and December 2018 at Shanghai Jiao Tong University Affiliated Sixth People's Hospital and Heilongjiang Provincial Hospital Affiliated to Harbin Institute of Technology were retrospectively reviewed. The population of this study consisted of 34 patients undergoing curative Whipple procedure and 150 patients undergoing curative pylorus-preserving procedure (PPPD). This study was approved by the ethics committee of Shanghai Jiao Tong University and was conducted according to the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from each patient.

Surgical procedure and chemotherapy

Curative resection was regarded as a negative resection margin and the complete resection of all metastatic lymph nodes. All patients underwent surgery with standard regional lymphadenectomy including the peripancreatic lymph nodes, the common and proper hepatic artery lymph nodes, the hepatoduodenal ligament lymph nodes, and those along the right lateral area of the superior mesenteric vessel. The aortocaval or paraaortic lymph nodes were dissected when they were enlarged seen in pre-operative imaging. Referral for adjuvant chemotherapy was done based on a consensus of the local multidisciplinary team. The chemotherapy regime was chosen at the discretion of the treating oncologist. No patients received radiotherapy. Chemotherapy regimens were extremely heterogeneous, but gemcitabine-based regimens were the most frequently adopted.

Pathological examination

One experienced pathologist in each center independently made the diagnoses and classified the histopathological subtypes. The classification was conducted as described previously[2,4]. Protein expression of CDX2, CK20, CK7, MUC2, MUC1, and MUC5a was detected by immunochemistry. The intestinal subtype was defined as positive immunostaining of CDX2, CK20, and MUC2, whereas the pancreatobiliary subtype was defined as positive immunostaining of MUC1, MUC5a, and CK7. TNM staging was performed according to the American Joint Committee on Cancer 8th edition[5].

Follow-up

Follow-up at 3-month intervals comprised of physical examination, laboratory tests, and tumor markers. CT or MR was arranged every 3 months in the 1st year and then every 6 months in the 2nd year. CT of the thorax, bone scan, and MR of the brain were performed if clinical examination led to a suspicion of metastasis or PET-CT was performed if other metastasis was suspected. The primary endpoint of the study was recurrence. The secondary endpoints were and disease-free survival and overall survival.

Statistical analysis

Continuous variables were expressed as median and range or mean ± standard deviation. Categorical variables were expressed as numbers and percentages. Normally distributed data were expressed as mean ± standard deviation and those that are not normally distributed were expressed as median and range. Chi-squared test was used for normal data. Univariate analysis was performed using the χ^2 test or Fisher's exact test for categorical variables. When the data did not normally distribute, the non-parametric Mann–Whitney U test was used. The survival was analyzed by Kaplan–Meier method with a log-rank test. Significant factors in univariate analysis were subjected to multivariate analysis by cox proportional hazard regression. Data were considered significant for $p < 0.05$. SPSS 20 statistical software (SPSS, Chicago, IL) was used for analyses.

Results

Comparison of the characteristics of intestinal and pancreatobiliary subtypes

The characteristics of intestinal and pancreatobiliary subtypes of ampullary adenocarcinoma were compared in table 1. Pancreatobiliary subtype had a higher prevalence of jaundice before operation than the intestinal subtype (58.3% vs. 45.7%, $p < 0.05$) whereas the pancreatobiliary subtype had a larger tumor size (> 2 mm) ($p < 0.01$) and poorer differentiation ($p < 0.05$) than intestinal subtype. Perineural invasion more frequently occurred in pancreatobiliary subtype than the intestinal subtype ($p < 0.01$). In addition, pancreatobiliary subtype had a higher prevalence of positive dissected lymph nodes ($p < 0.05$) with a more advanced disease stage (T, N, and TNM stages) ($p < 0.01$) than the intestinal subtype.

Comparison of survivals of intestinal and pancreatobiliary subtypes

Patients with pancreatobiliary subtype had poorer disease-free and overall survival than patients with the intestinal subtype ($p < 0.05$ and $p < 0.01$) (Fig. 1A and B). In multivariate analysis, jaundice, N stage, and perineural invasion were independently associated with disease-free and overall survival in patients with intestinal subtype. Meanwhile, T stage, N stage, and perineural invasion were independently associated with disease-free and overall survival in patients with pancreatobiliary subtype (Table 2). In addition, adjuvant chemotherapy was administered to 34.6% of the patients with the intestinal subtype and 26.2% of the patients with the pancreatobiliary subtype. No survival benefit of adjuvant chemotherapy was found in either patients with intestinal subtype or pancreatobiliary subtype ($p > 0.05$) (Table 3).

Comparison of recurrent patterns of intestinal and pancreatobiliary subtypes after curative resection

Eighty-eight patients experienced tumor recurrence. The patterns of recurrence are shown in table 4. Distant recurrence was found more frequently occurred than locoregional recurrence in both intestinal and pancreatobiliary subtypes. In distant recurrence patients, liver metastasis was identified as the most frequent occurrence, followed by distant lymph node metastasis and lung metastasis. No significant difference was found in any subtypes regarding recurrent regions ($p > 0.05$) (Table 4).

Discussion

Ampullary adenocarcinoma is a rare cancer. It is proven to have a better prognosis than bile duct cancer and pancreatic cancer. A 5-year survival rate of 45% was found in ampullary adenocarcinoma patients[6]. It is reasonable that an early symptom occurred due to obstructive jaundice caused by distal bile duct occlusion explains partially the better prognosis of ampullary carcinoma. It seems that tumor biological characteristics contribute to the favorable prognosis.

Noticeably, ampullary adenocarcinoma may arise from duodenal, pancreatic, or biliary epithelia. Two distinct histological subtypes (intestinal and pancreatobiliary) were identified based on the original epithelium. In this study, 81 carcinomas were classified into the intestinal (44.0%) and 103 into pancreatobiliary subtypes (56.0 %). We found that patients of pancreatobiliary subtype had poorer disease-free and overall survival than patients of the intestinal subtype. Furthermore, the pepancreatobiliary subtype was associated with a bigger tumor size, an advanced tumor stage, poorer differentiation, and more lymph node metastasis and perineural invasion, consisting with Kim's findings[7]. This could explain the poor prognosis of the pancreatobiliary subtype. Furthermore, jaundice, N stage, and perineural invasion were independently associated with disease-free and overall survival in patients of the intestinal subtype. Meanwhile, T stage, N stage, and perineural invasion were independently associated with disease-free and overall survival in patients of the pancreatobiliary subtype.

The effect of adjuvant chemotherapy remains indistinct for ampullary adenocarcinoma. Kurihara found that adjuvant chemotherapy did not show any survival benefits[8]. Although histological subtypes of ampullary adenocarcinoma have been widely admitted, the impact of subtypes on the response to chemotherapy is not clear. Ecker reported that there was no correlation between adjuvant chemotherapy and survival, regardless of histological subtypes[9]. In this study, no survival benefit of adjuvant chemotherapy was found in either patients of the intestinal subtype or pancreatobiliary subtype. In line with the previous reports[8,9].

In addition, patterns of recurrence after curative resection are not well known. We analyzed 88 patients experiencing tumor recurrence in the present study.

Table 1. Characteristic comparison between intestinal and pancreatobiliary subtypes of ampullary adenocarcinoma

Characteristic	Intestinal (n = 81)	Pancreatobiliary (n = 103)	p value
Gender, n (%)			NS
Male	42 (51.9%)	56 (54.4%)	
Female	39 (48.1%)	47 (45.6%)	
Mean age (years), (± SD)	64.7 ± 11.7	67.6 ± 11.6	NS
Mean BMI, (± SD)	23.6 ± 3.6	23.6 ± 3.6	NS
CA199 (U/ml), (median [range])	51 (1.5-559)	62.2 (1.5-728)	NS
Bilibubin (mg/dL), (median [range])	5.6 (1.4-10.5)	8.1 (1.5-13.8)	NS
Jaundice, n (%)			< 0.05
Absent	44 (54.3%)	43 (41.7%)	
Present	37 (45.7%)	60 (58.3%)	
Type of surgery, n (%)			NS
Whipple	17 (21.0%)	17 (16.5%)	
PPPD	64 (79.0%)	86 (83.5%)	
Tumor size (cm), (± SD)	2.2 ± 1.2	2.6 ± 1.2	< 0.01
T stage, n (%)			< 0.01
T1 + T2	81 (100.0%)	0 (0.0%)	
T3 + T4	0 (0.0%)	103 (100.0%)	
N stage, n (%)			< 0.01
Node negative	65 (80.2%)	67 (65.0%)	
Node positive	16 (19.8%)	36 (35.0%)	
TNM stage, n (%)			< 0.01
I + II	81 (100.0%)	79 (76.7%)	
III + IV	0 (0.0%)	24 (23.3%)	
Differentiation, n (%)			< 0.05
Well	30 (37.0%)	27 (26.2%)	
Moderate	46 (56.8%)	64 (62.1%)	
Poor	5 (6.2%)	12 (11.7%)	
Perineural invasion, n (%)			< 0.01
Absent	69 (85.2%)	73 (70.9%)	
Present	12 (14.8%)	30 (29.1%)	
Lymphovascular invasion, n (%)			NS
Absent	54 (66.7%)	65 (63.1%)	
Present	26 (33.3%)	38 (36.9%)	
Total lymph node harvested, n (median range)	10 (0-38)	12(0-43)	NS
Positive lymph node, n (median range)	1 (0-11)	1(0-14)	NS
Lymph node ratio, (median range)	0.05 (0.00-0.50)	0.09(0.00-1.00)	< 0.05
Adjuvant chemotherapy, n (%)			NS
Absent	53 (65.4%)	76 (73.8%)	
Present	28 (34.6%)	27 (26.2%)	

NS: not significant; PPPD: pylorus-preserving pancreaticoduodenectomy.

Distant recurrence was found more frequently occurred than locoregional recurrence in both the intestinal subtype and pancreatobiliary subtype. In distant recurrent patients, liver metastasis was identified as most frequently occurring, followed by distant lymph node metastasis and lung metastasis. No significant difference was found in any subtypes regarding recurrent regions.

In the queue of patients we studied, all patients were eligible for pancreaticoduodenectomy or PPPD after evaluation, compared to endoscopic papillectomy and transduodenal local resection, pancreaticoduodenectomy

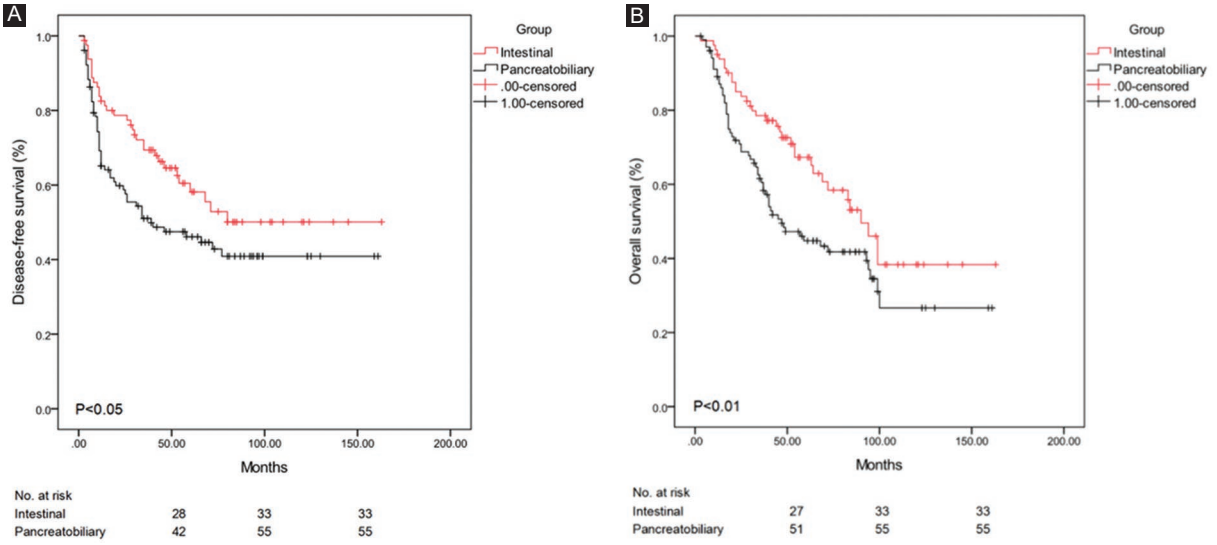

Figure 1. *Diseaese-free survival and overall survival of patients.* **A:** *patients of pancreatobiliary subtype had poorer disease-free than patients of intestinal subtype (p < 0.05).* **B:** *patients of pancreatobiliary subtype had poorer overall survival than patients of intestinal subtype (p < 0.01).*

Table 2. Multivariate analysis for predictive factors influencing survival in patients with intestinal and pancreatobiliary subtypes of ampullary adenocarcinoma

Subtype	Disease-free survival			Overall survival		
	HR	95% CI	p value	HR	95% CI	p value
Intestinal						
Jaundice	2.4	1.2-4.8	< 0.05	3.4	1.6-7.0	< 0.01
N stage	2.6	1.4-4.1	< 0.01	2.7	1.2-4.2	< 0.01
Perineural invasion				3.1	1.4-7.1	< 0.01
Pancreatobiliary						
T stage	2.3	1.2-3.9	< 0.01	2.6	1.3-4.4	< 0.01
N stage	3.1	1.6-4.6	< 0.01	2.0	1.2-3.1	< 0.01
Perineural invasion	2.0	1.1-3.4	< 0.01	1.9	1.1-3.2	< 0.05

Table 3. Univariate analysis for adjuvant chemotherapy influencing intestinal and pancreatobiliary subtypes of ampullary adenocarcinoma

Subtype	Disease-free survival			Overall survival		
	HR	95% CI	p value	HR	95% CI	p value
Intestinal (n = 81) Absent (n = 53) Present (n = 28)	0.8	0.4-1.7	> 0.05	1.0	0.5-1.9	> 0.05
Pancreatobiliary (n = 103) Absent (n = 76) Present (n = 27)	1.4	0.8-2.4	> 0.05	1.4	0.8-2.3	> 0.05

has a more thorough surgical margin and lower recurrence rate, but with slightly higher perioperative morbidity and mortality rates[10]. In addition, whether adjuvant chemotherapy was used had no impact on DFS and OS in either intestinal or pancreatobiliary subtypes. Although the choice of chemotherapy drugs may differ, the most commonly used drug in our center is gemcitabine, which is contradictory to the research results of Duke University, which showed that adjuvant radiotherapy and chemotherapy had a significant effect on the 3-year local recurrence (88% vs. 55%, p = 0.001) and was beneficial for disease-free survival (66% vs. 48%, p = 0.09) and overall survival (62% vs. 46%, p = 0.074)[11]. In addition, there is evidence to suggest that gemcitabine-based regimens may be particularly useful for patients with

Table 4. Patterns of recurrence after curative resection

Site	No of recurrence (n = 88)		p value
	Intestinal (n = 33)	Pancreatobiliary (n = 55)	
Locoregional, n (%)	8 (24.2%)	14 (25.5%)	NS
Distant, n (%)	25 (75.8%)	41 (74.5%)	
Liver	12 (48.0%)	20 (48.8%)	NS
Lymph node	5 (20.0%)	8 (19.5%)	NS
Lung	5 (20.0%)	6 (14.6%)	NS
Seeding	3 (12.0%)	3 (7.3%)	NS
Bone	0 (0.0%)	2 (4.9%)	NS
Brain	0 (0.0%)	2 (4.9%)	NS

NS: not significant

pancreaticobiliary-type ampullary carcinoma, while 5-fluorouracil-based regimens may be beneficial for those with intestinal-type ampullary carcinoma[12]. It is possible that differences in the selection of chemotherapy agents and the histological composition of patient populations may have led to different conclusions in different research centers.

In addition, molecular alterations in ampullary adenocarcinoma are receiving increasing attention. Different histological subtypes involve different molecular changes, which can also lead to differences in prognosis. Studies have shown that chromosomal 17p deletion is an indicator of poor prognosis and can help determine whether patients need adjuvant therapy beyond surgery. In addition, molecular changes involving TP53, K-RAS, APC, ELF-3, and ERBB2 in ampullary cancer are being increasingly discovered[10,13]. These molecules activate pathways such as WNT and PI3K, and increase microsatellite instability, which is becoming increasingly important for treatment and prognosis[14].

This study had some limitations due to its retrospective character. Although there were limitations in this study, the differences between the groups were dramatic.

Conclusions

Patients of pancreatobiliary subtype exhibited a higher risk of recurrence and disease-related death with more unfavorable pathological characteristics than patients of the intestinal subtype. Therefore, it is important to strengthen the pre-operative classification and post-operative follow-up of these patients, select the most appropriate treatment method according to different subtypes, and improve the prognosis of patients, which can greatly reduce the risk of death from ampullary adenocarcinoma.

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Conflicts of interest

The authors state no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective and observational study.

References

1. Kimura W, Ohtsubo K. Incidence, sites of origin, and immunohistochemical and histochemical characteristics of atypical epithelium and minute carcinoma of the papilla of Vater. Cancer. 1988;61:1394-402.
2. Kimura W, Futakawa N, Yamagata S, Wada Y, Kuroda A, Muto T, et al. Different clinicopathologic findings in two histologic types of carcinoma of papilla of Vater. Jpn J Cancer Res Gann. 1994;85:161-6.
3. Carter JT, Grenert JP, Rubenstein L, Stewart L, Way LW. Tumors of the ampulla of vater: histopathologic classification and predictors of survival. J Am Coll Surg. 2008;207:210-8.
4. Chang DK, Jamieson NB, Johns AL, Scarlett CJ, Pajic M, Chou A, et al. Histomolecular phenotypes and outcome in adenocarcinoma of the ampulla of vater. J Clin Oncol. 2013;31:1348-56.
5. Amin MB, Greene FL, Edge SB, Compton CC, Gershenwald JE, Brookland RK, et al. The Eighth Edition AJCC cancer staging manual: continuing to build a bridge from a population-based to a more "personalized" approach to cancer staging. CA Cancer J Clin. 2017;67:93-9.
6. Sarmiento JM, Nagomey DM, Sarr MG, Farnell MB. Periampullary cancers: are there differences? Surg Clin North Am. 2001;81:543-55.
7. Kim WS, Choi DW, Choi SH, Heo JS, You DD, Lee HG. Clinical significance of pathologic subtype in curatively resected ampulla of Vater cancer. J Surg Oncol. 2012;105:266-72.
8. Kurihara C, Yoshimi F, Sasaki K, Iijima T, Kawasaki H, Nagai H. Clinical value of serum CA19-9 as a prognostic factor for the ampulla of Vater carcinoma. Hepatogastroenterology. 2013;60:1588-91.
9. Ecker BL, Vollmer CM Jr., Behrman SW, Allegrini V, Aversa J, Ball CG, et al. Role of adjuvant multimodality therapy after curative-intent resection of ampullary carcinoma. JAMA Surg. 2019;154:706-14.
10. Regalla DK, Jacob R, Manne A, Paluri RK. Therapeutic options for ampullary carcinomas. A review. Oncol Rev. 2019;13:440.
11. Palta M, Patel P, Broadwater G, Willett C, Pepek J, Tyler D, et al. Carcinoma of the ampulla of Vater: patterns of failure following resection and benefit of chemoradiotherapy. Ann Surg Oncol. 2012;19:1535-40.
12. Hong SM. Histologic subtyping of ampullary carcinoma for targeted therapy. J Pathol Transl Med. 2021;55:235.
13. Hechtman JF, Liu W, Sadowska J, Zhen L, Borsu L, Arcila ME, et al. Sequencing of 279 cancer genes in ampullary carcinoma reveals trends relating to histologic subtypes and frequent amplification and overexpression of ERBB2 (HER2). Mod Pathol. 2015;28:1123-9.
14. Gingras MC, Covington KR, Chang DK, Donehower LA, Gill AJ, Ittmann MM, et al. Ampullary cancers harbor ELF3 tumor suppressor gene mutations and exhibit frequent WNT dysregulation. Cell Rep. 2016;14:907-19.

ORIGINAL ARTICLE

Protective effects of Passiflora Incarnata on ischemia-reperfusion injury in testicular torsion: an experimental study in a rat model

Efectos protectores de Passiflora incarnata en la lesión por isquemia-reperfusión en la torsión testicular: un estudio experimental en un modelo de rata

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Abstract

Objective: *The current study aimed to explore the potential protective effect of Passiflora Incarnata L., (PI) in treating IR injury after testicular torsion in rats.* **Materials and methods:** *This research investigated the impact of PI on IR damage in male Wistar albino rats. Animals were divided to three groups: group 1 (sham), group 2 (IR), and group 3 (IR+PI).* **Results:** *The malondialdehyde (MDA), myeloperoxidase (MPO) and glutathione (GSH) levels did not significantly differ across the groups ($p = 0.830$, $p = 0.153$ and $p=0.140$, respectively). However, Group 3 demonstrated a superior total antioxidant status (TAS) value compared to Group 2 ($p = 0.020$). Concurrently, Group 3 presented a significantly diminished mean total oxidant status (TOS) relative to Group 2 ($p = 0.009$). Furthermore, Group 3 showed a markedly improved Johnsen score relative to Group 2 ($p < 0.01$). IR caused cell degeneration, apoptosis, and fibrosis in testicular tissues. PI treatment, however, mitigated these effects, preserved seminiferous tubule integrity and promoted regular spermatogenesis. Furthermore, it reduced expression of tumor necrosis factor-alpha (TNF-α), Bax, and Annexin V, signifying diminished inflammation and apoptosis, thereby supporting cell survival ($p < 0.01$, $p < 0.01$, $p < 0.01$, respectively).* **Conclusions:** *This study revealed that PI significantly reduces oxidative stress and testicular damage, potentially benefiting therapies for IR injuries.*

Keywords: *Passiflora Incarnata. Ischemia reperfusion. Testicular torsion. Testicular damage. Spermatogenesis.*

Resumen

Objetivo: *Explorar el posible efecto protector de Passiflora incarnata L. (PI) en el tratamiento de la lesión por isquemia-reperfusión (IR) después de una torsión testicular en ratas.* **Método:** *Se estudió el impacto de Passiflora incarnata en el daño por IR en ratas Wistar albinas machos. Los animales se dividieron tres grupos: 1 (simulado), 2 (IR) y 3 (IR+PI).* **Resultados:** *Los niveles de malondialdehyde (MDA), myeloperoxidase (MPO) y glutathione (GSH) no difirieron significativamente entre los grupos ($p = 0.830$, $p = 0.153$ y $p = 0.140$, respectivamente). Sin embargo, el grupo 3 tuvo un valor de estado antioxidante total (TAS) superior en comparación con el grupo 2 ($p = 0.020$). Al mismo tiempo, el grupo 3 presentó un estado oxidante total (TOS) medio significativamente disminuido en comparación con el grupo 2 ($p = 0.009$). El grupo 3 mostró una mejora notable en la puntuación de Johnsen en comparación con el grupo 2 ($p < 0.01$). La IR causó degeneración celular, apoptosis*

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y fibrosis en los tejidos testiculares. El tratamiento con PI mitigó estos efectos, preservó la integridad de los túbulos seminíferos y promovió la espermatogénesis regular. Además, redujo la expresión de factor de necrosis tumoral alfa, Bax y anexina V, lo que significa una disminución de la inflamación y de la apoptosis, respaldando así la supervivencia celular ($p < 0.01$, $p < 0.01$ y $p < 0.01$, respectivamente). **Conclusiones:** *Este estudio reveló que PI reduce significativamente el estrés oxidativo y el daño testicular, beneficiando potencialmente las terapias para lesiones por IR.*

Palabras clave: *Passiflora incarnata. Isquemia-reperfusión. Torsión testicular. Daño testicular. Espermatogénesis.*

Introduction

Acute scrotum, a urological emergency, presents as sudden scrotal pain, redness, and swelling. Testicular torsion (TT), which makes up approximately 35% to 42% of acute scrotal conditions, is the culprit behind this urological issue[1]. This condition results from a twisted spermatic cord, interrupting the flow of blood to the testicle. It's imperative to intervene early to prevent tissue damage resulting from ischemia[1,2]. Instead of being employed as a diagnostic method, the preferred approach to treating testicular torsion involves executing manual or surgical detorsion as an emergency procedure. Literature suggests that detorsion, either manual or surgical, carried out within the initial six hours results in a high rate of testicular tissue preservation[2]. The reported rates of orchiectomy vary widely, with most studies indicating a range between 39% to 71%[3]. The principal factors contributing to the damage of testicular parenchymal tissue include elevated reactive oxygen species (ROS) levels, increased calcium levels within mitochondria, and cellular apoptosis. In an effort to limit the negative impacts of ischemia-reperfusion injury, a variety of medical treatments, used in tandem with manual or surgical detorsion, are currently under investigation[4-6].

The passionflower, scientifically known as PI is a perennial plant capable of reaching heights of up to 10 meters, bearing egg-shaped edible fruits. Originally found in South America, Australia, and Southeast Asia, it is now cultivated for pharmaceutical applications. Among the Passiflora genus[7], PI is recognized for its documented therapeutic benefits. Various parts of the plant, including aerial parts, flowers, and fruits, are harnessed for medicinal uses due to their anthelmintic, antispasmodic, and anxiolytic properties. Passionflower is employed as a treatment for a variety of conditions, ranging from burns and diarrhea to painful menstruation, neurotic disorders, and insomnia, among others[6,7]. Soumya et al.'s study first revealed that passionflower extract juice could mitigate myocardial infarction, partially through oxidative stress inhibition[8]. It's also useful in treating morphine dependency and can be beneficial for convulsions or neuralgia[7,9].

The current study aimed to investigate the potential protective effect of PI in treating ischemia-reperfusion injury after testicular torsion in rats. To the best of our knowledge, this is the first study administering PI to rats in a testis torsion-induced model.

Materials and methods

This research investigated the impact of PI on ischemia-reperfusion damage in male Wistar albino rats. A total of 21 rats, each 12 weeks old and weighing an average of 240 g, were used in compliance with the guidelines of the institution and the National Research Council's principles for the Care and Use of Laboratory Animals. The Dicle University Animal Studies Ethical Committee granted ethical clearance for the research (approval number: 2023/08, date:30.03.2023).

The rats were kept under conditions with a temperature between 20-23°C and a light/dark cycle of 12 hours. Their diet consisted of standard pellets and water supplied freely. They were randomly separated into three groups: Group 1 (sham), Group 2 (ischemia-reperfusion), and Group 3 (treatment). In group 1, all surgical procedures except for testicular torsion-detorsion were performed. This was done to establish base values for all parameters. The testicle was extracted via a scrotal incision and then placed back in its usual position within the scrotum. No testicular torsion was applied in this particular group. Group 2 experienced testicular torsion and detorsion without any medication. Group 3 was administered 500 mg/kg/day of PI orally (Pasiflora incarnata tablet form, Megafarma- Istanbul, Turkey) for 5 days prior to performing I/R. The PI was diluted with a 0.9% saline solution just before use. In Groups 2 and 3, ischemia-reperfusion injury was induced in the rat testes using a method that involved pulling out the testis through an inguinoscrotal incision, rotating it 720 degrees clockwise, and then securing it to the

scrotum for two hours using a 5.0 prolene suture. The aim was to establish a controlled testicular torsion model to investigate the impact of ischemia and the subsequent reperfusion. Post-ischemia, the testis was detorsioned and allowed to remain in its regular position for four hours to evaluate reperfusion damage. Finally, orchiectomy was performed to obtain testis tissue for histopathological examination, and blood was drawn via cardiac puncture for biochemical analysis. All surgical procedures were carried out under appropriate anesthesia and sterile conditions. For this, rats were given a mix of two anesthetic drugs, xylazine hydrochloride (Rompun 2%, Bayer, Turkey) and ketamine hydrochloride (Alfamine 10%, Ege Vet, Turkey) at dosages of 10 mg/kg and 50 mg/kg respectively, both administered intraperitoneally. Xylazine hydrochloride served as a sedative and muscle relaxant, whereas ketamine hydrochloride was used for its dissociative anesthetic effects. The use of these agents helped ensure the rats' comfort and pain minimization during the procedures (Fig. 1).

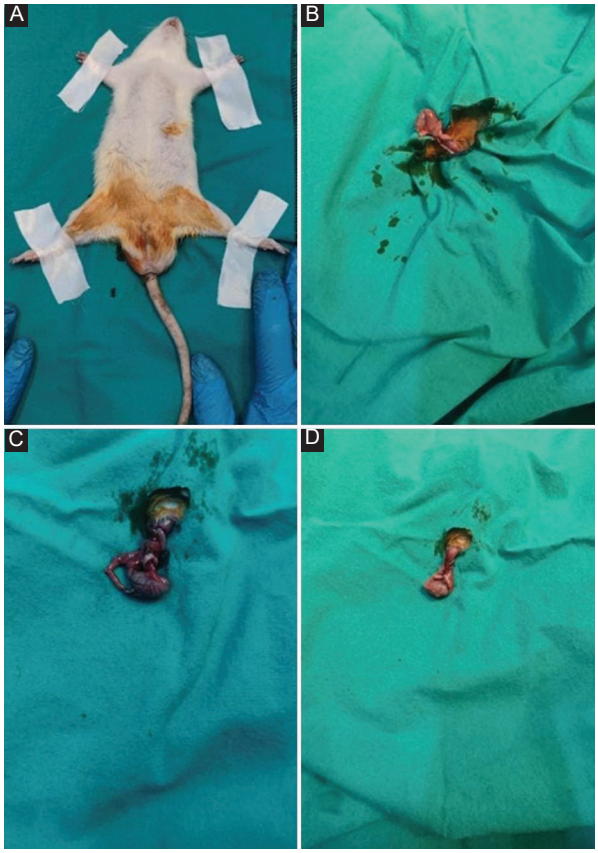

Figure 1. *A: preoperative.* **B:** *before torsion procedure.* **C:** *torsion was performed.* **D:** *detorsion.*

Biochemical evaluation

Following a cardiac puncture, blood samples were swiftly moved to the biochemistry lab on ice. These samples were then centrifuged at 4,000 rotations per minute for 5 minutes, and the serum was isolated. Analyses were done for total antioxidant status (TAS), total antioxidant status (TOS), Malondialdehyde (MDA), Myeloperoxidase (MPO), and Glutathione (GSH). Using an Abbott Architect C16000 auto analyzer, the TAS and TOS levels were gauged via commercial kits supplied by Rel Assay Diagnostics from Gaziantep, Turkey, and through automated colorimetric methods designed by Erel et al[10,11]. The TAS findings are given in micromolar trolox equivalent per liter, while the TOS findings are provided in micromolar hydrogen peroxide equivalent per liter. MDA content was assessed through a spectrophotometric method based on the color change that occurs when thiobarbituric acid reacts with MDA, as previously described[12]. Similarly, MPO activity was also evaluated spectrophotometrically, as mentioned before[6,13]. The method proposed by Paglia et al., was utilized to measure the glutathione peroxidase (GSH-Px) activity, which checks the enzyme's capacity to aid the conversion of reduced glutathione (GSH) into oxidized glutathione (GSSG) in the presence of hydrogen peroxide[4,14].

Immunohistochemical examination

Testicular tissues were excised for histological sampling. Dissected cerebral samples were further analyzed for histological evaluation. Samples were immersed in zinc-formalin and dehydrated through grading alcohol series and incubated in paraffin wax. 5 μm sections were cut from paraffin blocks and stained for hematoxylin eosin dye and immune staining. Testicular sections were dewaxed, hydrated in grading alcohol series and washed in distilled water. 3% hydrogen peroxide (H2O2) was dropped on slides to block endogen peroxidase activity. After washing in PBS, sections were incubated with anti-blood brain barrier (catalog no:836804, Biolegend, California, US). Annexin V (catalog no:0902012, Boster Biology Tech., 1/100) and TNF-α and Bax (catalog no: 15970 and 17069, Biorbyt, 1/100) overnight at + 4°C. Sections were biotinylated and allowed to react with streptavidin peroxidase solution (Thermo Fischer, US) for 15 minutes. After PBS washing, diaminobenzidine (DAB) chromogen was used as a chromogen to observe color change. The

reactions were stopped with PBS solution and sections were counter stained with hematoxylin dye. Slides were mounted and imaged with Zeiss Imager A2 light microscope. All images were processed and quantified using ImageJ software.Staining intensity of protein expression was measured by Image J software (version 1.53, http://imagej.nih.gov/ij). Measurement was calculated by method of Crowe et al.[15] Spermatogenesis were histologically evaluated for each sample with ten fields count by method of Johnsen et al.[16] A Johnsen score of 10 indicates maximum spermatogenesis activity, whereas a score of 1 indicates complete absence of germ cells. Histological scoring was performed by two blind experts (Table 1).

Table 1. Johnsen scoring for spermatogenesis

Johnsen Biopsy parameters	Score
Regular, dense spermatogenesis and tubule structure	10
Dense spermatozoa in the lumen but irregularity in the spermatogenic line	9
The small amount of spermatozoa present in the lumen	8
No spermatozoa in the lumen but spermatids are present	7
The low number of spermatids	6
No spermatozoa and spermatids but dense spermatocytes	5
Low amount of spermatocytes	4
Only Spermatogonia available	3
There are no germ cells	2
No germ cells or Sertoli cells	1

Statistical analysis

The statistical analysis was carried out with IBM SPSS 25.0 software (IBM, Armonk, New York, US). The data distribution was determined by applying the Shapiro-Wilk and Kolmogorov-Smirnov tests. If the data conformed to a normal distribution, it was recorded as the mean and standard deviation, and the ANOVA test was used. If not, data was presented as the median (IQR). For comparisons involving more than two groups, the non-parametric Kruskal-Wallis test was employed, and due to the small sample size in the groups, the post-hoc Dunn test was used. Statistical significance was recognized for values less than 0.05.

Results

The MDA levels were similar across all groups, with means of 1.36±0.55, 1.26±0.15, and 1.25±0.18 for groups 1, 2, and 3, respectively ($p = 0.830$). Similarly, MPO and GSH levels did not significantly differ across the three groups ($p = 0.153$ and $p = 0.140$, respectively). However, TAS levels were significantly different between groups 2 and 3 ($p = 0.031$) and groups 1 and 3 ($p = 0.049$) with an overall p-value of 0.020. TOS levels significantly varied between groups 2 and 3 ($p = 0.026$), and groups 1 and 2 ($p = 0.012$) with an overall p-value of 0.009. The tissue assessments revealed significant disparities in the Johnson score, a metric for testicular damage evaluation. Group 1 and Group 2 showed a clear difference, as did Group 2 and Group 3, with the overall p-value being less than 0.01. The same significant differences were observed for TNF-α, Bax, and Annexin V immunostaining percentages ($p < 0.01$ for each), reflecting the inflammation and apoptosis brought about by ischemia-reperfusion and the protective effects of the treatment (Table 2).

The hematoxylin and eosin staining of the testicular tissues is displayed in Fig. 2. In the sham group sections, a normal testicular tissue structure was observed. The seminiferous tubule membranes and spermatogenic line were seen naturally. Leydig cells were localized in the interstitial area. In the IR group, it was observed that spermatogenic cells were undergoing degeneration and apoptosis, the seminiferous tubule membranes were thickened, and fibrosis was developing in the interstitial area. Pycnosis was seen in the nuclei of Leydig cells. In the group where ischemia-reperfusion and PI were applied (group 3), improvement in the histopathology resulting from the IR damage was observed. It was seen that the integrity of the seminiferous tubule was preserved, the cells in the spermatogenesis line were regular, and the blood vessels and Leydig cells in the interstitial area looked almost normal histologically after the IR damage.

The immunoreactivity of TNF-α in the testicular tissues is demonstrated in Fig. 3. In the sham group, TNF-α expression was generally negative in the seminiferous tubules, spermatogenic cells, and interstitial area. In the IR group, TNF-α expression was intensely observed in the spermatogenic cells, interstitial area, and the membrane of the seminiferous tubule. After Passiflora treatment, a decrease in the TNF-α immune reaction was observed. It could be stated that due to Passiflora's anti-inflammatory effect.

Table 2. Biochemical and immunohistopathological parameters of all groups

	Group 1	Group 2	Group 3	p-value	Meaningful comparisons (intergroup)
Blood					
MDA	1.36 ± 0.55	1.26 ± 0.15	1.25 ± 0.18	0.830	
MPO	12.01 ± 2.83	11.83 ± 0.76	14.61 ± 3.69	0.153	2 and 3 (p = 0.031); 1 and
GSH	183.44 ± 66.94	166.45 ± 43.82	243.56 ± 89.15	0.140	3 (p = 0.049)
TAS	0.65 ± 0.08	0.62 ± 0.12	0.93 ± 0.29	0.020	2 and 3 (p = 0.026); 1 and
TOS	14.20 ± 8.49	136.58 ± 104.19	32.85 ± 43.33	0.009	2 (p = 0.012)
Tissue					
Johnson score	9 (9-10)	3 (1.25-3)	6 (5.25-7)	< 0.01	1 and 2; 2 and 3
TNF-α immunostaining*	17.52%	41.20%	21.87%	< 0.01	1 and 2; 2 and 3
Bax immunostaining*	12.73%	39.22%	23.20%	< 0.01	1 and 2; 2 and 3
Annexin V immunostaining*	13.88%	42.50%	30.03%	< 0.01	1 and 2; 2 and 3

*Percentage.
MDA: malondialdehyde; MPO: myeloperoxidase; GSH: glutathione; TAS: Total Antioxidant Status; TOS: Total Oxidant Status; TNF-α: tumor necrosis factor-alpha.

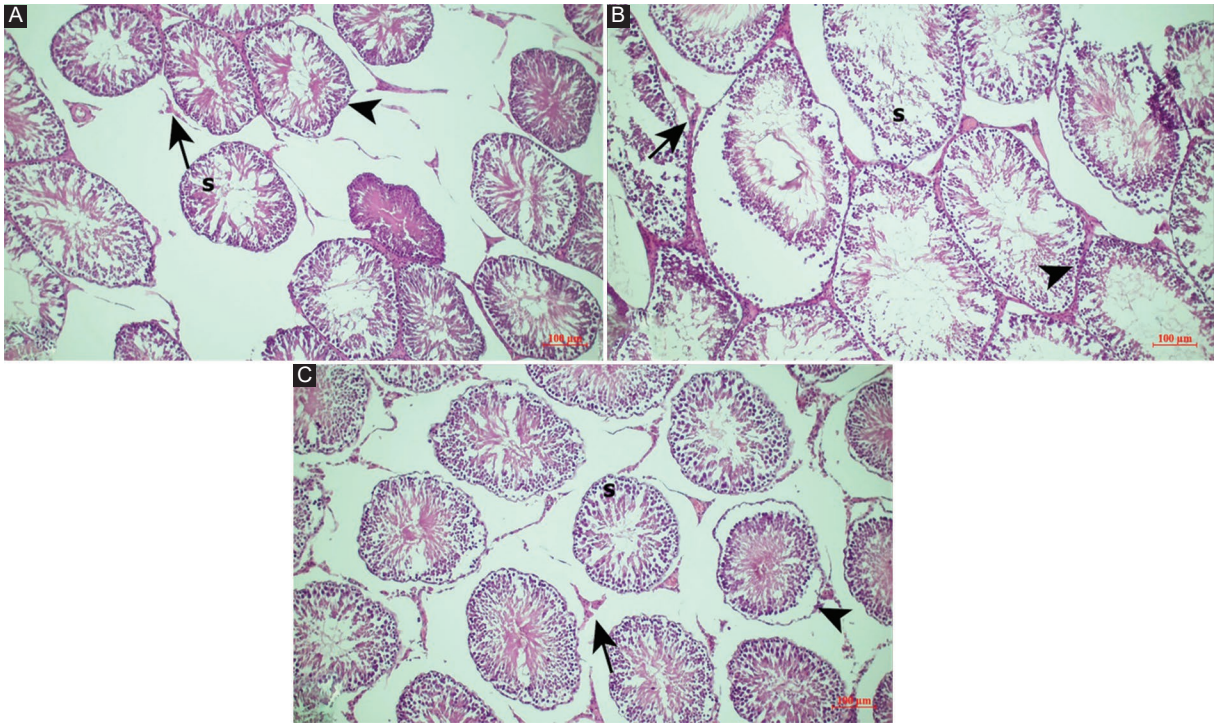

Figure 2. Hematoxyline eosin staining. **A:** *sham group.* **B:** *IR group.* **C:** *IR+PI group. S: spermatogenic cell line; Arrow: leydig cells; arrowhead: seminiferous tubule basement membrane. Scale bar: 100 µm; magnification: 10x.*

The immunoreactivity of Bax in the testicular tissues is illustrated in figure 4. In the sham group, the negative Bax expression was observed in the epithelium of seminiferous tubules, spermatogenic cells, and in the interstitial area. IR damage activated the apoptotic pathway and increased Bax expression. The Bax immune reaction was intensely observed in spermatogenic cells, the interstitial area, and the membrane of the seminiferous tubule. Due to Passiflora's antiapoptotic effect, proapoptotic Bax expression decreased and cell survival was supported. The Bax immune reactivity showed a decrease in the seminiferous tubules, spermatogenic cells, and Leydig cells.

The immunoreactivity of Annexin V in testicular tissues is presented in figure 5. In the sham group, Annexin V immune reactivity was mostly observed to be negative. Negative Annexin V reactions were detected in the epithelium of seminiferous tubules, spermatogenic cell lines, and

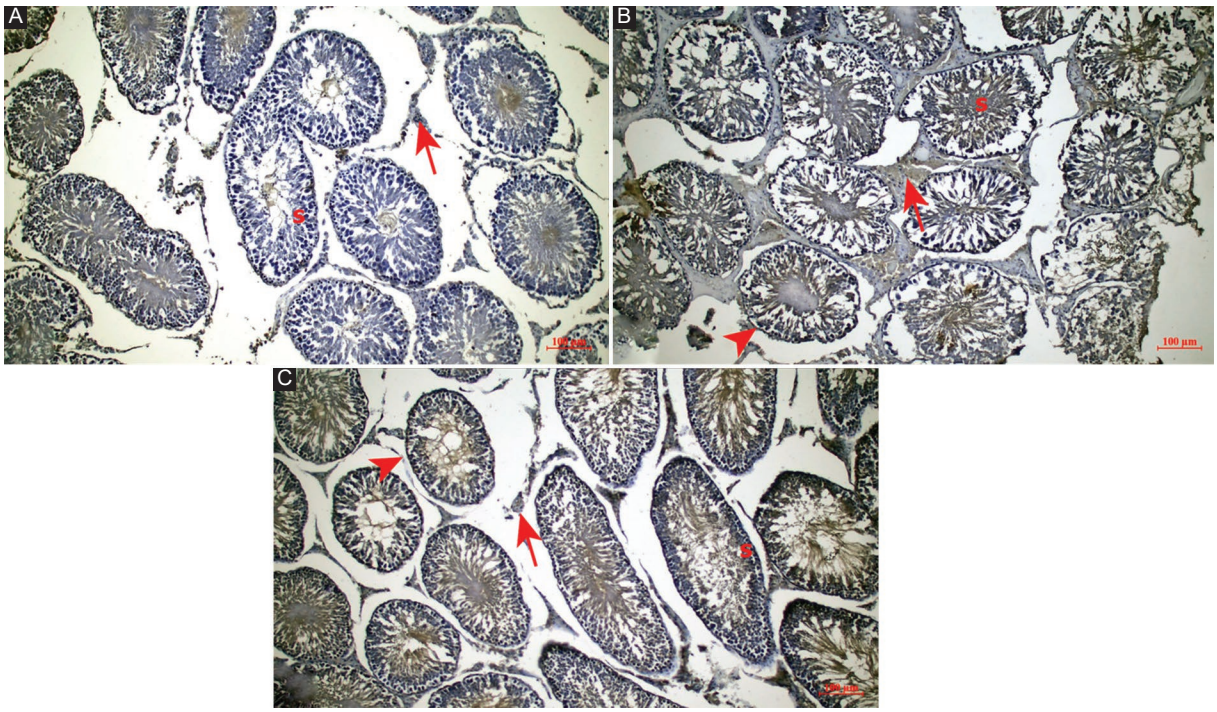

Figure 3. *TNF-α immunostaining.* **A:** *sham group.* **B:** *IR group.* **C:** *IR+PI group. S: spermatogenic cell line; Arrow: leydig cells; arrowhead: seminiferous tubule basement membrane. Scale bar: 100 µm; magnification: 10x.*

Leydig cells. In the IR group, due to the activation of the apoptotic pathway resulting from IR, Annexin V expression was observed intensely in spermatogenic cells, in the interstitial area, and the membrane of the seminiferous tubule. Due to the antiapoptotic effect of Passiflora, there was a significant decrease in the immune reaction of Annexin V, which is used as a marker of apoptotic cells. Annexin V expression showed a decrease in the seminiferous tubules, spermatogenic cells, and Leydig cells.

Discussion

Testicular torsion is a urological emergency that can cause infertility, damage to germ cells, and testicular atrophy. Urologists must take prompt action to treat the urgent situation of testicular torsion. One in 4000 guys between the ages of one and 25 experience this disorder annually[17]. Since severe testicular ischemia damage can happen after four to eight hours, prompt diagnosis and treatment are essential to preserve both testicular function and fertility. When surgical exploration is performed within six hours of the onset of symptoms, the testicles can be saved with a reported success rate of 90% to 100%[18]. When symptoms last for more than 12 hours, the rates drop to 50%, and when they last for 24 hours or longer, they often drop below 10%[19]. The literature has a wide range of orchiectomy rates, with the majority of series showing a range of 39% to 71%[17-19]. The main treatment for testicular torsion is surgical surgery, which involves reversing the torsion and restoring blood flow to the testis[1,4]. Given that the length of the torsion is strongly related to the chance of losing a testicle, prompt surgical intervention is absolutely necessary. In an effort to reduce IR damage related to TT, several strategies have been used such as cordycepin, roflumilast and ibuprofen, arbutin, thymoquinone, and syringic acid[4-6,20-22]. However this is the first study To the best of our knowledge, this is the first study administering PI to rats in a testis torsion-induced model.

The study of Okur et al.[5] found that cordycepin significantly reduced TNF-α and MDA levels and increased TAS while decreasing TOS in the testicular tissue of rats subjected to I/R, compared to the I/R group without cordycepin treatment, indicating its potential protective effect against I/R-induced testicular damage. Özgür et al.[6] study highlighted that both ibuprofen and roflumilast offer protective effects as antioxidant treatments in testicular ischemia-reperfusion injury, with roflumilast demonstrating superior benefits. Gökçe et al.[22] study found that in the testicular IR group, TOS, OSI, and MDA levels were higher than in the control group, while Thymoquinone (TQ) treatment effectively reduced MDA,

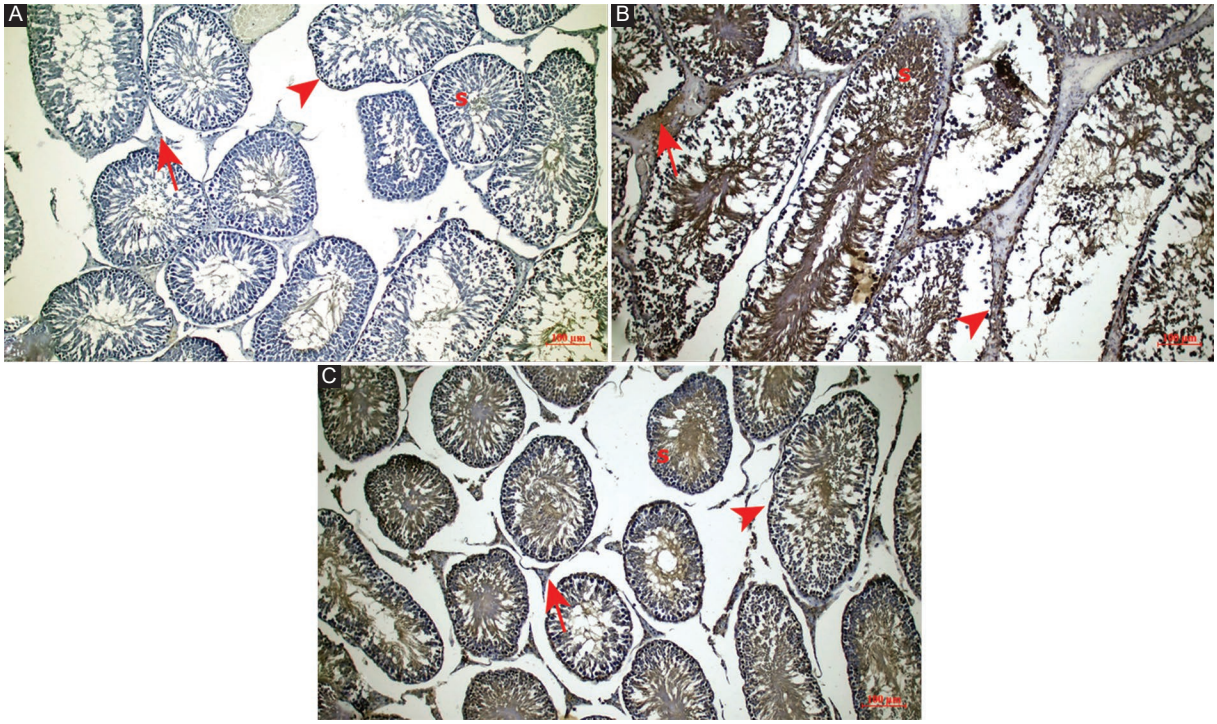

Figure 4. *Bax immunostaining.* **A:** *sham group.* **B:** *IR group.* **C:** *IR+PI group. S: spermatogenic cell line; Arrow: leydig cells; arrowhead: seminiferous tubule basement membrane. Scale bar: 100 μm; magnification: 10x.*

TOS, and OSI values, but had no impact on TAC and MPO activity. The research conducted by Sarikaya and his colleagues[4], revealed that syringic acid could mitigate the tissue damage brought about by ischemia-reperfusion. They noted an elevation in serum levels of antioxidants like SOD and GSH-Px, along with a reduction in MDA, which signifies lipid peroxidation. Moreover, rats treated with syringic acid exhibited improved seminiferous tubule morphology, spermatogenesis processes, and scores on both the Johnsen and Cosentino scoring systems, suggesting enhanced germ cell maturation. The results of their experimental study suggest the potential of syringic acid as an effective alternative therapeutic method to mitigate ischemia-reperfusion damage post-detorsion procedures in rats suffering from testicular torsion.

On the other hand, PI is highly regarded for its proven therapeutic advantages. Due to the plant's anthelmintic, antispasmodic, and anxiolytic characteristics, various components, including the aerial parts, flowers, and fruits, are used medicinally[23]. PI has shown potential in reducing stress, enhancing motivation, improving memory, managing insomnia, and alleviating anxiety and depressive states[23]. Pre-treatment with PI juice (2 ml/kg) for 28 days followed by isoproterenol treatment demonstrated protective effects against ISO-induced myocardial infarction in rats[8]. Another study concluded that Passiflora species, via their extracts and flavonoids such as quercetin, apigenin, and vitexin, have the potential to serve as a robust source of anti-inflammatory and antioxidant treatments[24]. These could be instrumental in preventing and controlling a wide range of diseases marked by complex inflammatory processes.

The findings from our research indicate that no significant differences in MDA, MPO, and GSH levels across the three groups. However, the Total Antioxidant Status (TAS) and Total Oxidant Status (TOS) levels varied significantly between the groups, particularly between groups 2 and 3 and groups 1 and 2, indicating variations in oxidative stress. The Johnson score, a metric for testicular damage, also showed significant differences between the groups, reflecting inflammation, apoptosis, and the impact of treatment with PI. The protective effects of treatment with PI were further confirmed by immunostaining results for TNF-α, Bax, and Annexin V. The histopathology analysis showed normal tissue structure in the control group, degeneration, and fibrosis in the ischemia-reperfusion group, and an improvement in tissue structure in the group treated with PI. Similarly, immunoreactivity for TNF-α, Bax, and Annexin V in testicular tissues further confirmed the protective effect of PI, demonstrating a reduction in inflammation and apoptosis after the administration of PI.

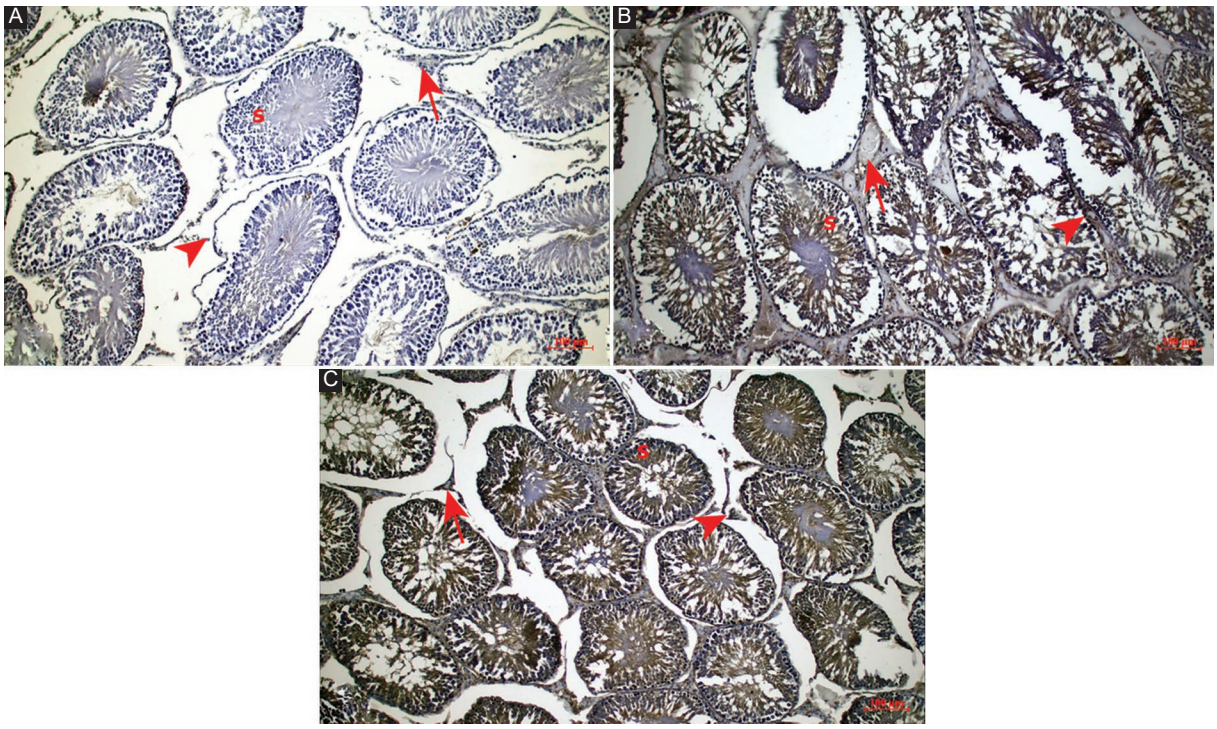

Figure 5. *Annexin V immunostaining.* **A:** *sham group.* **B:** *IR group.* **C:** *IR+PI group. S: spermatogenic cell line; Arrow: leydig cells; arrowhead: seminiferous tubule basement membrane. Scale bar: 100 μm; magnification: 10x.*

As evidenced by past research, various molecules have been employed to mitigate ischemic and reperfusion damage in testes. Additionally, PI has been proven to possess anti-inflammatory, antioxidant, analgesic, anthelmintic, antispasmodic, anxiolytic properties, and the ability to inhibit oxidative stress. Notably, this study represents the first exploration of PI impact on testicular ischemia-reperfusion. Overall, the results of this study showed the protective effect of on testicular torsion.

Conclusions

This study demonstrated that PI significantly mitigates oxidative stress and histopathological damage in testicular torsion. It reduced inflammation and apoptosis, confirming its potential as a therapeutic strategy against ischemia-reperfusion injury. To clarify the precise mechanism of the protective effects of PI, further studies are needed, and in progress.

Funding

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

Use of artificial intelligence for generating text. The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript, nor for the creation of images, graphics, tables, or their corresponding captions.

References

1. Arslan S, Azizoğlu A, Kamci TO, Basuguy E, Aydogdu B, Okur MH, et al. The value of hematological inflammatory parameters in the differential diagnosis of testicular torsion and epididymo-orchitis in children. Exp Biomed Res. 2023;6(3):212-217.

2. Kuas N, Ergun E, Göllü G, Çakmak M, Ates U. Türkiye'de ele gelmeyen testis hastalarına güncel yaklaşım farklılıkları.Turkish J Ped Surg. 2022;36:26-33. doi: 10.29228/JTAPS.58049
3. Shunmugam M, Goldman RD. Testicular torsion in children. Can Fam Physician. 2021;67(9):669-671.
4. Sarikaya K, Kölükçü E, Unsal V, Özdemir S. Protective Effects of Syringic Acid on Ischemia-Reperfusion Injury in Testicular Torsion: An Experimental Study in a Rat Model. Cureus. 2023;15(7):e42390.
5. Aydogdu B, Basuguy E, Arslan S, Azizoğlu M, Ibiloglu İ, Kaplan İ, Aydogdu G, et al. The effect of low-dose Cordyceps on ischemia-reperfusion injury of the kidney in rats. Cir Cir. 2022;90(S2):69-74. English. doi: 10.24875/CIRU.22000303. PMID: 36480757.
6. Özgür BC, Surer H, Yücetürk CN, Karakan T, Özer E, Ogus E. The protective effect of roflumilast and ibuprofen on testicular ischemia reperfusion injury: An experimental study. Ulus Travma Acil Cerrahi Derg. 2022;28(6):730-735.
7. Patel S. Passiflora Incarnata Linn: A phytopharmacological review. Int. J. Green Pharm. 2009;3:277–280.
8. Soumya RS, Raj KB, Abraham A. Passiflora edulis (var. Flavicarpa) Juice Supplementation Mitigates Isoproterenol-induced Myocardial Infarction in Rats. Plant Foods Hum Nutr. 2021;76(2):189-195.
9. European Medicines Agency. Assessment Report on Passiflora Incarnata L. herba. Volume 22 European Medicines Agency; Amsterdam, The Netherlands: 2014.
10. Erel O. A novel automated method to measure total antioxidant response against potent free radical reactions. Clin Biochem. 2004;37:112–119.
11. Erel O. A new automated colorimetric method for measuring total oxidant status. Clin Biochem. 2005;38(12):1103– 1111.
12. Esterbauer H, Cheeseman KH. Determination of aldehydic lipid peroxidation products: Malonaldehyde and 4- hidroxynonenal. Meth Enzymol. 1990;186:407–421.
13. Bradley PP, Priebat DA, Christensen RD, Rothstein G. Measurement of cutaneous inflammation: estimation of neutrophil content with an enzyme marker. J Invest Dermatol. 1982;78(3):206-209.
14. Paglia DE, Valentine WN. Studies on the quantitative and qualitative characterization of erythrocyte glutathione peroxidase. J Lab Clin Med. 1967;70(1):158-69.
15. Crowe AR, Yue W. Semi-quantitative Determination of Protein Expression using Immunohistochemistry Staining and Analysis: An Integrated Protocol. Bio Protoc. 2019;9(24):e3465.
16. Johnsen SG. Testicular biopsy score count--a method for registration of spermatogenesis in human testes: normal values and results in 335 hypogonadal males. Hormones. 1970;1(1):2-25.
17. Lacy A, Smith A, Koyfman A, Long B. High risk and low prevalence diseases: Testicular torsion. Am J Emerg Med. 2023;66:98-104.
18. Mäkelä E, Lahdes-Vasama T, Rajakorpi H, Wikström S. A 19-year review of paediatric patients with acute scrotum. Scand J Surg. 2007;96(1):62-66.
19. Yecies T, Bandari J, Schneck F, Cannon G. Direction of Rotation in Testicular Torsion and Identification of Predictors of Testicular Salvage. Urology. 2018;114:163-166.
20. Demir EA, Demir S, Kazaz IO, Kucuk H, Alemdar NT, Buyuk A, et al. Arbutin abrogates testicular ischemia/reperfusion injury in rats through repression of inflammation and ER stress. Tissue Cell. 2023; 82:102056.
21. Khezri MR, Ghasemnejad-Berenji H, Ghasemnejad-Berenji M. Protective effects of empagliflozin on testicular injury induced by torsion/detorsion in adult male rats. J Pediatr Urol. 2023:S1477-5131(23)00244-9.
22. Gökçe A, Oktar S, Koc A, Gonenci R, Yalcinkaya F, Yonden Z, et al. Protective effect of thymoquinone in experimental testicular torsion. Urol Int. 2010;85(4):461-5.
23. Kim M, Lim HS, Lee HH, Kim TH. Role Identification of Passiflora Incarnata Linnaeus: A Mini Review. J Menopausal Med. 2017;23(3): 156-159.
24. Janda K, Wojtkowska K, Jakubczyk K, Antoniewicz J, Skonieczna-Żydecka K. Passiflora incarnata in Neuropsychiatric Disorders-A Systematic Review. Nutrients. 2020;12(12):3894.

ORIGINAL ARTICLE

Comparison of laparoscopic-guided versus ultrasound-guided TAP block in laparoscopic cholecystectomy

Comparación del bloqueo TAP guiado por laparoscopia frente al ecoguiado en la colecistectomía laparoscópica

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Abstract

Introduction: *Transversus abdominis plane (TAP) block is a widely used anesthetic technique of the abdominal wall, where ultrasound guidance is considered the gold standard. In this study, we aimed to compare the effectiveness of laparoscopic-assisted TAP (LTAP) block with ultrasound-assisted TAP (UTAP) block for post-operative pain, nausea, vomiting, duration of the block, and bowel function.* **Materials and methods:** *This study included 60 patients who were randomly assigned to two groups to undergo either the LTAP or UTAP block technique after laparoscopic cholecystectomy. The time taken for administering the block, post-operative nausea and vomiting, post-operative pain, respiratory rate, bowel movements, and analgesia requirements were reported.* **Results***: The time taken for the LTAP block was shorter ($p < 0.001$). Post-operative mean tramadol consumption, paracetamol consumption, and analgesic requirement were comparable between the two groups ($p = 0.76$, $p = 0.513$, and $p = 0.26$, respectively). The visual analog scale at 6, 24, and 48 h was statistically not significant ($p = 0.632$, $p = 0.802$, and $p = 0.173$, respectively). Nausea with vomiting and the necessity of an antiemetic medication was lower in the UTAP group ($p = 0.004$ and $p = 0.009$, respectively).* **Conclusion:** *The LTAP block is an easy and fast technique to perform in patients as an alternative method where ultrasound guidance or an anesthesiologist is not available.*

Keywords: *Laparoscopic cholecystectomy. Transversus abdominis plane block. Perioperative analgesia. Visual Analog Scale. Pain.*

Resumen

Antecedentes: *El bloqueo del plano transverso del abdomen (TAP) es una técnica anestésica de la pared abdominal ampliamente utilizada, en la cual la guía ecográfica se considera el método de referencia.* **Objetivo:** *Comparar la efectividad del bloqueo TAP asistido por laparoscopia (LTAP) con el bloqueo TAP asistido por ultrasonido (UTAP) para el dolor posoperatorio, las náuseas y los vómitos, y la función intestinal.* **Método:** *El estudio incluyó 60 pacientes que fueron asignados aleatoriamente a dos grupos para someterse a la técnica de bloqueo LTAP o UTAP después de una colecistectomía laparoscópica. Se informaron el tiempo de administración del bloqueo, las náuseas y los vómitos posoperatorios, el dolor posoperatorio, la frecuencia respiratoria, las evacuaciones y los requerimientos de analgesia.* **Resultados:** *El tiempo de bloqueo LTAP fue menor ($p < 0.001$). El consumo medio de tramadol, el consumo de paracetamol y el requerimiento de analgésicos posoperatorios fueron comparables entre los dos grupos ($p = 0.76$, $p = 0.513$ y $p = 0.26$, respectivamente). El dolor en la escala analógica visual a las 6, 24 y 48 horas no fue estadísticamente significativo ($p = 0.632$, $p = 0.802$ y $p = 0.173$, respectivamente).*

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Conclusiones: *El bloqueo PATL es una técnica fácil y rápida de realizar en pacientes como método alternativo cuando no se dispone de guía ecográfica o anestesióloga.*

Palabras clave**:** *Colecistectomía laparoscópica. Bloqueo del plano transverso abdominal. Analgesia perioperatoria. Escala visual analógica. Dolor.*

Introduction

Post-operative pain following cholecystectomy is an important morbidity and a common reason for prolonged hospitalization. Nearly, 55% of patients experience moderate-to-severe pain and complications may arise in up to one-third of patients within the post-operative 30-day period. A statistically significant association has been shown between post-operative pain and the occurrence of post-operative complications. Post-operative pain impairs mobilization and coughing, thus increasing the risk of respiratory complications such as atelectasis and pulmonary infections. Both post-operative pain and the adverse effects of analgesics may delay oral intake and impair bowel function after surgery[1]. Several intravenous treatments and regional anesthetic techniques have been studied for establishing high-quality post-operative analgesia. Studies showing the effect of post-operative analgesia techniques such as opioids and regional analgesia on morbidity and mortality are also present in the literature[2].

Laparoscopic cholecystectomy offers major benefits to patients such as early mobilization, shorter duration of hospital stay, smaller incisions, fewer wound infection rates, and less post-operative pain. Although laparoscopic cholecystectomy is considered the gold standard procedure, post-operative pain is still associated with moderate-to-severe complications, especially within the first 24 h of surgery[3,4].

Several methods have been studied to decrease post-operative pain following laparoscopic cholecystectomy. These include pre-operative, intraoperative, and post-operative use of analgesics such as NSAIDs, paracetamol, dexamethasone, opioids, the use of a local anesthetic into the wound, establishing a low-pressure pneumoperitoneum, local lavage with saline and suction, and miniport laparoscopic technique[5].

Transversus abdominis plane (TAP) block provides a sensorial block between the internal oblique muscle and transverse abdominis muscle by innervating spinal nerves. The local anesthetic infiltration in the TAP block affects 7-12th thoracic intercostal nerves, the ilioinguinal nerve, the iliohypogastric nerve, and 1-3rd lumbar nerves in the lateral cutaneous branches[6]. TAP block is usually performed under ultrasound guidance while laparoscopic guidance has become an area of interest[7]. Several studies on the use of ultrasound-guided TAP block on pain management are available[8,9]. The aim of this study was is to compare laparoscopic-assisted TAP (LTAP) block with ultrasound-assisted TAP (UTAP) block in patients undergoing elective laparoscopic cholecystectomy.

Materials and methods

Ethics approval was obtained from the Health Sciences University Prof. Dr. Cemil Tascioglu Hospital Ethics Committee (September 24, 2019/1427). This study was performed on patients undergoing elective laparoscopic cholecystectomy between October 2019 and March 2020. Patients older than 18 years of age and those with ASA 1 and 2 participated in the study. Patients with a history of a local anesthetic allergy, history of opioid or alcohol addiction, diagnosis of pre-operative and perioperative acute cholecystitis, a contraindication for laparoscopic surgery, and those with ASA III-IV score were excluded from the study.

This prospective study was performed on 60 patients. The patients were randomly divided into two groups using closed envelopes, where 50% (n = 30) of the patients received LTAP block and the other 50% (n = 30) received UTAP block. At the end of the study, randomization was planned to check that there was no difference between the groups in terms of age, gender, body mass index, ASA score, and comorbidities.

The LTAP block was performed by a single surgeon. A pilot study was done to understand the efficacy of analgesia in ten patients before the study. The UTAP block was performed by a single anesthesiologist with 11 years of experience.

Standardized general anesthesia was applied to all patients. Propofol 2 mg/kg and rocuronium 0.5 mg/kg were utilized for induction. The endotracheal intubation was performed and anesthesia was maintained with 50-50% O_2-air mixture and sevoflurane.

The UTAP block was performed after intubation. The probe was placed below the 12th costal margin and rectus abdominis muscles, and the posterior

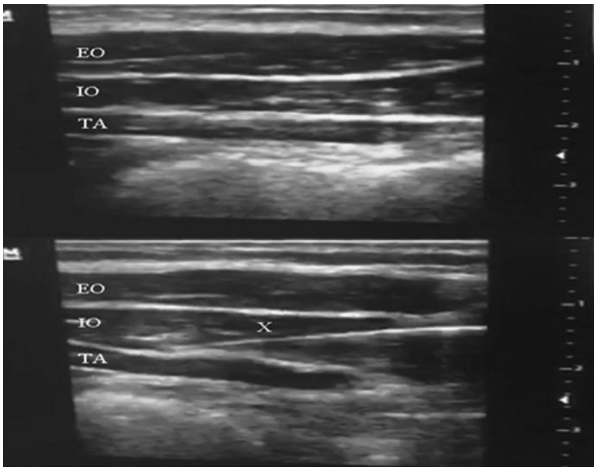

Figure 1. *Administration of bupivacaine into the transversus abdominis plane.*

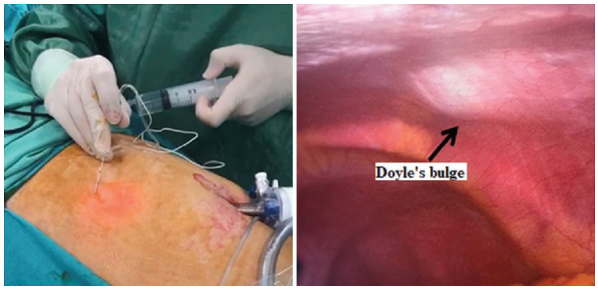

Figure 2. *Visualization of the Doyle's bulge after local anesthetic infiltration.*

Table 1. Comparison of patient characteristics

Parameters	LTAP (n = 30)	UTAP (n = 30)	p-value
Age*	43.7 ± 15.54	48.97 ± 13.68	0.16
Sex			1
Male	6	6	
Female	24	24	
BMI*	28.33 ± 5.11	27.33 ± 3.46	0.377
ASA class			0.44
I	15	18	
II	15	12	
Comorbidities			0.3
DM	6	4	
HT	7	4	
DM and HT	2	3	
Operation Time (min)*	46.83 ± 10.70	45.03 ± 8.38	0.419

*Mean ± standard deviation. LTAP: laparoscopic TAP block; UTAP: ultrasound TAP block; BMI: body mass index; DM: diabetes mellitus; HT: hypertension; min: minute.

rectus sheath and transversus abdominis muscles were identified. Block needle of 100 mm, 22G (Stimuplex Pajunk, Germany) was targeted in the TAP (Fig. 1). Bupivacaine 20 mL of 0.25% was administered bilaterally.

After induction of general anesthesia, the first 10-mm trocar was inserted and an abdominal pressure of 12 mmHg was established. Puncture with a 100 mm 22G block needle (Stimuplex Pajunk, Germany) was performed at the intersection point of the midclavicular line and the 12th costa bilaterally. Under the view of laparoscopy, 20 mL of 0.25% bupivacaine was administered and Doyle's bulge, which is a local anesthetic infiltration where the peritoneum is pushed internally, was seen by visualizing laparoscopic camera (Fig. 2)[10,11]. After both methods, standard cholecystectomy was performed. No perioperative complications were observed in the patients.

All patients received tramadol of 1 mg/kg before extubation and were taken to the recovery room. Nausea and vomiting were evaluated in the recovery room. Post-operative pain scores at 6th, 24th, and 48th h were documented using the VAS score. The patients received 1 g of paracetamol when the VAS score was >4. Post-operative respiratory rates at 6th, 24th, and 48th h, time of passage of first flatus and stool, nausea, vomiting, the necessity of antiemetic medication use, and analgesic consumption were collected and recorded.

Statistical analysis was performed using the SPSS program. Age, gender, body mass index, ASA, comorbidities, and operation times were evaluated and compared within the groups. The Student's t-test was used to compare, the time taken for the block, the time of passage of first flatus and stool, post-operative pain scores, post-operative respiratory rates, and perioperative and post-operative analgesic consumption. A Chi-square test was used to compare post-operative nausea and vomiting and antiemetic use, amount of analgesic consumption in the post-operative period, and nausea and vomiting in the recovery room. $p < 0.05$ was considered to be statistically significant.

Results

The demographic data of the patients are shown in table 1. The mean time taken for performing the LTAP group was 3.57 ± 0.47 min and that in the UTAP group was 8.09 ± 1.55 min. The difference between the groups was statistically significant ($p < 0.001$) (Table 2 and Fig. 3). The VAS score at 6 h was found to be 5.13 ± 1.279 in the LTAP group and 4.97 ± 1.402 in the UTAP group. The VAS score at 24 h was found to be 2.97 ± 1.732

Table 2. Comparison of time taken for block, post-operative analgesic requirements (tramadol), post-operative analgesic requirements (paracetamol), and time of passage of first stools

Parameters	LTAP	UTAP	p-value
Time taken for block (min)*	3.57 ± 0.47	8.09 ± 1.55	< 0.001
Post-operative analgesic requirements (Tramadol) (mg)*	73.33 ± 12.954	72.33 ± 12.229	0.76
Post-operative analgesic requirements (Paracetamol) (gr)*	1.03 ± 0.765	0.90 ± 0.803	0.513
Time of passage of first stools (hour)*	12.03 ± 2.834	11.20 ± 2.074	0.199

*Mean ± standard deviation.
min: minute; mg: milligram; gr: gram; LTAP: laparoscopic TAP block; UTAP: ultrasound TAP block.

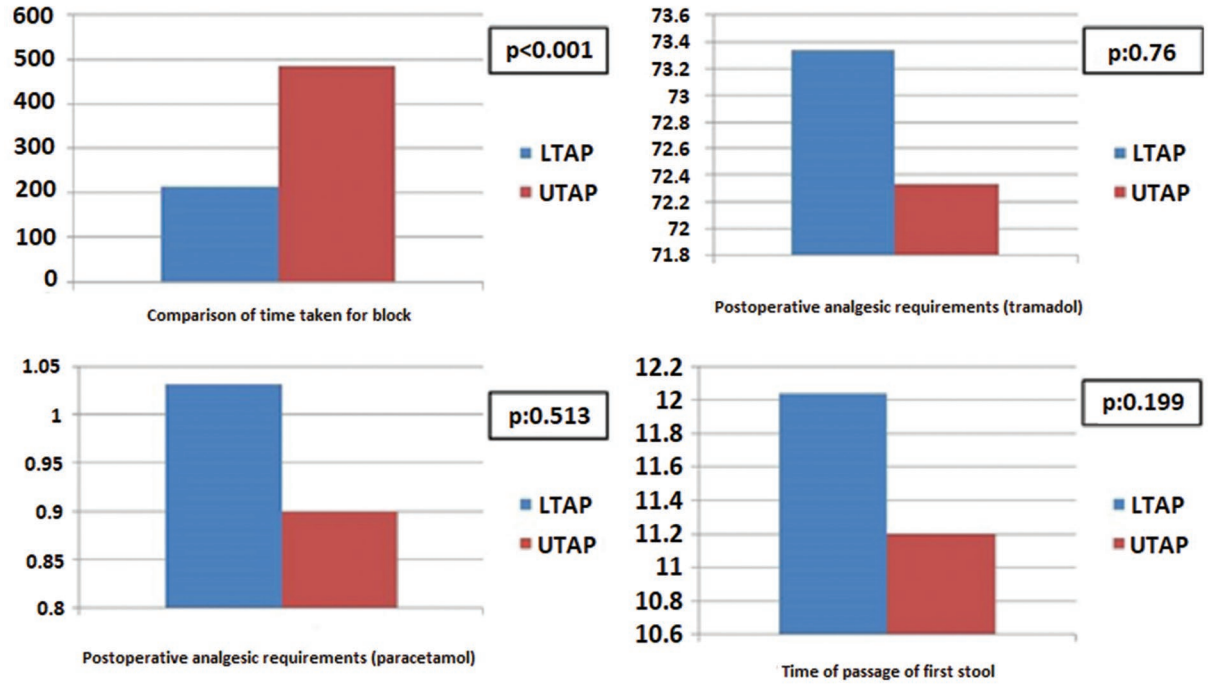

Figure 3. *Comparison of time taken for block, post-operative analgesic requirements (tramadol), post-operative analgesic requirements (paracetamol), and time of passage of first stools.*

in the LTAP group and 2.87 ± 1.306 in the UTAP group. The VAS score at 48 h was found to be 0.90 ± 1.470 in the LTAP group and 0.50 ± 0.572 in the UTAP group. The differences were statistically not significant when compared between the two groups (Table 3 and Fig. 4).

The mean post-operative paracetamol consumption in the LTAP group was 1.03 ± 0.765 gr which was comparable with a mean value of 0.90 ± 0.803 gr in the UTAP group. No statistically significant difference was found between the two groups (p = 0.513) (Table 2 and Fig. 3). In the study, 18 patients did not require post-operative analgesia management. Groups were evaluated according to the patients' VAS scores at 6, 24, and 48th h. Paracetamol of 1 g as rescue analgesia was given to patients having VAS score > 4. In the study, 37 patients who had a VAS score > 4 at 6 h received 1 g of paracetamol, seven patients who had a VAS score > 4 at 24 h received 1 g of paracetamol, and two patients who had a VAS score >4 at 48 h received 1 g of paracetamol. In each group, one patient received an additional 1 g of paracetamol.

The post-operative mean respiratory rate at 6 h in the LTAP group was 23.07 ± 3.290 and in the UTAP group, it was 23.40 ± 3.883 with no significant difference (p = 0.721). The post-operative mean respiratory rate at 24 h in the LTAP group was 21.60 ± 3.510 and in the UTAP group, it was 20.70 ± 3.436 with no significant difference (p = 0.320). The post-operative mean respiratory rate at 48 h in the LTAP group was 19.77 ± 3.170 and in the UTAP group, it was

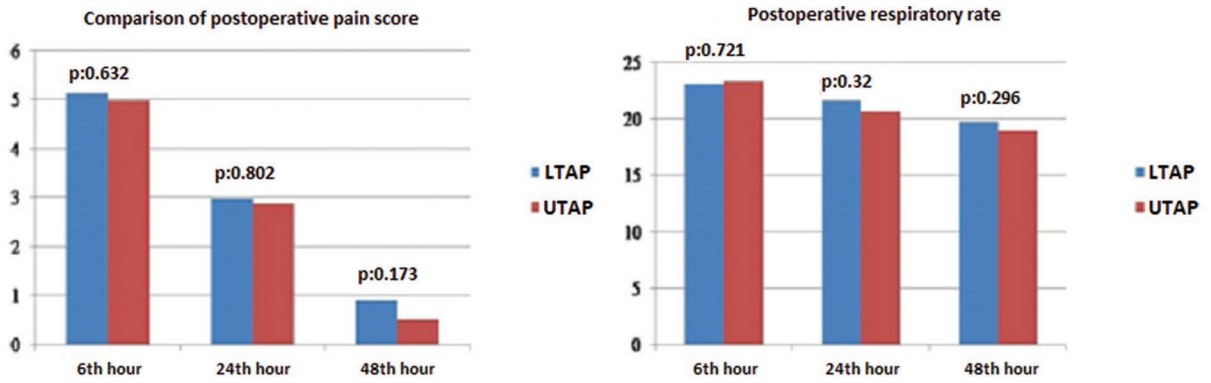

Figure 4. *Comparison of post-operative pain scores and post-operative respiratory rate.*

Table 3. Comparison of post-operative pain scores and post-operative respiratory rate

Parameters	Post-operative pain scores*			Post-operative respiratory rate*		
	LTAP	UTAP	p-value	LTAP	UTAP	p-value
6th h	5.13 ± 1.279	4.97 ± 1.402	0.632	23.07 ± 3.290	23.40 ± 3.883	0.721
24th h	2.97 ± 1.732	2.87 ± 1.306	0.802	21.60 ± 3.510	20.70 ± 3.436	0.32
48th h	0.90 ± 1.470	0.50 ± 0.572	0.173	19.77 ± 3.170	19.00 ± 2.407	0.296

*Mean ± Standard deviation.
LTAP: laparoscopic TAP block; UTAP: ultrasound TAP block.

Table 4. Comparison of nausea and vomiting in the recovery room

Parameters	Yes (%)	No (%)	p-value
0th min			
LTAP	7 (23.3)	23 (76.7)	0.754
UTAP	6 (20)	24 (80)	
10th min			
LTAP	5 (8.3)	25 (41.7)	1
UTAP	5 (8.3)	25 (41.7)	
20th min	3 (5)	27 (45)	
LTAP	1 (1.7)	29 (48.3)	0.306
UTAP			
30th min			
LTAP	2 (3.3)	28 (46.7)	0.5
UTAP	3 (5)	27 (45)	

min: minute; LTAP: laparoscopic TAP block (n: 30); UTAP: ultrasound TAP block (n: 30).

Table 5. Comparison of post-operative nausea vomiting, nausea requiring an antiemetic medication, and post-operative analgesic requirements

Parameters	LTAP (n = 30) (%)	UTAP (n = 30) (%)	p-value
Post-operative nausea vomiting			0.004
Yes	19 (63.3)	8 (26.7)	
No	11 (36.7)	22 (73.3)	
Nausea requiring antiemetic			
Yes	18 (60)	8 (26.7)	0.009
No	12 (40)	22 (73.3)	
Post-operative analgesic requirements			
Yes	23 (76.7)	19 (63.3)	0.26
No	7 (23.3)	11 (36.7)	

LTAP: laparoscopic TAP block; UTAP: ultrasound TAP block.

19.00 ± 2.407 with no significant difference (p = 0.296) (Table 3 and Fig. 4). However, post-operative nausea and vomiting at patient wards and the necessity of using an antiemetic medication between the two groups were found to be statistically significant. Nausea, vomiting, and the necessity of using an antiemetic medication were found less in the UTAP group when compared with the LTAP group (p = 0.004 and p = 0.009, respectively). There was no statistical significance between the two groups for nausea and vomiting in the recovery room (Table 4). Post-operative analgesia requirements between the two groups were not found to be statistically significant (p = 0.260) (Table 5).

Discussion

Ravichandran et al. have reported that the mean time taken for the LTAP block was 5.38 min, while the mean time taken for the UTAP block was 13.6 min and the difference between the two groups was found to be statistically significant[9]. In our study, the time taken for the blocks was the most significant difference between the two techniques. The mean LTAP block time was 3.57 ± 0.47 min and the mean UTAP block time was 8.09 ± 1.55 min. The difference between the groups was statistically significant ($p < 0.001$). This leads to the conclusion that the LTAP technique leads to a shorter duration of medication administration, which is advantageous for the patient.

The most significant advantage of TAP block is reducing the consumption of opioids and thereby its associated adverse effects. In several studies evaluating the efficacy of LTAP and UTAP blocks after laparoscopic cholecystectomy, morphine was used as an opioid analgesic, and TAP block provided better pain scores and a reduced intake of morphine. Some studies in the literature compared LTAP with UTAP blocks and reported that the total consumption of morphine was less in the UTAP block group[8,9]. Bhatia et al. reported that the 24-h analgesic requirement was 125 mg opioid in the control group, 89 mg opioid in ultrasound-guided posterior TAP block, and 27 mg opioid in ultrasound-guided subcostal TAP block and a standard post-operative analgesic regime consisting of intravenous paracetamol of 1 g every 6 h was used in all patients[12]. In our study, the mean tramadol and paracetamol consumption and the number of patients who received analgesics in the LTAP group were higher than the UTAP group; however, the post-operative analgesia requirements reduced similarly in both two groups.

Post-operative pain and opioids can also induce bowel dysfunction and constipation. Ravichandran et al. reported that the mean time taken for patients to notice the passage of the first flatus postoperatively was 30.2 h in the LTAP group and 32.17 h in the UTAP group. They observed that the mean time taken for passage of first stools was 42.8 h in the UTAP group and 51.3 h in the LTAP group. The difference between the two groups was found to be statistically significant[9]. In our study, the time of passage of first stools was less in the UTAP group when compared with the LTAP group.

Post-operative pain and opioid use have been related to post-operative nausea, vomiting, and requiring the use of antiemetic medication. Ravichandran et al. have reported that in the LTAP group, 53.3% did not have nausea, 10% of the patients had nausea, 16.7% had experienced vomiting, and 20% had the necessity of antiemetic medication usage. In the UTAP group, 50% of the patients did not have nausea, 30% of patients had nausea, 16.7% of the patients had nausea requiring an antiemetic medication, and 3.3% of the patients experienced vomiting[9]. In our study, we found that in the LTAP group, 63.3% of the patients had nausea, and 60% of the patients had nausea requiring an antiemetic medication. On the contrary, in the UTAP group, 26.7% of patients had nausea, and 26.7% of patients had nausea requiring an antiemetic medication. No statistical significance between the two groups for nausea and vomiting was observed in the recovery room. Although LTAP block reduced nausea and vomiting in the early post-operative period, it did not reduce vomiting and the requirement of an antiemetic medication in the following hours.

Another side effect of post-operative pain is that increases the risk of pulmonary complications by reducing coughing and deep inspiration. Some studies have reported that patients in the UTAP group had a higher peak expiratory flow rate when compared with the LTAP group[9,13]. In our study, the efficacy of TAP block on respiratory system evaluated with respiratory rate showed comparable results between the two groups.

According to a meta-analysis by Peng et al. which compared UTAP block and a control group in laparoscopic cholecystectomy, significantly lower pain scores at all times were reported in patients receiving TAP blocks compared with those receiving conventional treatment, except for the data at post-operative 6th h[14]. Elamin et al. observed that the VAS score at 3rd and 6th h was significantly different in the LTAP group; however, VAS scores at 12th and 24th h were not statistically significant between the LTAP and the control group[15]. Tihan et al. reported that patients in the LTAP group had lower VAS scores at 24 h when compared with the control group and this difference was statistically significant[16]. Ravichandran et al. reported that patients in the UTAP group had lower VAS scores at 6th and 24th h when compared with the LTAP group. However, this difference was not statistically significant[9]. Venkatraman et al. evaluated that patients in the UTAP group had a lower VAS score at 8 h than the LTAP group, a higher VAS score at 8-18 h, and a lower VAS score at 18 h[8]. Studies that compared UTAP block or LTAP block with control groups have shown that TAP block decreased pain scores. In our study, we compared LTAP block with UTAP block and

we have noticed that patients in the UTAP group had lower pain scores, although this finding was not statistically significant.

This study has some limitations. First, there are a relatively small number of patients. Second, the investigator who evaluated the results of the study knew which technique was used for TAP block in patients. Another limitation is that there was not a control group in the study.

Conclusion

Pain management after laparoscopic cholecystectomy has been an important criterion for early mobilization, recovery, discharge, and return to daily activities. Similar to the current literature, no significant difference was observed between TAP block groups in most of the parameters evaluated in our study. The UTAP block has some disadvantages such as a longer duration of time, the necessity of an experienced physician, and requires additional equipment. In addition, it is difficult to perform UTAP block in patients with high body mass index. In light of these, an alternative method, the LTAP block, is equally efficacious, faster, and easy to perform in patients than UTAP block and does not require additional equipment and an experienced anesthesiologist.

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Conflicts of interest

The authors have no conflicts of interest to declare.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

Use of artificial intelligence for generating text. The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript nor for the creation of images, graphics, tables, or their corresponding captions.

References

1. van Boekel RL, Warlé MC, Nielen RG, Vissers KC, van der Sande R, Bronkhorst EM, et al. Relationship between postoperative pain and overall 30-day complications in a broad surgical population: an observational study. Ann Surg. 2019;269:856-65.
2. Liu SS, Wu CL. Effect of postoperative analgesia on major postoperative complications: a systematic update of the evidence. Anesth Analg. 2007;104:689-702.
3. Takrouri MS. Anesthesia for laparoscopic general surgery. A special review. Middle East J Anesthesiol. 1999;15:39-62.
4. Gerbershagen HJ, Aduckathil S, van Wijck AJ, Peelen LM, Kalkman CJ, Meissner W. Pain intensity on the first day after surgery: a prospective cohort study comparing 179 surgical procedures. Anesthesiology. 2013;118:934-44.
5. Barazanchi AW, MacFater WS, Rahiri JL, Tutone S, Hill AG, Joshi GP, et al. Evidence-based management of pain after laparoscopic cholecystectomy: a PROSPECT review update. Br J Anaesth. 2018;121:787-803.
6. Şahin AS, Ay N, Şahbaz NA, Akay MK, Demiraran Y, Derbent A. Analgesic effects of ultrasound-guided transverse abdominis plane block using different volumes and concentrations of local analgesics after laparoscopic cholecystectomy. J Int Med Res. 2017;45:211-9.
7. Magee C, Clarke C, Lewis A. Laparoscopic TAP block for laparoscopic cholecystectomy: description of a novel technique. Surgeon. 2011;9:352-53.
8. Venkatraman R, Saravanan R, Dhas M, Pushparani A. Comparison of laparoscopy-guided with ultrasound-guided subcostal transversus abdominis plane block in laparoscopic cholecystectomy - a prospective, randomised study. Indian J Anaesth. 2020;64:1012-7.
9. Ravichandran NT, Sistla SC, Kundra P, Ali SM, Dhanapal B, Galidevara I. Laparoscopic-assisted tranversus abdominis plane (TAP) block versus ultrasonography-guided transversus abdominis plane block in postlaparoscopic cholecystectomy pain relief: randomized controlled trial. Surg Laparosc Endosc Percutan Tech. 2017;27:228-32.
10. Chetwood A, Agrawal S, Hrouda D, Doyle P. Laparoscopic assisted transversus abdominis plane block: a novel insertion technique during laparoscopic nephrectomy. Anaesthesia. 2011;66:317-8.
11. Hassan AM, Nashed GA, Ibrahim AK, Balamoun HA. Efficacy of laparoscopic-guided TAP block in postoperative pain management of laparoscopic bariatric patients. Egypt J Surg. 2022;41:279-86.
12. Bhatia N, Arora S, Jyotsna W, Kaur G. Comparison of posterior and subcostal approaches to ultrasound-guided transverse abdominis plane block for postoperative analgesia in laparoscopic cholecystectomy. J Clin Anesth. 2014;26:294-9.
13. Basaran B, Basaran A, Kozanhan B, Kasdogan E, Eryilmaz MA, Ozmen S. Analgesia and respiratory function after laparoscopic cholecystectomy in patients receiving ultrasound-guided bilateral oblique subcostal transversus abdominis plane block: a randomized double-blind study. Med Sci Monit. 2015;21:1304-12.
14. Peng K, Ji FH, Liu HY, Wu SR. Ultrasound-guided transversus abdominis plane block for analgesia in laparoscopic cholecystectomy: a systematic review and meta-analysis. Med Princ Pract. 2016;25:237-46.
15. Elamin G, Waters PS, Hamid H, O'Keefe HM, Waldron RM, Duggan M, et al. Efficacy of a laparoscopically delivered transversus abdominis plane block technique during elective laparoscopic cholecystectomy: a prospective, double-blind randomized trial. J Am Coll Surg. 2015;221:335-44.
16. Tihan D, Totoz T, Tokocin M, Ercan G, Calikoglu TK, Vartanoglu T, et al. Efficacy of laparoscopic transversus abdominis plane block for elective laparoscopic cholecystectomy in elderly patients. Bosn J Basic Med Sci. 2016;14:139-44.

ORIGINAL ARTICLE

Lymphocyte-to-C-reactive protein ratio as a new biomarker for predicting mortality and morbidity in Fournier's gangrene

El cociente linfocito-proteína C reactiva como nuevo marcador predictivo de mortalidad y morbilidad en la gangrena de Fournier

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Abstract

Objective: *The purpose of this study was to research the neutrophil–lymphocyte ratio (NLR), lymphocyte-to-C-reactive protein ratio (LCR), and Fournier's Gangrene Severity Index (FGSI) for predicting prognosis and mortality in patients with Fournier's gangrene (FG).* **Material and Methods:** *Patients diagnosed with FG and treated in a tertiary referral hospital in the period from January 2013 to June 2020 were reviewed. LCR, FGSI, and NLR values were calculated.* **Results**: *Our series included a total of 41 patients. Of the patients, 78% survived and 21.9% (n = 9) died. Survivors were significantly younger than non-survivors (p = 0.009). Hospital costs were higher in non-survivors and close to statistical significance (p = 0.08). The ROC analysis revealed that the FGSI, LCR, and NLR parameters were significant in identifying survivors and non-survivors (AUC = 0.941 [0.870-1.000], p < 0.001; AUC = 0.747 [0.593-0.900], p = 0.025; and AUC = 0.724 [0.548-0.900], p = 0.042).* **Conclusion**: *A low LCR value can be used as a marker to assess mortality and disease severity in patients with Fournier's gangrene.*

Keywords: *Fournier's gangrene. Lymphocyte C-reactive protein ratio. Mortality. Cost effective.*

Resumen

Objetivo: *Investigar el cociente neutrófilos-linfocitos (CNL), el cociente linfocitos-proteína C reactiva (CLP) y el índice de gravedad de la gangrena de Fournier (IGGF) para predecir el pronóstico y la mortalidad en pacientes con gangrena de Fournier (GF).* **Método:** *Se revisaron los pacientes diagnosticados de GF y atendidos en un hospital de tercer nivel de referencia en el período de enero de 2013 a junio de 2020. Se calcularon los valores de CLP, IGGF y CNL.* **Resultados:** *Nuestra serie incluyó 41 pacientes, de los cuales el 78% sobrevivieron y el 21.9% (n = 9) fallecieron. Los supervivientes eran significativamente más jóvenes que los no supervivientes (p = 0.009). Los costes hospitalarios fueron mayores en los no supervivientes y cercanos a la significación estadística (p = 0.08). El análisis ROC reveló que los parámetros IGGF, CLP y CNL fueron significativos para identificar supervivientes y no supervivientes (AUC: 0.941 [0.870-1.000], p < 0.001; AUC: 0.747 [0.593-0.900], p = 0.025; AUC: 0.724 [0.548-0.900], p = 0.042).* **Conclusiones:** *Un valor bajo de CLP se puede utilizar como marcador para evaluar la mortalidad y la gravedad de la enfermedad en pacientes con GF.*

Palabras clave: *Gangrena de Fournier. Cociente linfocitos-proteína C reactiva. Mortalidad. Coste-efectividad.*

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Introduction

Fournier's gangrene (FG) is quickly progressing fasciitis of the perianal and genital regions. Because lag in diagnosis and treatment can be fatal, it is crucial not to overlook any symptoms, even if they are non-specific. Although initially described by Bauriene in 1764, the disease was named in 1883 after Jean Alfred Fournier, a dermatologist and venereologist from Paris[1]. The infection can progress rapidly, extending throughout the fascial planes toward the abdominal wall, legs, and the thorax[2]. Mortality rates for FG range from 3% to 45%[3]. Previous case series of FG reported a mortality rate of almost 80%, which later decreased to below 40% over the last 15 years[4]. Eke investigated 1726 cases and found a total mortality rate of 16% in the study[3]. Several studies have demonstrated prognostic factors that unfavorably act on survival including advanced age, disseminated disease, delayed treatment, a positive blood culture, diabetes, high urea levels, an anorectal origin of infection, presence of shock or sepsis at admission, and immunosuppressive states[5].

With regard to the prognosis of the disease, Laor et al.[6] have developed the Fournier's Gangrene Severity Index (FGSI) by adjusting the acute physiology and chronic health evaluation (APACHE II) scoring system. The authors showed that FGSI scores could be used to predict mortality and survival reliably at rates of 75% and 78%, respectively. However; there is an ongoing debate in the current literature about the prognostic value of FGSI. An increased neutrophil–lymphocyte ratio (NLR) has been shown to predict poor prognosis in FG patients[7]. Therefore, we aimed to evaluate whether different parameters could help predict the course of the disease.

Today, lymphocyte-to-C-reactive protein ratio (LCR) has been used to predict prognosis and mortality, especially in reflecting the state of inflammation in different cancer cases. In our prior study, we demonstrated that low pre-operative LCR values could be used to predict strangulation in incarcerated abdominal wall hernias[8]. Furthermore, it has been demonstrated that LCR can be used to predict prognosis in many cancer types[9,10]. One recent study has reported that high low LCR levels predicted a bad prognosis and higher in-hospital mortality in patients with coronavirus disease 2019 (COVID-19)[11].

The aim of this study is to determine the prognostic significance of LCR, a new inflammatory marker, to predict mortality in patients with FG.

Materials and methods

We case series analysis reviewed patients treated for FG in the School of Medicine Hospital of the Tokat Gaziosmanpasa University in the period from January 2013 to June 2020. The study was approved by the Ethics Committee of the School of Medicine of Tokat Gaziosmanpasa University (20- KAEK-293).

The diagnoses and International Classification of Diseases-10 (N49.3) code of the patients were retrieved from the hospital database and recorded. The recorded data included demographic information; clinical, laboratory, and radiological findings; and medical history, comorbidities, the length of hospital stay, the time elapsed from the time of admission until surgery, further debridements, intestinal diversion, and the need for orchiectomy. The diagnosis was made based on the clinical examination findings of foul odor, skin necrosis, and subcutaneous crepitations in the perianal region and/or based on the observation of perianal abscess and foci of air in radiological imaging tests. A definitive diagnosis was made based on the classical tissue appearance observed during surgery. Patients with less medical records, restricted perianal or scrotal abscesses, and no soft-tissue extension were excluded from this study. The patients were separated into two groups as survivors and non-survivors. The parameters that could be associated with mortality were evaluated.

Laboratory tests consisted of complete blood count and biochemical and microbiological tests at admission including the levels of serum glucose, serum creatinine, serum electrolytes, and C-reactive protein and blood gas analysis, lymphocyte count, neutrophil count, and wound cultures.

The LCR was obtained as the ratio of the lymphocyte count (count per microliter) to the CRP level (mg/l). NLR was obtained as the neutrophil count (count per microliter) to the lymphocyte count (count per microliter). Mean LCR, NLR, and FGSI values were compared between the groups of survivors and non-survivors to examine the association of these parameters with poor prognosis and mortality.

Treatment costs were calculated as the amount invoiced to the social security institution covering the period from the time of admission to the hospital discharge.

Statistical analysis

In our study, statistical analyses were performed with the SPSS package program (Version 22.0, SPSS

Inc., Chicago, IL, USA, License: Gaziosmanpasa University). Restrictive statistics were offered as mean ± standard deviation for normally distributed continuous data, median (min–max) for non-normally distributed continuous data, percentage (%), and number for categorical data. The normal distribution of the data was analyzed with the Shapiro–Wilk test. In comparing numerical variables between two free groups, the Student's t-test was used for normally distributed data, and the Mann- Whitney U test was used for non-normally distributed data. The Receiver Operating Characteristic (ROC) analysis method was used to evaluate whether NLR, LCR, and FGSI values can be used to predict survival and non-survival mortality status. The Youden Index (maximum specificity and sensitivity) was used to determine the most cutoff point in the ROC analysis. For the statistical significance level, $p < 0.05$ was accepted.

Results

A total of 41 patients participated in the study. Of the patients, 26.8% (n = 11) were women and 73.2% (n = 30) were men. The mean age of the patients was 58.17 ± 14.91 (24-95) years. Of the patients, 78% (n = 32) survived but 21.9% (n = 9) died. The mean age was statistically significantly higher in non-survivors ($p = 0.009$). There was a statistically significant difference between the groups in terms of the length of hospital stay, body temperature, and heart rate ($p = 0.027$, $p < 0.001$, and $p = 0.035$, respectively, Table 1). There were no significant differences in the other parameters between the groups ($p > 0.05$). Descriptive statistics and the comparisons of the other parameters between the groups are presented in table 1.

Of the comorbidities and predisposing factors, diabetes mellitus (DM) was the most common as it was found in 26 (63.4%) patients. DM was followed by congestive heart failure in four patients (9.8%), hypertension and paraplegia in five (12.2%), malignancy in three, and chronic renal failure in two patients. Immunosuppression was present in two patients due to chemotherapy and in one patient due to chronic corticosteroid use. Three patients had chronic alcohol use and 12 had a habit of smoking. Comorbidities were similar between survivors and non-survivors. As for the history of surgery, two patients underwent left hemicolectomy and low anterior resection due to colon/rectum tumors, two underwent surgery for inguinal hernia, one was operated on for a brain tumor, and two patients were operated for anal fistulas.

The most common complaint at admission was perianal pain and swelling (64.5%) followed by fever (50.1%-49.1%), purulent discharge in the perianal region (41.86%), and poor general condition (52.4%). The most common clinical presentation was necrosis in the perineal and scrotal regions.

Diverting colostomy was performed on nine survivors and six non-survivors. Orchiectomy was performed on two survivors and three non-survivors.

Etiological factors for mortality in non-survivors included severe sepsis (n = 3), acute renal failure (n = 1), multiple organ failure (n = 3), respiratory failure due to lung cancers (n = 1), and congestive heart failure (n = 1). All of the non-survivors and 40.6% of the survivors were treated in the intensive care unit. Patients hospitalized in the intensive care unit were compared between survivors and non-survivors, and it was found to be statistically significant in favor of survivors ($p = 0.02$) (Table 1). This showed us the importance of mechanical ventilator support and combating sepsis in the intensive care unit.

Hospital costs were higher in non-survivors compared to survivors and the difference was close to statistical significance ($p = 0.08$) (Table 1).

The comparison of the laboratory test results and the values of NLR, LCR, and FGSI between non-survivors and survivors are presented in Table 2. There were statistically significant differences in creatinine, hematocrit, CRP, and lactic acid levels in the neutrophil count, and in the values of NLR, LCR, and FGSI between the groups ($p = 0.003$, $p = 0.020$, $p = 0.004$, $p < 0.001$, $p < 0.001$, $p = 0.041$, $p = 0.024$, $p < 0.001$, respectively; Table 2). However, the levels of sodium (Na), potassium (K), glucose, white blood cell, serum bicarbonate, and lymphocyte counts were not statistically significantly different between the groups ($p = 0.343$, $p = 0.210$, $p = 0.060$, $p = 0.376$, $p = 0.889$, $p = 0.722$, respectively, Table 2). Non-survivors had significantly higher FGSI and NLR values and significantly lower LCR values compared to survivors (Table 2 and Fig. 1).

The results of the ROC analysis; the sensitivity, specificity, and positive and negative predictive values; and the likelihood ratios (+) of the FGSI, NLR, and LCR parameters are presented in table 3. Figure 2 shows the ROC curves. The ROC analysis revealed that the FGSI, LCR, and NLR parameters were significant in distinguishing between survivors and non-survivors (AUC = 0.941

Table 1. Comparison of baseline characteristics describing survivors and non-survivors

Variables	Total n (%) (n = 41)	Survivor n (%) (n = 32)	Non-survivor n (%) (n = 9)	p-values
Gender				
Female	11 (26.8)	10 (90.9)	1 (9.1)	0.401*
Male	30 (73.2)	22 (73.3)	8 (26.7)	
Comorbidity				
DM				
-	15 (36.6)	11 (73.3)	4 (26.7)	0.701*
+	26 (63.4)	21 (80.8)	5 (19.2)	
CHF				
-	37 (90.2)	28 (75.7)	9 (24.3)	0.559*
+	4 (9.8)	4 (100)	0 (0)	
HT				
-	36 (87.8)	28 (77.8)	8 (22.2)	1.000*
+	5 (12.2)	4 (80)	1 (20)	
Asthma				
-	38 (92.7)	29 (76.3)	9 (23.7)	1.000*
+	3 (7.3)	3 (100)	0 (20)	
CRF				
-	39 (95.1)	31 (79.5)	8 (20.5)	0.395*
+	2 (4.9)	1 (50)	1 (50)	
Paraplegia				
-	6 (87.8)	27 (75)	9 (25)	0.568*
+	5 (12.2)	5 (100)	0 (0)	
Colon/Rectum tumor				
-	36 (87.8)	30 (83.3)	6 (16.7)	0.395*
+	2 (4.9)	1 (50)	1 (50)	
CAH				
-	37 (90.2)	29 (78.4)	8 (21.6)	1.000*
+	4 (9.8)	3 (75)	1 (25)	
Brain tumor				
-	40 (97.6)	32 (80)	8 (20)	0.220*
+	1 (2.4)	0 (0)	1 (100)	
Lung tumor				
-	40 (97.6)	32 (80)	8 (20)	0.220*
+	1 (2.4)	0 (0)	1 (100)	
Colostomy				
-	26 (63.4)	23 (88.5)	3 (11.5)	0.053*
+	15 (36.6)	9 (60)	6 (40)	
Orchiectomy				
-	36 (87.8)	30 (83.3)	6 (16.7)	0.061*
+	5 (12.2)	2 (40)	3 (60)	
Debridement				
1	11 (26.8)	11 (100)	0 (0)	0.083*
>1	30 (73.2)	21 (70)	9 (30)	
Intensive care				
-	19 (46.3)	19 (100)	0 (0)	0.002*
+	22 (53.7)	13 (59.1)	9 (40.9)	
Bacterial Cultures				
Bacteria reproduction				
-	8 (19.5)	8 (100)	0 (0)	0.164*
+	33 (80.5)	24 (72.7)	9 (27.3)	
Escherichia coli				
-	17 (41.5)	15 (88.2)	2 (11.8)	0.262*
+	24 (58.5)	17 (70.8)	7 (29.2)	
Staphylococcus				
-	35 (85.4)	27 (77.1)	8(22.9)	1.000*
+	6 (14.6)	5 (83.3)	1 (16.7)	
Pseudomonas				
-	36 (87.8)	28 (77.8)	8 (22.2)	1.000*
+	5 (12.2)	4 (80)	1 (20)	
Others (*Streptococcus, Klebsiella, Acinetobacter*, Staph saprophyticus, *Enterococcus*)				
-	31 (75.6)	25 (80.6)	6 (19.4)	0.662*
+	10 (24.4)	7 (70)	3 (30)	
VAC				
-	21 (51.2)	16 (76.2)	5 (23.8)	1.000*
+	20 (48.8)	16 (80)	4 (20)	

(Continues)

Table 1. Comparison of baseline characteristics describing survivors and non-survivors *(continued)*

Variables	Total n (%) (n = 41)	Survivor n (%) (n = 32)	Non-survivor n (%) (n = 9)	p-values
	Median (min-max)	Median (min-max)	Median (min-max)	
Age	57 (24-95)	56.5 (24-95)	77 (48-81)	0.009†
Length of hospital stay, days	20 (3-75)	20.5 (7-75)	15 (3-45)	0.027†
Time between application date and surgery date (Hours)	3 (1-8)	3 (1-8)	3 (1-6)	0.466†
Cost, $	2316 (181-14492)	1823 (181-14448)	3432 (637-14492)	0.080†
Temperature, °C	37 (36-39)	37 (36-38)	39 (37-39)	<0.001†
Heart rate, bpm	100 (68-130)	96.5 (68-130)	115 (88-120)	0.035†
Respiration rate, rpm	20 (16-26)	20 (16-24)	20 (18-26)	0.653

*Fisher exact test. †Mann–Whitney U test with median (min–max).
DM: diabetes mellitus; CHF: congestive heart failure; HT: hypertension; CRF: chronic kidney diseases; CAH: coronary artery disease; bpm: beats per minute; rpm: breaths per minute; tm: tumor; VAC: vacuum-assisted closing.

Table 2. Comparison of laboratory values NLR and LCR values of patients according to mortality status

Variables	Survivor (n = 32)	Non-survivor (n = 9)	p-values
Na, mmol/L	134.5 (119-153)	135 (131-143)	0.343*
K, mmol/L	4.22 ± 0.79	4.59 ± 0.65	0.210†
Creatinine, mg/dL	1.03 (0.42-3.67)	3 (0.92-4)	0.003*
Hct, %	35.6 (25-43.2)	29.5 (20-37.3)	0.020*
WBC, ×1000/mm^3	12 (2.87-26.8)	14.6 (8.13-26.31)	0.060*
Lactic acid, mmol/L	2 (1-3)	3 (2-4)	< 0.001*
Glucose, mg/dL	151.1 (22-729)	214.5 (80.7-653.2)	0.376*
Venous bicarbonate, mmol/L	21 (16-29.2)	22 (18-28.1)	0.889*
Neutrophil count	10.71 ± 4.41	17.92 ± 4.06	< 0.001†
Lymphocyte count	1.08 (0.5-2.61)	1.20 (0.6-1.8)	0.722*
CRP, mg/dL	110.3 (8-435.6)	211 (140-400)	0.004*
NLR	9.43 (1.2-24)	14.09 (7.78-38.33)	0.041*
LCR	0.0116 (0.0024-0.1)	0.0057 (0.0028-0.0075)	0.024*
FGIS	5.16 ± 2.49	10.11 ± 1.76	< 0.001†

*Mann–Whitney U test with median (min–max). †Student's t-test with Mean±SD.
FGIS: Fournier's gangrene severity index; LCR: lymphocyte-to-C-reactive protein ratio; NLR: neutrophil-to-lymphocyte ratio; WBC: white blood cell; Htc: hematocrit; Na: sodium; K: potassium.

[0.870-1.000], p < 0.001; AUC = 0.747 [0.593-0.900], p = 0.025; AUC = 0.724 [0.548-0.900], p = 0.042, respectively, table 3). At the same time, the ROC areas under the curve (ROC AUC) were statistically compared. The AUC value for FGIS (0.941) was significantly higher (p = 0.038) than the AUC value of the LCR (0.747). AUC value for FGIS was significantly higher (0.724) than NLR's AUC value (p = 0.0499). There was no significant difference between the AUC values of LCR and NLR (p = 0.824).

ROC analysis was performed for CRP and neutrophil. ROC AUC for CRP 0.806 (0.671-0.940). The ROC AUC for neutrophil is 0.903 (0.806-0.999).

Table 3. ROC analysis results for FGIS, LCR, and NLR values with sensitivity, specificity, positive-negative predictive values, and likelihood ratio (+) values

Variables	FGIS	LCR	NLR
AUC (95% CI)	0.941 (0.870-1.000)	0.747 (0.593-0.900)	0.724 (0.548-0.900)
p-values	< 0.001	0.025	0.042
Cut-off	6.5	0.0088	9.19
Sensitivity (95% CI)	1 (0.628-1)	1 (0.628-1)	0.889 (0.506-0.994)
Specificity (95% CI)	0.812 (0.629-0.921)	0.563 (0.379-0.732)	0.5 (0.322-0.677)
PPV (95% CI)	0.6 (0.328-0.825)	0.391 (0.205-0.612)	0.333 (0.164-0.553)
NPV (95% CI)	1 (0.839-1)	1 (0.781-1)	0.941 (0.692-0.996)
LR + (95% CI)	5.33 (2.59-10.97)	2.29 (1.54-3.39)	1.78 (1.17-2.70)

FGIS: Fournier's gangrene severity index; LCR: lymphocyte-to-C-reactive protein ratio; NLR: neutrophil-to-lymphocyte ratio; AUC: area under the ROC curve; CI: confidence interval; PPV: positive predictive values; NPV: negative predictive values; LR: likelihood ratio; ROC: receiver operating characteristic.

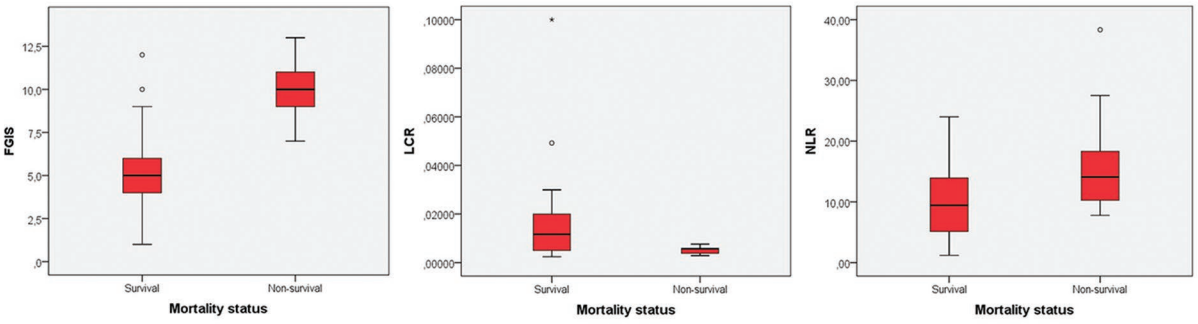

Figure 1. *Comparison of FGIS, LCR, and NLR values between mortality groups by box plot.*

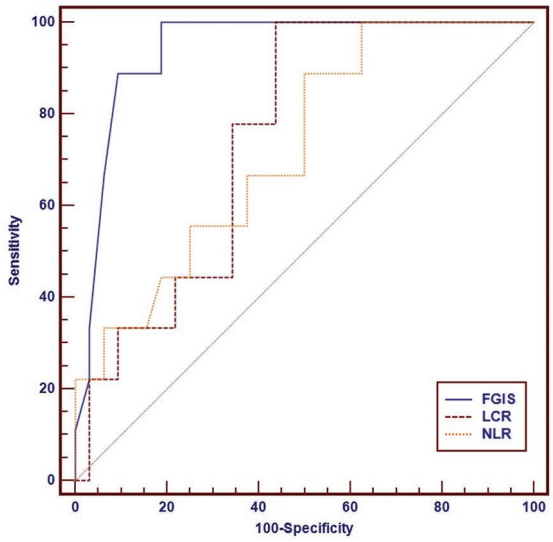

Figure 2. *Receiver operating characteristic curves.*

The cutoff point for FGSI was 6.5. For this cutoff point, classification success was determined as 100% sensitivity (62.8-100%) and 81.2% specificity (62.9-92.1%) (Table 3). The cutoff point for LCR was found to be 0.0088. For this cutoff point, classification success was determined as a sensitivity value of 100% (62.8-100%) and a specificity value of 56.3% (37.9-73.2%) (Table 3). The cutoff point for NLR was 9.19. For this cutoff point, classification success was determined through a sensitivity value of 88.9% (50.6-99.4%) and a specificity value of 50% (32.2-67.7%) (Table 3).

Discussion

FG is associated with high mortality rates when emergency intervention is not performed. Several

scoring systems and biomarkers have been used to predict prognosis and mortality in patients with FG. In our study, we investigated the usability of LCR, a new inflammatory marker, to predict mortality in FG. We found out in our study that a low LCR value is a free prognostic factor for mortality in patients with FG. Furthermore, NLR and FGSI values were significantly higher in non-survivors compared to survivors.

Despite the advanced diagnostic methods, treatment approaches, and intensive care facilities we have today, mortality rates for FG remain high. Stone and Martin (1972) reported the mortality rate as 88% in the study of 33 patients[12]. Mortality rates in FG range from 3% to 45% in recent case series in the literature. In our current series, the mortality rate was found as 21.9%, which falls within the range reported in the literature[3,13]. The key reasons for high mortality rates are the aggressive nature of the infection and the devastating effects of the accompanying predisposing factors.

In the past, FG was thought to occur only in young men. Recent studies have reported a gradual increase in the age of FG patients[14]. The effect of advanced age on mortality has been discussed in many studies; however, the results are conflicting. Sorensen et al.[13] in a large-scale population-based study on 1641 patients and Bozkurt et al.[15] reported that advanced age has been associated with mortality. In our study, the mean age of the patients was 57 years and survivors were significantly younger than non-survivors as reported by the previously mentioned studies. On the contrary, some authors have reported no significant differences in age between survivors and non-survivors[10,16].

Several scoring systems have been developed for determining the severity of the infection and predicting prognosis in patients with FG. The most commonly used scoring system is FGSI developed by Laor et al.[6] A threshold parameter is used in the FGSI system to predict outcomes. It is reported that an FGSI value of < 9 corresponds to a survival rate of 78% and an FGSI value of ≥ 9 corresponds to a probability of death at a rate of 75%. In our series, FGSI scores were significantly lower in non-surviving patients compared to survivors ($p = 0.001$). The mean FGSI score of survivors was about half of the mean FGSI score of non-survivors (5.11 ± 2.49 and 10.11 ± 1.76, respectively) and the cutoff value was 6.5. There are other studies, which demonstrated that the FGSI scoring system was not associated with mortality and did not predict prognosis.

Several studies about various diseases have demonstrated that NLR is associated with the severity of systemic inflammation and indicate the disease severity[17-19]. We found only a few studies about the prognostic significance of NLR and its association with mortality in FG patients in the scientific literature. In a 33-patient series study by Bozkurt et al., NLR, FGSI, and the Laboratory Risk Indicator for Necrotising Fasciitis scoring system were investigated. That study reported that all three parameters could be used to predict poor prognosis, including mortality and the need for mechanical ventilation[16]. In another study, the authors reported that FG patients, who needed multiple debridements, had higher mean NLR levels (> 8) compared to the patients, who needed only one debridement procedure[7]. In our study, NLR was significantly higher in non-survivors compared to survivors ($p = 0.04$). We associated increased NLR levels with poor prognosis and high mortality.

LCR has recently received attention and has been reported as a potential predictor of prognosis and inflammation. Recent studies have demonstrated that LCR predicted prognosis in specific types of cancer such as colon and stomach cancers. In patients with colorectal cancer, low pre-operative LCR levels were associated with the highest recurrence rate[20]. In a recent study of 2,424 stage IV cancer cases, 13 different inflammatory markers were studied. Researchers stated that LCR score can be used to predict prognosis in stage IV patients according to other evaluated inflammation indicators[21]. In another study about stomach cancer, low pre-operative LCR levels were associated with peritoneal metastasis, advanced stage, and distant organ metastasis. In long-term results, low pre-operative LCR levels have been reported as an independent prognostic factor for both disease-free survival and overall survival[10]. LCR has also been employed in global studies about the coronavirus disease 2019 (COVID-19) pandemic caused by the novel severe acute respiratory syndrome coronavirus-2. Those studies have reported that the use of LCR is feasible as an indicator of systemic inflammation caused by the cytokine storm[22]. In a meta-analysis, Lagunas-Rangel reviewed six studies and concluded that increased NLR and decreased LCR values might be associated with the severity of COVID-19[11]. In light of the abovementioned data, we investigated whether LCR could predict disease severity and mortality in patients with FG. In our series, LCR values were significantly lower in non-survivors compared to survivors ($p = 0.025$).

Our study had certain limitations. First, our study had a small sample size because of the retrospective design and the rarity of the disease. Second, the study was carried out in only one tertiary referral hospital, meaning that the patients may have been treated by different surgeons and through different methods. There is a need for a multi-center prospective study with a larger sample size to further confirm the prognostic value of LCR and its association with mortality in FG.

Conclusion

FG continues to be an important health problem with high mortality rates. Early diagnosis and treatment are extremely crucial in FG. Low LCR and high FGSI and NLR values can be used for predicting poor prognosis and mortality. This is the first study in the literature that investigated the possible association of LCR with the prognosis in FG. However, although FGSI has the best area under the curve and has been proven in many studies, we think that this area should be kept in mind in LCR. However, prospective multicenter studies are needed on this subject.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

References

1. Fournier JA. Jean-Alfred Fournier 1832-914. Gangrènefoudroyante de la verge (overwhelming gangrene). Sem Med 1883. Dis Colon Rectum. 1988;31:984-8.
2. Benjelloun EB, Souiki T, Yakla N, Ousadden A, Mazaz K, Louchi A, et al. Fournier's gangrene: our experience with 50 patients and analysis of factors affecting mortality. World J Emerg Surg. 2013;8:13.
3. Eke N. Fournier's gangrene: a review of 1726 cases. Br J Surg. 2000;87:718-28.
4. Thwaini A, Khan A, Malik A, Cherian J, Barua J, Shergill I, et al. Fournier's gangrene and its emergency management. Postgrad Med J. 2006;82:516-9.
5. Yaghan RJ, Al-Jaberi TM, Bani-Hani I. Fournier's gangrene: changing face of the disease. Dis Colon Rectum. 2000;43:1300-8.
6. Laor E, Palmer LS, Tolia BM, Reid RE, Winter HI. Outcome prediction in patients with Fournier's gangrene. J Urol. 1995;154:89-92.
7. Kahramanca S, Kaya O, Özgehan G, Irem B, Dural I, Küçükpınar T, et al. Are neutrophil-lymphocyte ratio and platelet-lymphocyte ratio as effective as Fournier's gangrene severity index for predicting the number of debridements in Fourner's gangrene? Ulus Travma Acil Cerrahi Derg. 2014;20:107-12.
8. Yildirim M, Dasiran F, Angin YS, Okan I. I. Lymphocyte-C-reactive protein ratio: a putative predictive factor for intestinal ischemia in strangulated abdominal wall hernias. Hernia. 2021;25:733-9.
9. Okugawa Y, Toiyama Y, Fujikawa H, Ide S, Yamamoto A, Omura Y, et al. Prognostic potential of lymphocyte-C-reactive protein ratio in patients with rectal cancer receiving preoperative chemoradiotherapy. J Gastrointest Surg. 2021;25:492-502.
10. Okugawa Y, Toiyama Y, Yamamoto A, Shigemori T, Ichikawa T, Yin C, et al. Lymphocyte-to-C-reactive protein ratio and score are clinically feasible biomarkers in gastric cancer patients. J Clin Oncol. 2019;37:4.
11. Lagunas-Rangel FA. Neutrophil-to-lymphocyte ratio and lymphocyte-to-C-reactive protein ratio in patients with severe coronavirus disease 2019 (COVID-19): a meta-analysis. J Med Virol. 2020;92:1733-4.
12. Stone HH, Martin JD Jr. Synergistic necrotizing cellulitis. Ann Surg. 1972;175:702-11.
13. Sorensen MD, Krieger JN, Rivara FP, Broghammer JA, Klein MB, Mack CD, et al. Fournier's gangrene: population based epidemiology and outcomes. J Urol. 2009;181:2120-6.
14. García Marín A, Martín Gil J, Vaquero Rodríguez A, Sánchez Rodríguez T, de Tomás Palacios J, Lago Oliver J. et al. Fournier's gangrene: analysis of prognostic variables in 34 patients. Eur J Trauma Emerg Surg. 2011;37:141-5.
15. Bozkurt O, Sen V, Demir O, Esen A. Evaluation of the utility of different scoring systems (FGSI, LRINEC and NLR) in the management of Fournier's gangrene. Int Urol Nephrol. 2015;47:243-8.
16. Erol B, Tuncel A, Hanci V, Tokgoz H, Yildiz A, Akduman B, et al. Fournier's gangrene: overview of prognostic factors and definition of new prognostic parameter. Urology. 2010;75:1193-8.
17. Ni J, Wang H, Li Y, Shu Y, Liu Y. Neutrophil to lymphocyte ratio (NLR) as a prognostic marker for in-hospital mortality of patients with sepsis: a secondary analysis based on a single-center, retrospective, cohort study. Medicine (Baltimore). 2019;98:e18029.
18. Park KS, Lee SH, Yun SJ, Ryu S, Kim K. Neutrophil-to-lymphocyte ratio as a feasible prognostic marker for pyogenic liver abscess in the emergency department. Eur J Trauma Emerg Surg. 2019;45:343-51.
19. Yoon JB, Lee SH. The neutrophil-to-lymphocyte ratio has feasible predictive value for hospital mortality in patients with small bowel obstruction in the emergency department. Am J Emerg Med. 2021 Jun;44:428-433.
20. Okugawa Y, Toiyama Y, Yamamoto A, Shigemori T, Ide S, Kitajima T, et al. Lymphocyte-C-reactive protein ratio as promising new marker for predicting surgical and oncological outcomes in colorectal cancer. Ann Surg. 2020;272:342-51.
21. Zhang HY, Xie HL, Ruan GT, Zhang Q, Ge YZ, Liu XY, et al. Lymphocyte to C-reactive protein ratio could better predict the prognosis of patients with stage IV cancer. BMC Cancer. 2022;22:1080.
22. Ullah W, Basyal B, Tariq S, Almas T, Saeed R, Roomi S, et al. Lymphocyte-to-C-reactive protein ratio: a novel predictor of adverse outcomes in COVID-19. J Clin Med Res. 2020;12:415-22.

ORIGINAL ARTICLE

Comparison of early and late removal of the urinary catheter after rectal cancer surgery

Comparación de la retirada precoz y tardía de la sonda urinaria tras la cirugía de cáncer rectal

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Abstract

Objective: *This study is aiming to compare the results of early and late removal of urinary catheters after rectal cancer surgery.* **Materials and methods:** *Patients who undergone rectal cancer surgery in a single center were included in this prospective randomized study. The timing of the urinary catheter removal was randomized by a computer-assisted program and divided into 2 groups, which are early (first 48 h) and late (after 48 h). The primary outcome of this study was to compare the urinary retention and re-catheterization rates between patients with early and those with late catheter removal.* **Results:** *Sixty-six patients were included in this study. The median age was 60 (31-88 years), and the patient group was predominantly male (n: 40, 60.9%). Urinary retention after catheter removal developed in 8 (12%) of 66 patients. There was no difference between the two groups in terms of the need for re-catheterization (14% vs. 10%, p: 0.63). All the patients who required re-catheterization (n: 8) and were discharged with a urinary catheter (n: 4) were male. When the male and female patients were evaluated separately, there was no difference in urinary retention in the early or late groups.* **Conclusions:** *Early or late removal of the catheter does not play a role in the development of urinary retention in patients undergoing rectal cancer surgery.*

Keywords: *Rectal cancer. Catheter. Catheter removal time. Pelvic surgery.*

Resumen

Objetivo: *Comparar los resultados de la retirada precoz y tardía de la sonda urinaria tras la cirugía de cáncer rectal.* **Método:** *Estudio prospectivo aleatorizado que incluyó pacientes sometidos a cirugía de cáncer rectal en un único centro. El momento de la retirada de la sonda urinaria se aleatorizó y se dividió en dos grupos: primeras 48 horas y después de 48 horas. Se compararon las tasas de retención urinaria y de nueva cateterización entre los pacientes con retirada precoz y tardía de la sonda.* **Resultados:** *Se incluyeron 66 pacientes, con una mediana de edad de 60 años (31-88 años) y predominio del sexo masculino (n = 40, 60.9%). Se produjo retención urinaria tras la retirada de la sonda en 8 (12%). No hubo diferencias entre los dos grupos en cuanto a necesidad de nueva cateterización (14% frente a 10%, p = 0.63). Todos los pacientes que precisaron un nuevo cateterismo (n = 8) y fueron dados de alta con una sonda urinaria (n = 4) eran varones.* **Conclusiones:** *La retirada precoz o tardía de la sonda no influye en la aparición de retención urinaria en pacientes intervenidos de cáncer de recto.*

Palabras clave: *Cáncer rectal. Catéter. Tiempo de retirada del catéter. Cirugía pélvica.*

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Introduction

Before abdominal surgery, a urinary catheter is usually inserted to allow for better visualization of the operative field. The catheter protects the bladder from injury and allows for easier monitoring of kidney function during and after surgery. Because of the high risk of nerve injuries resulting in urinary retention or bladder dysfunction, it is especially useful during rectal cancer surgery[1]. The time to remove the catheter varies depending on the operation. The catheter is typically kept for 7 days because early removal of the urinary catheter has been linked to an increased risk of urinary retention[2,3].

Acute urinary retention affects approximately 20% of patients after abdominopelvic surgery[4]. Elderly patients and male patients with benign prostatic hypertrophy are at increased risk. It may cause bladder outlet obstruction by activating α-adrenergic receptors in the bladder neck through various mechanisms after pelvic surgery[5]. Therefore, a urethral catheter is placed during rectal surgery to prevent retention. However, urinary catheters are associated with an increased risk of urinary tract infection (UTI) with the duration of catheterization[6]. Enhanced recovery after surgery (ERAS) guidelines recommend withdrawal within 48 h of colon or rectal surgery post-operative period. Especially long-term catheters in place prolonged the hospitalization period of the patient and, at the same time, increased UTIs. The results of studies trying to determine the optimal duration of catheterization after rectal surgery are variable, and the risk-benefit balance of early catheter removal remains unclear[7].

In this prospective randomized study, we aimed to compare the outcomes between the patients with early or late catheter removal.

Materials and method

This prospective randomized trial was conducted at a single center in Marmara University Hospital All patients who underwent elective rectal surgery between March 2021 and March 2022, either low anterior resection (LAR), Low very anterior resection (VLAR), or Abdominoperineal resection (APR), were included in the study. Randomization was performed according to a computer randomization program. Patients who have urgent surgery, a previous history of urinary tract malignancy, a chronic indwelling urethral catheter, a neurogenic bladder, previous lower urinary tract surgery, a history of prior ureteral stent placement, and those who did not give consent to participate in this trial were excluded from the study.

A single dose of intravenous prophylactic antibiotics was given to all patients 1 h before the incision. Urinary catheters were placed before the incision. Catheter removal time was conducted according to a randomization scale. Urine culture and urine analysis were performed for all the patients after the removal of the urinary catheter.

Early removal was defined as the removal of the catheter within 48 h post-operative. Late removal was defined as the removal of the catheter after a period of 48 h.

Data including age, gender, body mass index (BMI), American Society of Anesthesiologists classification (ASA), neoadjuvant chemoradiotherapy, surgical approach (laparoscopic or open), type of surgery (LAR, VLAR, or APR), Foley catheter removal time, post-operative urinary retention, and post-operative hospital stay were collected prospectively.

The primary outcome of this study was to compare the urinary retention and re-catheterization rates between patients with early and those with late catheter removal. Secondary outcomes were investigating the possible associated factors may related to urinary retention after catheter removal.

This study was approved by Marmara university Ethics and Research committee also, registered in the Clinical Trial Identifier with no: NCT05020613.

Statistical analysis

We performed statistical analyses using the Statistical Package for Social Sciences for Windows version 20 (SPSS Inc.; Chicago, IL, USA). To compare categorical variables, two-tailed Chi-square or Fisher exact tests were used. An independent 2-sample t-test, or Mann–Whitney U, was performed for comparison of ordinal data. $p < 0.05$ were considered statistically significant.

Results

Between March 2021 and March 2022, 101 patients underwent rectal surgery. Among them, a total of 31 patients were excluded from the study because of urgent surgery, neurogenic bladder, and who did not give consent to participate in this trial. Four patients

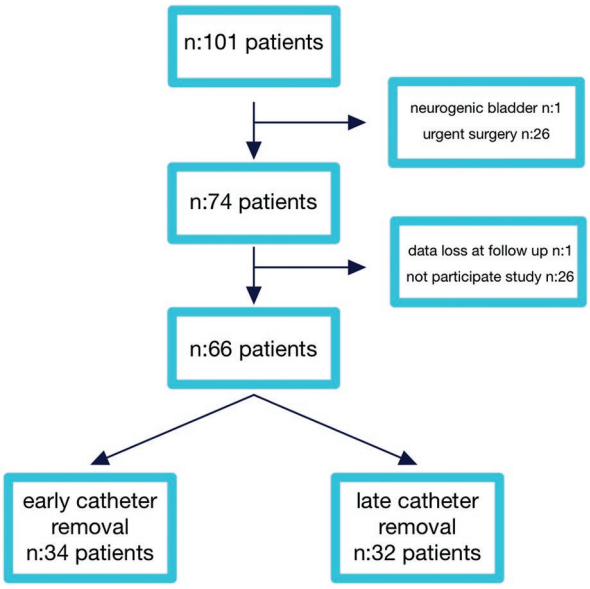

Figure 1. *Flowchart of the study.*

were excluded because of loss of follow-up during the study (Fig. 1).

A total of 66 patients were included in the study. There were 34 patients in the early catheter removal group and 32 patients in the late removal group. The median age of all cohorts was 60 (31-88 years), and the majority of patients (n = 40, 60.9%) were male. VLAR was performed in 15 (23%) patients, LAR in 39 (59%) patients, and APR in 12 (18%) patients. Only 2 (3%) patients underwent laparoscopic operation. Out of the 66 patients included, eight (12%) developed urinary retention after catheter removal. No significant difference was observed between the 2 groups regarding age, gender, BMI, ASA scores, and neoadjuvant chemotherapy.

No significant difference was found between the two groups in terms of urinary retention (14% vs. 10%, p: 0.63) (Table 1).

All the patients with urinary retention (n: 8) were male. Male and female patients were evaluated separately regarding urinary retention after catheter removal. No significant difference was observed between the 2 groups (early and late removal) in each gender regarding age, gender, BMI, ASA scores, and neoadjuvant chemotherapy. Furthermore, there was no significant difference between the two groups in terms of urinary retention (0% vs. 0%, p = 1.0) or (25% vs. 15%, p: 0.42) for each gender, respectively (Tables 2 and 3). Among 8 male patients who revealed urinary retention, only 3 (37%) had a history of BPH.

Table 1. Comparison of demographics and post-operative outcomes between early and late removal group

Variables	Early removal (n = 34)	Late removal (n = 32)	p-value
Age	61	58	0.38
Gender			0.76
Female	14 (41)	12 (37)	
Male	20 (59)	20 (62)	
BMI	27.2	27.7	0.67
ASA			0.32
1	1 (4)	4 (13)	
2	26 (77)	21 (65)	
3	7 (20)	7 (22)	
Neoadjuvant therapy	17 (53)	17 (50)	0.8
BPH presence	3 (8)	4 (12)	0.8
Operation type			0.42
VLAR	9 (26)	6 (18)	
LAR	21 (62)	18 (56)	
APR	4 (12)	8 (25)	
Tumor Stage			0.6
0	2 (6)	3 (9)	
1	8 (24)	4 (12)	
2	8 (23)	10 (31)	
3	15 (44)	14 (44)	
4	1 (3)	1 (3)	
Urinary Retention	5 (14)	3 (10)	0.5
Hospital Stay	6.6	5.9	0.3
Discharge with urinary Catheter	3 (9)	1 (3)	0.3

Discussion

This study prospective randomized study showed that urinary retention rates were similar in both early and late catheter removal groups in both genders.

Urinary catheter removal timing is still a controversial issue in both clinical studies and daily practice. Very few randomized prospective studies in the literature discuss this issue. Therefore, this prospective randomized study highlighted this issue and may fill the gap in the less discussed issue in the literature. Patients were evaluated separately according to gender, which may prevent selection bias during statistical analysis. The small sample size and small number of patients with laparoscopic approaches, the lack of power analysis, and the loss of data regarding epidural analgesia were the limitations of this study.

In recent studies, including randomized controlled studies, early removal of the urinary catheter was

Table 2. Comparison of demographics and post-operative outcomes between early and late removal group in female patients

Variables	Early removal (n = 14)	Late removal (n = 12)	p-value
Age	59	59	0.96
BMI	28.3	27.3	0.49
ASA			0.26
1	0 (0)	2 (17)	
2	12 (86)	9 (75)	
3	2 (14)	1 (8)	
Neoadjuvant Therapy	6 (43)	7 (58)	0.43
Operation Type			0.39
VLAR	1 (7)	3 (25)	
LAR	10 (71)	6 (50)	
APR	3 (22)	3 (25)	
Tumor stage			0.8
0	1 (7)	1 (8)	
1	3 (21)	2 (17)	
2	5 (36)	6 (50)	
3	4 (29)	3 (25)	
4	1 (7)	0 (0)	
Urinary retention	0	0	1.0
Hospital stay	4.9	5.9	0.27

Table 3. Comparison of demographics and post-operative outcomes between early and late removal group in male patients

Variables	Early removal (n = 20) (%)	Late removal (n = 20) (%)	p-value
Age	58	62	0.85
BMI	27	27.2	0.9
ASA			0.74
1	1 (5)	2 (10)	
2	14 (70)	12 (60)	
3	5 (25)	6 (30)	
Neoadjuvant Therapy	11 (55)	10 (50)	0.75
Operation Type			0.15
VLAR	8 (40)	3 (15)	
LAR	11 (55)	12 (60)	
APR	1 (5)	5 (25)	
Tumor Stage			0.59
0	1 (5)	2 (10)	
1	5 (25)	2 (10)	
2	3 (15)	4 (20)	
3	11 (55)	11 (55)	
4	0 (0)	1 (5)	
BPH presence	2 (10)	4 (20)	0.66
Urinary Retention	5 (25)	3 (15)	0.42
Hospital Stay (median) (range)	6 (4–22)	5 (3–14)	0.12

associated with increased urinary retention[8,9]. While others claimed the opposite and reported contradictory results, early removal on post-operative day 1 was thought to be similar to late catheter removal[8-10].

In the meta-analysis, although urinary retention rates were not different between the 1st and 3rd days post-operatively, significantly more retention was observed compared to the 5th day. On the contrary, UTI was much higher in the late group[7]. In a prospective study after pelvic surgery, three groups were compared. Post-operative 1, 3, and 5 days were selected for catheter removal. Urinary retention was higher on the 1st and the 5th days. It was concluded that the optimal timing was 3 days[11].

Operations such as APR and total proctocolectomy are associated with increased retention rates due to nerve dissection compared to other colorectal operations. In addition, operations performed for malignancy increase the size of the mesorectal dissection and therefore the risk of post-operative retention[12,13]. Our study did not detect any difference between operations in terms of retention in patients who underwent rectal surgery. The ERAS protocol is now commonly recommended for patients who have undergone colorectal surgery. In a recent study, which includes the ERAS protocol, it was also shown that the optimal timing for a urinary catheter was post-operative 3 days for improved urinary retention and infection rates[14]. In our study, early removal of the urinary catheter was not associated with increased urinary retention rates in patients undergoing rectal cancer surgery. This supported the data on early removal recommendations and consistent with the ERAS protocol. Although it is one of the components of ERAS protocol, epidural analgesia is suggested to be a risk factor for urinary retention[15].

While older age, male gender, history of benign prostatic hyperplasia, and epidural anesthesia are considered as risk factors for retention[15], none of them was shown to be a risk factor in this study, which could be explained by the small number of the study cohort. However, all the patients with urinary retention were male. In our study, there was no documented data regarding epidural analgesia, but it is usually applied routinely to patients who underwent open colorectal surgery in our practice.

In a recent prospective study, it was shown that urinary catheter removal after laparoscopic colorectal surgery is safe[16]. Nevertheless, in our study, the lack of a laparoscopic approach in the study cohort is considered as another limitation of the study. Further prospective randomized studies with a large number of patients are needed in the future.

Conclusion

This study showed that early urinary catheter removal is not associated with increased urinary retention rates. Thus, early catheter removal is safe and could be recommended after rectal cancer surgery.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for the analysis and publication of routinely acquired clinical data, and informed consent was not required for this retrospective observational study.

Use of artificial intelligence for generating text. The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript or for the creation of images, graphics, tables, or their corresponding captions.

References

1. Xu L, Tao ZY, Lu JY, Zhang GN, Qiu HZ, Wu B, et al. A single-center, prospective, randomized clinical trial to investigate the optimal removal time of the urinary catheter after laparoscopic anterior resection of the rectum: study protocol for a randomized controlled trial. Trials. 2019;20:133.
2. Feneley RC, Hopley IB, Wells PN. Urinary catheters: history, current status, adverse events and research agenda. J Med Eng Technol. 2015;39:459-70.
3. Roulet M, Delbarre B, Vénara A, Hamy A, Barbieux J. Urine drainage management in colorectal surgery. J Visc Surg. 2020;157:309-16.
4. Eveno C, Lamblin A, Mariette C, Pocard M. Sexual and urinary dysfunction after proctectomy for rectal cancer. J Visc Surg. 2010;147:e21-30.
5. Toyonaga T, Matsushima M, Sogawa N, Jiang SF, Matsumura N, Shimojima Y, et al. Postoperative urinary retention after surgery for benign anorectal disease: potential risk factors and strategy for prevention. Int J Colorectal Dis. 2006;21:676-82.
6. Nagle D, Curran T, Anez-Bustillo L, Poylin V. Reducing urinary tract infections in colon and rectal surgery. Dis Colon Rectum. 2014;57:91-7.
7. Lee Y, McKechnie T, Springer JE, Doumouras AG, Hong D, Eskicioglu C. Optimal timing of urinary catheter removal following pelvic colorectal surgery: a systematic review and meta-analysis. Int J Colorectal Dis. 2019;34:2011-21.
8. Patel DN, Felder SI, Luu M, Daskivich TJ, Zaghiyan KN, Fleshner P. Early urinary catheter removal following pelvic colorectal surgery: a prospective, randomized, noninferiority trial. Dis Colon Rectum. 2018;61:1180-6.
9. Xie N, Hu Z, Ye Z, Xu Q, Chen J, Lin Y. A systematic review comparing early with late removal of indwelling urinary catheters after pelvic organ prolapse surgery. Int Urogynecol J. 2021;32:1361-72.
10. Yoo BE, Kye BH, Kim HJ, Kim G, Kim JG, Cho HM. Early removal of the urinary catheter after total or tumor-specific mesorectal excision for rectal cancer is safe. Dis Colon Rectum. 2015;58:686-91.
11. Zmora O, Madbouly K, Tulchinsky H, Hussein A, Khaikin M. Urinary bladder catheter drainage following pelvic surgery - is it necessary for that long? Dis Colon Rectum. 2010;53:321-6.
12. Zhang B, Zhuo GZ, Tian L, Zhao K, Zhao Y, Zhao YJ, et al. Risk factors of coloanal anastomotic stricture after laparoscopic intersphincteric resection for low rectal cancer. Zhonghua Wei Chang Wai Ke Za Zhi. 2019;22:755-61.
13. Meddings J, Skolarus TA, Fowler KE, Bernstein SJ, Dimick JB, Mann JD, et al. Michigan Appropriate Perioperative (MAP) criteria for urinary catheter use in common general and orthopaedic surgeries: results obtained using the RAND/UCLA appropriateness method. BMJ Qual Saf. 2019;28:56-66.
14. Meillat H, Magallon C, Brun C, de Chaisemartin C, Moureau-Zabotto L, Bonnet J, et al. Systematic early urinary catheter removal integrated in the full enhanced recovery after surgery (ERAS) protocol after laparoscopic mid to lower rectal cancer excision: a feasibility study. Ann Coloproctol. 2021;37:204-11.
15. Stubbs BM, Badcock KJ, Hyams C, Rizal FE, Warren S, Francis D. A prospective study of early removal of the urethral catheter after colorectal surgery in patients having epidural analgesia as part of the enhanced recovery after surgery programme. Color Dis. 2013;15:733-6.
16. Eriksen JR, Munk-Madsen P, Kehlet H, Gögenur I. Postoperative urinary retention after laparoscopic colorectal resection with early catheter removal: a prospective observational study. World J Surg. 2019;43:2090-8.

ORIGINAL ARTICLE

Effect of three training programs on surgical performance in single-port laparoscopic surgery

Efecto de tres programas de entrenamiento sobre el desempeño en cirugía laparoscópica por puerto único

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Abstract

Objective: *The aim of this study was to evaluate the effect of three training methodologies on the acquisition of psychomotor skills for laparoendoscopic single-site surgery (LESS), using straight and articulating instruments.* **Methods:** *A prospective study was conducted with subjects randomly divided into three groups, who performed a specific training for 12 days using three laparoscopic tasks in a laparoscopic simulator. Group-A trained in conventional laparoscopy setting using straight instruments and in LESS setting using both straight and articulating instruments. Group-B trained in LESS setting using straight and articulating instruments, whereas Group-C trained in LESS setting using articulating instruments. Participants' performance was recorded with a video-tracking system and evaluated with 12 motion analysis parameters (MAPs).* **Results:** *All groups obtained significant differences in their performance in most of the MAPs. Group-C showed an improvement in nine MAPs, with a high level of technical competence. Group-A presented a marked improvement in bimanual dexterity skills.* **Conclusions:** *Training in LESS surgery using articulating laparoscopic instruments improves the quality of skills and allows smoother learning curves.*

Keywords: *Laparoscopy. Single-incision. Articulating instruments. Objective assessment. Performance.*

Resumen

Objetivo: *Evaluar el efecto de tres métodos de entrenamiento en la adquisición de habilidades psicomotrices para la cirugía laparoendoscópica por puerto único (LESS, laparoendoscopic single-site surgery) utilizando instrumental recto y articulado.* **Método:** *Se realizó un estudio prospectivo con sujetos divididos aleatoriamente en tres grupos, quienes realizaron un entrenamiento específico durante 12 días utilizando tres tareas laparoscópicas en un simulador laparoscópico. El grupo A entrenó en el entorno laparoscópico convencional con instrumentos rectos, y en el entorno LESS con instrumentos rectos y articulados. El grupo B entrenó en el entorno LESS con instrumentos rectos y articulados. El Grupo C entrenó en el entorno LESS con instrumentos articulados. El desempeño de los participantes se registró con un sistema de seguimiento en video y fue evaluado con 12 parámetros de análisis de movimiento (MAP, motion analysis parameters).* **Resultados:** *Todos los grupos obtuvieron*

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diferencias significativas en su desempeño para la mayoría de los MAP. El grupo C mostró una mejora en nueve MAP, con un alto nivel de competencia técnica. El grupo A mostró una marcada mejora en la habilidad de destreza bimanual. **Conclusiones:** *El entrenamiento en cirugía LESS con instrumentos articulados mejora la calidad de las habilidades adquiridas y permite curvas de aprendizaje más suaves.*

Palabras clave: *Laparoscopia. Incisión única. Instrumentos articulados. Evaluación objetiva. Desempeño.*

Introduction

In recent years, one of the main targets in the field of surgery has been the reduction of iatrogenic trauma caused during surgical procedures. This objective has led to the innovation and invention of new techniques, which are included in what is called minimally invasive surgery (MIS)[1]. Within this surgical field, laparoscopic surgery has been the choice of surgeons for many years due to the miniaturization of large incisions, resulting in a reduction of tissue trauma, fewer postoperative complications, and better cosmetic results[2]. However, the need arises to implement a structured educational program for these surgical techniques, where the necessary technical skills and cognitive knowledge can be acquired to perform laparoscopic surgery in a safe and reliable manner.

In the education context, the American Society of Gastrointestinal and Endoscopic Surgeons developed the Fundamentals of Laparoscopic Surgery (FLS) educational program, in which surgeons can acquire and refine the minimally invasive technique through its basic laparoscopic training modules[3,4]. Nevertheless, the European Association of Endoscopic Surgery (EAES) has recently analyzed the current needs of skills training in MIS, detecting a significant educational gap, in which trainees were not undertaking enough training activities to feel confident in their skills[5]. Recently, new surgical techniques have been developed to further reduce the invasiveness generated by laparoscopic surgery, such as the case of laparoendoscopic single-site (LESS) surgery, where a single incision is made in the umbilicus through which a multi-access port is placed and can be used as the main access to the patient's abdominal cavity in its four quadrants[6]. This LESS technique, similar to conventional laparoscopic surgery (CLS), has demonstrated safety and efficacy, so it could therefore be considered a good surgical treatment option. However, it shows some disadvantages with respect to CLS such as a long learning curve, greater complexity, execution time, and higher cost in certain procedures, and poor ergonomics for the surgeon[7,8].

Some of the aforementioned limitations when performing surgical procedures by means of the LESS technique include the loss of triangulation with the reduction of the field of vision, inverted manipulation of the instruments due to the crossing of tools, less intuitive and imprecise movements requiring greater concentration, visual interference between the surgical instruments and the endoscopic camera due to the reduced working space, and the use of instruments with unfamiliar characteristics, making it difficult to maintain surgical safety for the patient and a significant technical challenger[9,10]. On the other hand, the use of articulating instruments can help to minimize these problems because they expand the work area and their steerable tips allow to perform triangulation more easily, making this kind of instrument the recommended choice when performing LESS procedures.

Regarding LESS learning, the EAES has recently published a consensus on LESS surgery, which gathers all the available evidence on this topic and outlines the advantages and disadvantages of LESS, addressing the general aspects of this surgical procedure as well as organ-specific issues[11]. There is a need to redesign specific training programs for the acquisition of skills in LESS, where surgeons can be prepared for the drawbacks related to this surgical technique. Several studies have been published regarding the learning process of LESS surgery. Most of them conclude that specific training in LESS is necessary and therefore a specific educational program for LESS surgery is needed. Therefore, training oriented to the use of the different specific access devices for LESS surgery[12], as well as the different types of laparoscopic instruments, such as straight, curved, and articulating, can considerably improve the quality of the surgeon's performance in this surgical technique[13].

The aim of this study is to evaluate the impact of three training settings on the acquisition of surgical skills for LESS surgery, using straight and articulating laparoscopic instruments. The study was conducted using a laparoscopic box trainer, adapted both for conventional and single-port laparoscopy configurations,

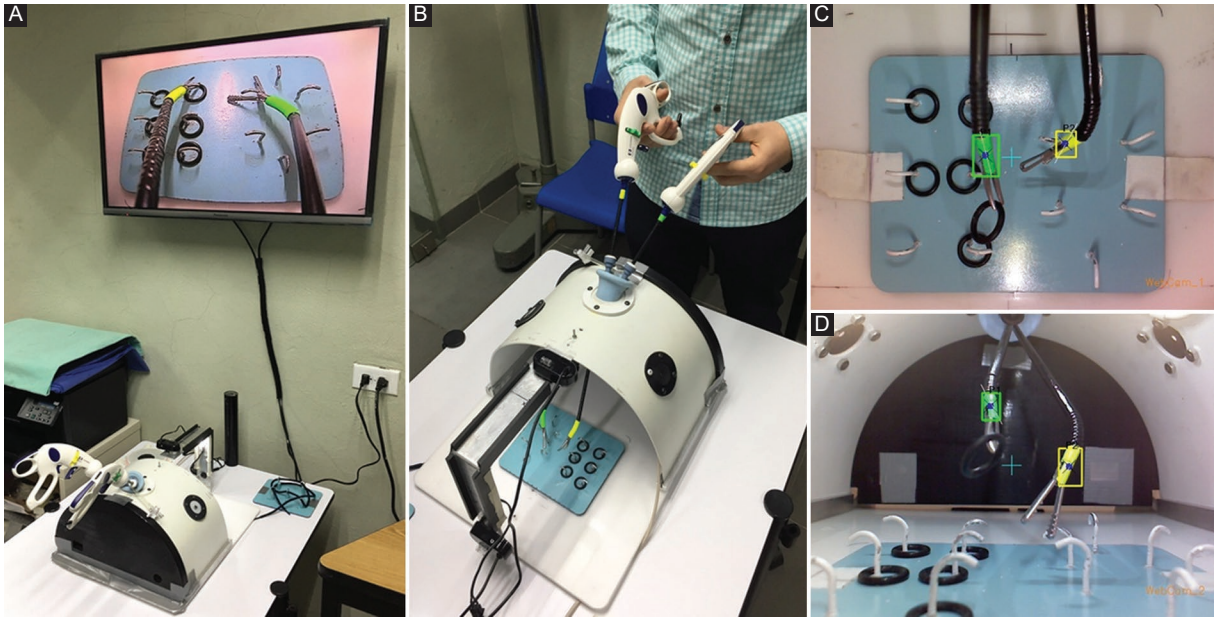

Figure 1. A: *experimental setup of the laparoscopic box simulator.* **B:** *adaptation allowing the use of the SILS™ access port. Motion tracking of the articulating laparoscopic instruments with the orthogonal video-based tracking system of the simulator.* **C:** *top.* **D:** *front views of the color markers in the instruments.*

with an integrated video tracking system. The performance of the participants was analyzed at the beginning and the end of the study using 12 motion analysis parameters (MAPs). With these training programs, we studied if acquiring experience in CLS with straight instruments before jumping to LESS with articulating instruments has an effect on the final proficiency achieved for LESS surgery. We hypothesized that dedicated training in a single-port surgery setting with articulating laparoscopic instruments would improve the acquisition and quality of skills, as well as the surgeon's performance metrics in basic laparoscopic tasks.

Materials and methods

Participants

A total of 30 final-year medical students from the Faculty of Medicine of the National Autonomous University of Mexico (UNAM) were invited to participate in the study. Thirty participants (14 female and 16 male) all right-handed and with no previous experience in minimally invasive surgical techniques, voluntarily enrolled in this study. At the time of the invitation, written informed consents were obtained from all individual participants included in this study. This research was approved by the Ethics, Biosafety, and Research Committee of the Faculty of Medicine at UNAM, under the number code 015/2016.

Equipment

For this study, a laparoscopic box trainer with a built-in orthogonal camera system inside was used, which allows the tracking and motion analysis of the surgical instruments (Fig. 1A). This orthogonal camera system captures the three-dimensional (3D) movements of the laparoscopic instruments within the workspace by means of color markers[14,15] (Figs. 1 C and D). In the study, this box trainer was adapted for training in two configurations: (1) CLS and (2) LESS surgery (Fig. 1B). As an intracorporeal camera, with 0-degree optics, a 750TVL resolution color mini-camera installed below the semicylindrical cavity of the box trainer was used. To simulate the single-port laparoscopic surgery configuration, a SILS™ access port (Medtronic, Minneapolis, MN, USA) was inserted in the center of the semicylindrical cavity, through which the surgical instruments were inserted inside the simulator. In the study, a set of 5-mm standard straight and articulating laparoscopic instruments, which include dissectors, forceps, and scissors (Medtronic, Minneapolis, MN, USA), was used to perform the training tasks with the laparoscopic box trainer in both settings. The straight laparoscopic instruments used include a pair of graspers with atraumatic tips, a pair of Maryland dissection forceps, and scissors, which allow 4° of freedom (DoFs) of movement around the incision point, whereas the articulating laparoscopic

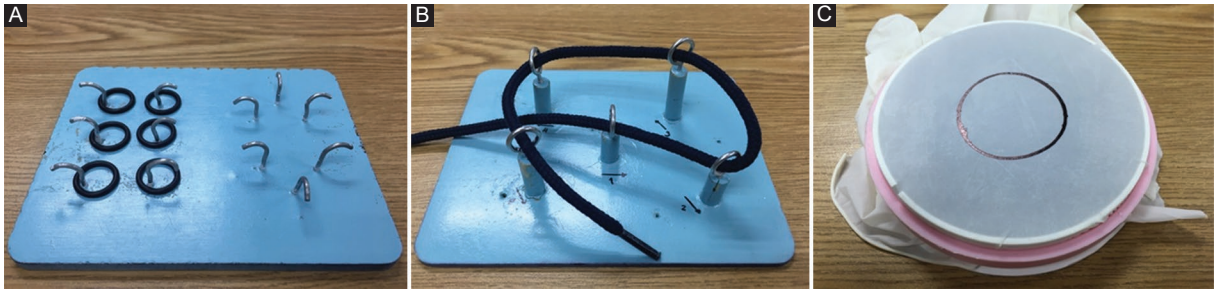

Figure 2. *Laparoscopic training tasks.* **A:** *peg transfer.* **B:** *labyrinth.* **C:** *circular cutting.*

instruments used include a pair of graspers with atraumatic tips, a pair of Maryland dissection forceps and scissors, which allow two additional DoFs of movement at their tips and they are deflectable up to 80° with respect to the incision point.

Tasks

Participants performed three laparoscopic tasks in this study, based on the FLS program and the MISTELS protocol[16,17], for 12 consecutive days. The tasks were performed in the following order:

- Peg transfer (PT): This task consisted of lifting six rubber rings (one by one) from one set of curved posts with the left laparoscopic grasper, transferring them to the right laparoscopic grasper, and placing them on the second set of curved posts (Fig. 2A)
- Labyrinth (L): This task entailed passing a thread through a circuit of five posts with rings placed at different positions and heights. The thread was inserted into each of the rings according to the assigned numbering and direction using both graspers (Fig. 2B)
- Circular cutting: This task consisted of cutting a 4.5-cm circle line on a latex glove stretched on a platform. Participants had to cut along the marked line as precisely as possible using the scissors while applying traction to the latex using the grasper. The task ended when the circle was completely cut out and separated from the glove (Fig. 2C).

Study design

The participants were randomly divided into three groups using the block randomization technique, Group-A, Group-B, and Group-C, of 10 participants each. Figure 3 shows a schematic illustrating the experimental study design. Group-A performed the three training tasks for 12 consecutive days in three phases. In the first phase, the participants trained in CLS setup using straight laparoscopic instruments for 4 days. In the second phase, they switched to LESS setup and trained for 4 days crossing the straight laparoscopic instruments. In the third phase, they continued in LESS setup and trained for the remaining 4 days crossing the articulating laparoscopic instruments. Group-B performed the three training tasks for 12 consecutive days in two phases. In the first phase, the participants trained in LESS setup for 6 days crossing the straight laparoscopic instruments. In the second phase, they continued in LESS setup and trained to cross the articulating laparoscopic instruments for the remaining 6 days. Finally, Group-C performed the three tasks in LESS setup and trained to cross the articulating laparoscopic instruments for 12 consecutive days. Before starting their specific training, all participants received instructions on how to perform and complete each of the three training tasks, as well as technical information about the use and degrees of freedom of straight and articulating laparoscopic instruments. The laparoscopic simulator was placed at a suitable height and position to comfortably perform all three tasks. To ensure the same conditions for all participants in the study, the position of the tasks inside the box trainer, the configuration of the input ports for conventional and single-port laparoscopy, and the position of the camera were standardized for each of them. During each day of the training process, all participants performed a minimum of three repetitions for each task, and no maximum limit of daily repetitions was imposed on them during the study.

Assessment of the psychomotor skills

In this study, the psychomotor MIS skills of all participants were evaluated before and after their 12-day assigned training program, using the box trainer in

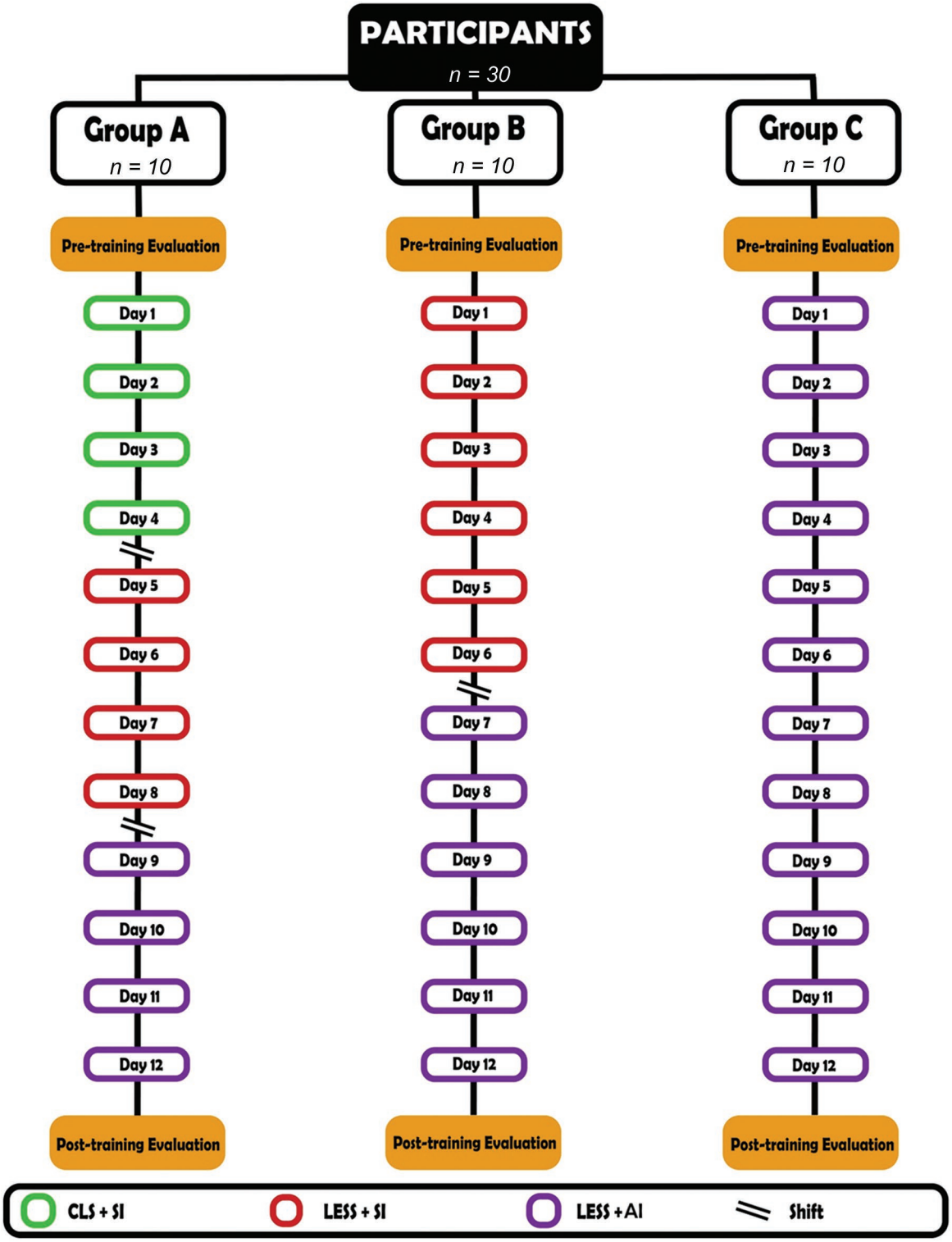

Figure 3. *Study protocol design. CLS+SI: conventional laparoscopic surgery configuration with straight instruments. LESS+SI: laparoendoscopic single-site configuration with straight instruments. LESS+AI: laparoendoscopic single-site configuration with articulating instruments.*

LESS surgery setting, (i.e., crossing the articulating laparoscopic instruments and performing the three laparoscopic tasks). The recorded motion data of the articulating laparoscopic instruments were analyzed using 12 MAPs (Table 1)[18-20]. These MAPs were calculated from the position $[x(t), y(t), z(t)]_{t=0}^{T}$ of the

Table 1. Selection of MAPs for assessing the LESS performance

Metrics	Definition	Equation
Time (T)	The total time required to perform the task. (seg)	T
Bimanual dexterity (BD)	The correlation between the velocities of both instruments during the task. (-)	$\frac{\sum_{n=1}^{N}\left(v_{left}(n)-\bar{v}_{left}\right)\left(v_{right}(n)-\bar{v}_{rigth}\right)}{\sqrt{\sum_{n=1}^{N}\left(v_{left}(n)-\bar{v}_{left}\right)^2\sum_{n=1}^{N}\left(v_{right}(n)-\bar{v}_{rigth}\right)^2}}$
Path length (PL)	Total path followed by the tip of the instrument while performing the task. (m)	$\int_{t=0}^{T}\sqrt{\left(\frac{dx}{dt}\right)^2+\left(\frac{dy}{dt}\right)^2+\left(\frac{dz}{dt}\right)^2}\,dt$
Depth perception (DP)	Total distance traveled by the instrument along its axis. (m)	$\int_{t=0}^{T}\sqrt{\left(\frac{dy}{dt}\right)^2+\left(\frac{dz}{dt}\right)^2}\,dt$
Motion smoothness (MS)	Abrupt changes in acceleration result in jerky movements of the instrument. (m/s^3)	$\sqrt{\frac{T^5}{2\cdot PL^2}\int_{t=0}^{T}\left(\left(\frac{d^3x}{dt^3}\right)^2+\left(\frac{d^3y}{dt^3}\right)^2+\left(\frac{d^3z}{dt^3}\right)^2\right)^2 dt}$
Average velocity (V)	Rate of change of the position of the instrument. (mm/s)	$\frac{1}{T}\int_{t=0}^{T}\sqrt{\left(\frac{dx}{dt}\right)^2+\left(\frac{dy}{dt}\right)^2+\left(\frac{dz}{dt}\right)^2}\,dt$
Average acceleration (A)	Rate of change of the velocity of the instrument. (mm/s^2)	$\frac{1}{T}\int_{t=0}^{T}\sqrt{\left(\frac{d^2x}{dt^2}\right)^2+\left(\frac{d^2y}{dt^2}\right)^2+\left(\frac{d^2z}{dt^2}\right)^2}\,dt$
Idle time (IT)	Percentage of time where the instrument was considered still. (%)	$\frac{\left\lvert\Im\right\rvert}{T}:\Im=\frac{1}{T}\int_{t=0}^{T}\sqrt{\left(\frac{dx}{dt}\right)^2+\left(\frac{dy}{dt}\right)^2+\left(\frac{dz}{dt}\right)^2}\,dt\le 5$
Economy of area (EOA)	Relation between the maximum surface area covered by the instrument and the total path. (-)	$\frac{\sqrt{\left[Max(x)-Min(x)\right].\left[Max(y)-Min(y)\right]}}{PL}$
		$\frac{\sum_{t=0}^{T}\left\lvert x_i\right\rvert^2+\sum_{t=0}^{T}\left\lvert y_i\right\rvert^2+\sum_{t=0}^{T}\left\lvert z_i\right\rvert^2}{\left[Max(x)-Min(x)\right]\cdot\left[Max(y)-Min(y)\right]\cdot\left[Max(z)-Min(z)\right]}$
Economy of volume (EOV)	Relation between the maximum volume covered by the instrument and the total path. (-)	$\frac{\sqrt[3]{\left[Max(x)-Min(x)\right]\cdot\left[Max(y)-Min(y)\right]\cdot\left[Max(z)-Min(z)\right]}}{PL}$
Energy of area (EA)	Energy inverted by the instrument over the surface area covered. (J/cm^2)	$\frac{\sum_{t=0}^{T}\left\lvert x_i\right\rvert^2+\sum_{t=0}^{T}\left\lvert y_i\right\rvert^2}{\left[Max(x)-Min(x)\right]\cdot\left[Max(y)-Min(y)\right]}$
Energy of volume (EV)	Energy is inverted by the instrument over the volume covered. (J/cm^3)	$\frac{\sum_{t=0}^{T}\left\lvert x_i\right\rvert^2+\sum_{t=0}^{T}\left\lvert y_i\right\rvert^2+\sum_{t=0}^{T}\left\lvert z_i\right\rvert^2}{\left[Max(x)-Min(x)\right]\cdot\left[Max(y)-Min(y)\right]\cdot\left[Max(z)-Min(z)\right]}$

surgical instruments recorded by the video-based tracking system installed in the simulator and computed in MATLAB Release 2020b (MathWorks, Natick, MA).

Statistical analysis

The MAPs' results were statistically analyzed using SPSS version 20.0 software for Windows (SPSS Inc., Chicago, IL, USA). Non-parametric tests were performed to analyze the data derived from the MAPs. To verify that the three groups confirmed the same level of psychomotor MIS skills at the beginning of the study, the Kruskal–Wallis and Mann–Whitney tests were used to find statistically significant differences in the initial performance between the three groups and for each pair of groups, respectively. Likewise, the Mann–Whitney test was performed to identify statistically significant differences between the initial and final performance of each of the three groups. In addition, the Kruskal–Wallis test was used to compare the performance between the three groups, and, where statistically significant differences were found, the Mann–Whitney test was used for pairwise comparisons of groups. In all cases, a value of $p < 0.05$ was considered statistically significant.

Results

A total of 27 participants completed the training during the study. Three participants, two in Group-A and one in Group-C, were unable to complete their assigned training due to conflicts with their schedules. The performance results of the 27 participants before and after specific training are presented in table 2. All MAPs, apart from time and bimanual dexterity, are presented separately for both the right and left hand.

Statistical analysis of the initial performance of the three groups did not show statistically significant differences in MAPs, confirming that they had a similar level of psychomotor MIS skills for the three laparoscopic tasks before starting their specific training in this study.

In general, all groups obtained statistically significant differences in their pre- and post-training in most of the MAPs analyzed for the three laparoscopic tasks. Group-B was the one that showed statistically significant improvement in performance for a higher number of MAPs after their assigned training, except for the PT task, in which it presented the same number of MAPs as Group-C. Furthermore, Group-B showed improvements in all their MAPs, except for bimanual dexterity, for the PT and L tasks. In addition, this group was the only one to achieve an improvement in idle time and energy invested in the working area and volume for both hands in all tasks. In the cutting task, none of the three groups showed significant changes in velocity and acceleration during the use of the articulated laparoscopic instruments. On the other hand, Group-A significantly improved bimanual dexterity in all three laparoscopic tasks. However, this group tended to hold both laparoscopic instruments longer in an idle state.

Concerning the PT task, after training, Group-C reduced the distance traveled by the instrument on the dominant hand and improved depth perception, the economy of the area, and energy invested in the volume of work by the non-dominant hand instrument with respect to Group-B. Group-C significantly reduced the energy invested in the working area by the instrument of the non-dominant hand with respect to the rest of the study groups. Regarding the L task, Group-C improved the motion smoothness in the use of the instrument handled by the dominant hand and increased the speed of movements and their acceleration with respect to Group-A. Similarly, for the instrument on the non-dominant hand, depth perception was improved. In the case of the cutting task, Group-C improved its bimanual dexterity. However, no significant differences were shown between study groups for the parameters evaluated for both the right and left hands.

Discussion

LESS surgery is considered an evolution from CLS due to the cosmetic advantages it presents[21]. However, this surgical approach involves important new technical challenges for the surgeon, different from those in CLS. The purpose of this study was to compare the acquisition of surgical skills for LESS surgery through three training modalities using straight and articulating instruments. We also evaluated trainees' performance and skill transfer in this single-access surgical technique using MAPs on a laparoscopic box trainer simulator with a video-based motion tracking system.

In the study, all three training groups showed improvement in their surgical performance using the LESS setting (Table 2). In particular, Group-C obtained the best results in their LESS performance after the 12-day training, reflecting an overall improvement in MAPs, with respect to the other groups for all three

Table 2. Results of the assessment Pre- versus Post-training in LESS configuration for the three laparoscopic tasks. For each MAPs, p-values are given

MAPs	Peg transfer			Labyrinth			Circular cutting		
	A	B	C	A	B	C	A	B	C
Time (s)	**0.002**	**0.000**	**0.000**	**0.001**	**0.000**	**0.000**	**0.001**	**0.000**	**0.000**
Bimanual Dexterity (-)	**0.002**	0.218	0.051	**0.015**	0.853	0.258	**0.021**	0.579	**0.006**
Right hand									
Path Length (cm)	**0.007**	**0.000**	**0.008**†	**0.007**	**0.005**	**0.003**	**0.003**	**0.000**	**0.001**
Depth Perception (cm)	**0.007**	**0.000**	**0.006**	**0.015**	**0.007**	**0.001**	**0.002**	**0.000**	**0.002**
Motion Smoothness (cm/s^3)	**0.002**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**‡	**0.003**	**0.000**	**0.000**
Velocity (mm/s)	**0.005**	**0.000**	**0.000**	0.083	**0.000**	**0.011**‡	0.798	0.218	0.050
Acceleration (mm/s^2)	**0.007**	**0.000**	**0.000**	0.130	**0.000**	**0.040**‡	0.328	0.247	0.063
Idle time (%)	**0.021**	**0.000**	**0.002**	0.234	**0.001**	0.051	0.328	**0.035**	0.113
EOA (-)	**0.005**	**0.000**	**0.003**	**0.010**	**0.002**	**0.006**	**0.003**	**0.000**	**0.002**
EOV (-)	**0.005**	**0.000**	**0.004**†	**0.005**	**0.002**	**0.002**	**0.003**	**0.000**	**0.002**
Energy in the Area (J/cm^2)	**0.002**	**0.001**	**0.000**	**0.021**	**0.019**	**0.031**	0.130	**0.011**	0.113
Energy in the Volume (J/cm^3)	**0.002**	**0.019**	**0.001**	0.105	**0.000**	0.222	0.195	**0.035**	**0.063**
Left hand									
Path Length (cm)	**0.003**	**0.000**	**0.004**	**0.001**	**0.001**	**0.008**	**0.003**	**0.000**	**0.000**
Depth Perception (cm)	**0.003**	**0.001**	**0.004**†	**0.003**	**0.001**	**0.014**‡	**0.007**	**0.001**	**0.000**
Motion Smoothness (cm/s^3)	**0.002**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.001**	**0.000**	**0.001**
Velocity (mm/s)	**0.049**	**0.000**	**0.000**‡	**0.007**	**0.001**	**0.008**	0.442	0.912	0.436
Acceleration (mm/s^2)	**0.028**	**0.000**	**0.000**	0.065	**0.001**	**0.024**	0.382	0.971	0.340
Idle time (%)	0.105	**0.003**	**0.000**	0.130	**0.007**	**0.004**	0.234	0.579	0.258
EOA (-)	**0.002**	**0.001**	**0.001**†	**0.002**	**0.000**	**0.011**	**0.007**	**0.000**	**0.000**
EOV (-)	**0.002**	**0.000**	**0.000**†	**0.001**	**0.001**	**0.014**	**0.001**	**0.000**	**0.000**
Energy in the Area (J/cm^2)	**0.038**	**0.000**	**0.002**‡†	**0.005**	**0.003**	0.063	0.574	**0.001**	0.931
Energy in the Volume (J/cm^3)	0.105	**0.000**	**0.004**†	**0.007**	**0.004**	0.063	0.798	**0.029**	0.730

Mann–Whitney *U*-test, significant differences at the $p < 0.05$ level are indicated in bold. Significant differences in final performance between groups B and C are marked as †, and between groups A and C are marked as ‡.

training tasks. These results confirm our initial hypothesis that this training focused solely on the single-port surgery approach with articulating instruments improves the acquisition and quality of LESS skills, achieving a decrease in the scores of all the MAPs analyzed. We believe that this is because the participants of this group quickly learned to master the LESS technique, as well as the coordination of movement and spatial orientation of the articulated instruments, (which makes this surgical technique more complex), and to correct the mistakes they made as the training progressed.

Group-A presented improvement in the ability to control both instruments in a coordinated fashion, being the only group to achieve statistically significant differences in the bimanual dexterity parameter for the three laparoscopic tasks performed. This interesting result could be due to this group had the opportunity to train with all instrument configurations (straight and articulating) and with all types of surgical approaches (standard ports and single-port), which most likely contributed greatly to improving the spatial orientation and movement coordination in the use of the surgical instruments with both hands. This finding suggests that Group-A learns quickly to master the skills and competencies required for the surgical modality in shift, such as conventional laparoscopy or single-port surgery. However, further studies are needed to explain this hypothesis. Group-B showed improvement in their performance, obtaining statistically significant differences in most of the MAPs analyzed for the three laparoscopic tasks. However, this group did not show improvement in the coordinated control of both instruments, as measured by the bimanual dexterity parameter. We believe that these results are due to participants having started their assigned training with straight instruments and a single-port approach, which greatly limited the spatial orientation and freedom of maneuvering in the handling of the instruments at the beginning of their training, which they had to correct later with the change to articulating instruments.

Comparing the final proficiency between the three groups, we found a few significant differences (Table 2). In the transfer task, 6 MAPs presented significant

differences between groups B and C, between groups A and C only two MAPs presented significant differences, and no significant differences were found between groups A and B. For the L task, four MAPs presented significant differences between groups A and C, meanwhile, no differences were found between groups B and C or A and B. Finally, in the cutting task, no significant differences were found in the final performance between any of the three groups. These results indicate us that the three groups' final proficiency significantly increased compared to their initial proficiency, as demonstrated by the improvement of most MAPs between the individual measures pre- and post-training, showing the effectiveness of the training schedules.

Overall, results showed that switching from straight instruments to articulating instruments had little influence on participants' skills training; however, the change of surgical configuration, from conventional laparoscopy to LESS setup, did prove to be a challenge in the process of acquiring LESS skills and competence of the participants. We believe that this finding was due to the ergonomic differences that exist between both surgical configurations, as LESS technique spatial location of instruments within the abdominal cavity is more complex, which does not allow for completely transfer the skills acquired in the traditional surgical technique and vice versa. However, more studies will be done to confirm this hypothesis.

Regarding the configuration of instruments for the acquisition of surgical skills, a previous study evaluated the relative technical difficulty and performance of articulating and curved instruments, combined or not with conventional laparoscopic tools, during the performance of two basic simulator tasks for LESS surgery[22,23]. This study showed a significant improvement in the quality of surgical performance and execution time in basic simulator coordination tasks after LESS training using a combination of articulating and conventional straight instruments compared to both articulating instruments. The EAES consensus statement on single-incision endoscopic surgery also recommended the use of a combination of one straight and one articulating/curved instrument during the learning curve of LESS surgery. Therefore, as a further study, it would be worthwhile to comprehensively analyze the effect of LESS surgery training on the use of articulating instruments in comparison with the combination of articulating and flexible instruments, including more advanced tasks such as intracorporeal suturing. As we have observed with Group-A of the present study, the inclusion in the LESS surgery training program of conventional laparoscopic training does not seem to present a significant improvement in surgical skills, except in bimanual dexterity. Other studies have also shown that previous experience in laparoscopic surgery does not lead to a significant improvement in the quality of surgical performance after training in LESS surgery[24].

Our study had some limitations, such as the use of only one type of access port for LESS surgery. For this investigation, we chose the Medtronic SILS™ single port due to its ease of adaptation to the laparoscopic box trainer and the video-based motion tracking system employed in this study. Although we believe that this decision did not generate a significant impact on surgical performance or alter the learning curve of the participants, in future work we will study the use of other commercial devices (e.g., XCone and GelPoint) and their combination with different types of instruments for LESS surgery (straight and articulating). Another limitation of our study is found in the post-training evaluation of the three groups, where LESS surgery configuration and articulating instruments were used to evaluate the skills and technical competence of the participants at the end of the study. We believe that this method could put Group-C at an advantage because they had the opportunity to practice in this surgical configuration for longer, obtaining better results in the post-training evaluation. In future work, we will evaluate the acquisition of laparoscopic MIS skills by combining in the final evaluation the two surgical configurations (conventional laparoscopy and LESS surgery) with both types of instruments (straight and articulating) and different training tasks in all study groups to assess the level and quality achieved of these skills learned through their type of assigned training. We will also study the introduction of a specialized training program for LESS surgery in the training curriculum of surgical residents and its impact on conventional laparoscopic surgical skills. Another important aspect to investigate will be possible improvements in the design of instruments for LESS surgery that improve surgical performance and surgeon ergonomics, as well as the creation of specific tasks that help in the acquisition of surgical skills and abilities in LESS surgery.

Further research is still required in aspects concerning the quality and structure of training. In this sense, this study did not include outcome measures of the task but rather relied on motion analysis of laparoscopic instruments, which has been linked to surgical skills[25,26]. Furthermore, future studies should consider aspects related to skill retention to design and structure

training programs; in this sense, several studies have shown that spacing of the training can increase its effectiveness on skills' acquisition and retention[27]. In our study, the intensity of training was equal for all three groups and massed in 12 days. Future studies will be planned considering different temporal spans for training and measuring skill retention at different moments after completing the program.

Conclusions

The study demonstrated that dedicated training in LESS surgery settings with articulating laparoscopic instruments improves the quality of skills and the performance of the surgeons, reflected in an overall improvement in MAPs. Training with different surgical configurations, conventional laparoscopy, and single-port surgery, improves the ability to control both instruments in a coordinated manner, particularly the surgeons' bimanual dexterity. Prolonged use of articulating laparoscopic instruments in this LESS surgery setting demonstrated a more efficient learning curve, with rapid adaptation to the reduced working space, resulting in a similar and smooth performance for all three training tasks. Overall, the results of this study suggest that structured laparoscopic skills training in LESS surgery should be included in existing surgical residency curricula to enhance the education of residents in conventional and LESS surgery. This training program would improve their skills in instrument handling and triangulation, hand-eye coordination, and a two-dimensional view of the operative field.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical disclosures

Protection of humans and animals. The authors declare that no experiments on humans or animals were performed for this research.

Confidentiality of data. The authors declare that they have followed their center's protocols for the publication of patient data.

Right to privacy and informed consent. The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the corresponding author.

References

1. Kwasnicki RM, Aggarwal R, Lewis TM, Purkayastha S, Darzi A, Paraskeva PA. A comparison of skill acquisition and transfer in single incision and multi-port laparoscopic surgery. J Surg Educ. 2013;70:172-9.
2. Sandberg EM, La Chapelle CF, van den Tweel MM, Schoones JW, Jansen FW. Laparoendoscopic single-site surgery versus conventional laparoscopy for hysterectomy: a systematic review and meta-analysis. Arch Gynecol Obstet. 2017;295:1089-103.
3. Lukovich P, Sionov VB, Kakucs T. Training with curved laparoscopic instruments in single-port setting improves performance using straight instruments: a prospective randomized simulation study. J Surg Educ. 2016;73:348-54.
4. Brown-Clerk B, de Laveaga AE, LaGrange CA, Wirth LM, Lowndes BR, Hallbeck MS. Laparoendoscopic single-site (LESS) surgery versus conventional laparoscopic surgery: comparison of surgical port performance in a surgical simulator with novices. Surg Endosc. 2011;25:2210-8.
5. Mahendran B, Celentano V, Soltes M, Popa D, Adamina M, Sanz CM, et al. EAES online educational resources: a survey of the membership of the European association for endoscopic surgery (EAES). Surg Endosc. 2021;35:2059-66.
6. Pearl JP, Ponsky JL. Natural orifice translumenal endoscopic surgery: a critical review. J Gastrointest Surg. 2008;12:1293-300.
7. Hoyuela C, Juvany M, Carvajal F. Single-incision laparoscopy versus standard laparoscopy for colorectal surgery: a systematic review and meta-analysis. Am J Surg. 2017;214:127-40.
8. Chow A, Purkayastha S, Aziz O, Pefanis D, Paraskeva P. Single-incision laparoscopic surgery for cholecystectomy: a retrospective comparison with 4-port laparoscopic cholecystectomy. Arch Surg. 2010;145:1187-91.
9. Marchini GS, Fioravanti ID Jr., Horta LV, Torricelli FC, Mitre AI, Arap MA. Specific training for LESS surgery results from a prospective study in the animal model. Int Braz J Urol. 2016;42:90-5.
10. Sánchez-Margallo FM, Pérez FJ, Azevedo AM, Sánchez-Margallo JA, Sánchez MA, Díaz-Güemes I. An analysis of skills acquisition during a training program for experienced laparoscopists in laparoendoscopic single-site surgery. Surg Innov. 2014;21:320-6.
11. Morales-Conde S, Peeters A, Meyer YM, Antoniou SA, Del Agua IA, Arezzo A, et al. European association for endoscopic surgery (EAES) consensus statement on single-incision endoscopic surgery. Surg Endosc. 2019;33:996-1019.
12. Santos BF, Enter D, Soper NJ, Hungness ES. Single-incision laparoscopic surgery (SILS™) versus standard laparoscopic surgery: a comparison of performance using a surgical simulator. Surg Endosc. 2011;25:483-90.
13. Wang D, Shi LQ, Wang JM, Jiang XH, Ji ZL. Comparison of different sets of instruments for laparoendoscopic single-site surgery in a surgical simulator with novices. ANZ J Surg. 2016;86:264-9.

14. Pérez-Escamirosa F, Chousleb-Kalach A, Hernández-Baro MD, Sánchez-Margallo JA, Lorias-Espinoza D, Minor-Martínez A. Construct validity of a video-tracking system based on orthogonal cameras approach for objective assessment of laparoscopic skills. Int J Comput Assist Radiol Surg. 2016;11:2283-93.
15. Pérez-Escamirosa F, Oropesa I, Sánchez-González P, Tapia-Jurado J, Ruiz-Lizarraga J, Minor-Martínez A. Orthogonal cameras system for tracking of laparoscopic instruments in training environments. Cir Cir. 2018;86:548-55.
16. Wenger L, Richardson C, Tsuda S. Retention of fundamentals of laparoscopic surgery (FLS) proficiency with a biannual mandatory training session. Surg Endosc. 2015;29:810-4.
17. Vassiliou MC, Ghitulescu GA, Feldman LS, Stanbridge D, Leffondré K, Sigman HH, et al. The MISTELS program to measure technical skill in laparoscopic surgery: evidence for reliability. Surg Endosc. 2006;20:744-7.
18. Oropesa I, Chmarra MK, Sánchez-González P, Lamata P, Rodrigues SP, Enciso S, et al. Relevance of motion-related assessment metrics in laparoscopic surgery. Surg Innov 2013;20:299-312.
19. Sánchez-Margallo JA, Sánchez-Margallo FM, Oropesa I, Enciso S, Gómez EJ. Objective assessment based on motion-related metrics and technical performance in laparoscopic suturing. Int J Comput Assist Radiol Surg. 2016;12:307-14.
20. Escamirosa FP, Flores RM, García IO, Vidal CR, Martínez AM. Face, content, and construct validity of the EndoViS training system for objective assessment of psychomotor skills of laparoscopic surgeons. Surg Endosc. 2015;29:3392-403.
21. Georgiou AN, Rassweiler J, Herrmann TR, Stolzenburg JU, Liatsikos EN, Do EM, et al. Evolution and simplified terminology of natural orifice transluminal endoscopic surgery (NOTES), laparoendoscopic single-site surgery (LESS), and mini-laparoscopy (ML). World J Urol. 2012; 30:573-80.
22. Müller EM, Cavazzola LT, Machado Grossi JV, Mariano MB, Morales C, Brun M. Training for laparoendoscopic single-site surgery (LESS). Int J Surg. 2010;8:64-8.
23. Sánchez-Margallo FM, Matos-Azevedo AM, Pérez-Duarte FJ, Enciso S, Martín-Portugués ID. Performance analysis on physical simulator of four different instrument setups in laparo-endoscopic single-site (LESS) surgery. Surg Endosc. 2014;28:1479-88.
24. Ha US, Lee KW, Kim SW, Jeon SH, Kwon TG, Park HK, et al. The influence of prior laparoscopic experience on learning laparoendoscopic single site surgery: a prospective comparative preliminary study using cystorraphy in a live porcine model. BMC Urol. 2017;17:57.
25. Oropesa I, Sánchez-González P, Lamata P, Chmarra MK, Pagador JB, Sánchez-Margallo JA, et al. Methods and tools for objective assessment of psychomotor skills in laparoscopic surgery. J Surg Res. 2011; 171:e81-95.
26. van Hove PD, Tuijthof GJ, Verdaasdonk EG, Stassen LP, Dankelman J. Objective assessment of technical surgical skills. Br J Surg. 2010; 97:972-87.
27. Spruit EN, Band GP, Hamming JF. Increasing efficiency of surgical training: effects of spacing practice on skill acquisition and retention in laparoscopy training. Surg Endosc. 2015;29:2235-43.

ORIGINAL ARTICLE

Erector spinae plane block as a rescue therapy in following cholecystectomy: a historical cohort study

Bloqueo del plano erector espinal como terapia de rescate tras colecistectomía: un estudio de cohorte histórica

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Abstract

Objective: *The aim of this study is to evaluate the effect of erector spinae plane block (ESPB) as a rescue therapy in the recovery room.* **Materials and methods:** *This single-center historical cohort study included patients who received either ESPB or intravenous meperidine for pain management in the recovery room. Patients' numeric rating scale (NRS) scores and opoid consumptions were evaluated.* **Results:** *One hundred and eight patients were included in the statistical analysis. Sixty-two (57%) patients received ESPB postoperatively (pESPB) and 46 (43%) patients were managed with IV meperidine boluses only (IV). The cumulative meperidine doses administered were 0 (0-40) and 30 (10-80) mg for the pESPB and IV groups, respectively ($p < 0.001$). NRS scores of group pESPB were significantly lower than those of Group IV on T30 and T60.* **Conclusion:** *ESPB reduces the frequency of opioid administration and the amount of opioids administered in the early post-operative period. When post-operative rescue therapy is required, it should be considered before opioids.*

Keywords: *Laparoscopic cholecystectomy. Acute post-operative pain. Regional anesthesia.*

Resumen

Objetivo: *Evaluar el efecto del bloqueo del plano erector espinal (ESPB) como terapia de rescate en la sala de recuperación.* **Método:** *Este estudio de cohortes histórico de un solo centro incluyó a pacientes que recibieron ESPB o meperidina intravenosa para el tratamiento del dolor en la sala de recuperación. Se evaluaron las puntuaciones de la escala de calificación numérica (NRS) de los pacientes y los consumos de opiáceos.* **Resultados:** *En el análisis estadístico se incluyeron 108 pacientes. Recibieron ESPB 62 (57%) pacientes y los otros 46 (43%) fueron manejados solo con bolos de meperidina intravenosa. Las dosis acumuladas de meperidina administradas fueron 0 (0-40) y 30 (10-80) mg para los grupos de ESPB y de meperidina sola, respectivamente ($p < 0.001$). Las puntuaciones de dolor del grupo ESPB fueron significativamente más bajas que las del grupo de meperidina sola en T30 y T60.* **Conclusiones:** *El ESPB reduce la frecuencia de administración de opiáceos y la cantidad de estos administrada en el posoperatorio temprano. Cuando se requiera terapia de rescate posoperatoria, se debe considerar antes que los opiáceos.*

***Palabras clave*:** *Colecistectomía laparoscópica. Dolor posoperatorio agudo. Anestesia regional.*

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Introduction

Laparoscopic cholecystectomy, one of the most commonly performed abdominal surgeries, is a gold standard therapy for the surgical treatment of benign biliary diseases. It has many advantages over open surgery including less surgical trauma and bleeding, better cosmetic results, early discharge from hospital, and reduced post-operative pain. Nonetheless, some patients may be suffered from moderate or even severe post-operative pain, and it may cause negative consequences such as prolonged hospital stay, so this requires well-planned analgesia management. The pain in this patient group consists of the following components: somatic pain on surgical port entries, visceral pain on the gallbladder resection area, and shoulder tip pain caused by peritoneal carbon dioxide exposure and peritoneal distension[1]. Multimodal analgesia is a mainstay strategy as it provides a synergistic analgesic effect using different analgesics together. Therefore, this strategy reduces the total doses of opioid and non-opioid analgesic agents used and protects patients from their side effects[2,3]. There is even a suggestion that opioids should not be routinely included in analgesia protocols after laparoscopic cholecystectomy and should be used only for rescue therapy[4]. As clinical experience in the use of truncal blocks increases, the frequency of their use in post-operative analgesia management also increases as a new part of multimodal analgesia with the potential to reduce post-operative pain and opioid consumption.

Erector spinae plane block (ESPB) was first presented in 2016 as the treatment of neuropathic pain in a case series, and gained popularity very quickly due to its safety applicability, and effect on both the visceral and parietal component of pain by providing paravertebral, transforaminal, and epidural spread[5,6]. Pre-operative application of ESPB has taken its place as a part of multimodal analgesia in laparoscopic cholecystectomy cases over time and has been shown to reduce post-operative pain scores and opioid consumption and to improve quality of recovery scores[7-10]. However, there is no data regarding the use of ESPB in the post-operative period as a rescue therapy.

The aim of this study is to evaluate the effect of ESP block as a rescue therapy retrospectively in terms of opioid consumption and numeric rating scale (NRS) scores in patients underwent laparoscopic cholecystectomy and needed additional analgesics in the recovery room.

Methodology

Study design and patient selection

This study was designed as a single-center historical cohort study of consecutive patients who needed intervention for pain management in the post-operative anesthesia care unit (PACU) following elective laparoscopic cholecystectomy between February 2022 and May 2022. Ethical approval was obtained from the Clinical Research Ethics Committee of Istanbul Basaksehir Cam and Sakura City Hospital, Turkey (2021.11.254) on November 24, 2021. The study was registered in clinical trials with the number NCT05706233. Written informed consent was waived due to the retrospective design of the study. Patients with the following conditions were excluded: ASA score > 2, age > 65, surgery following biliary pancreatitis, use of any regional technique preoperatively or intraoperatively, violation of the standard analgesia protocol for any reason, duration of surgery > 90 min or < 45 min.

Anesthesia management

A standardized perioperative care management protocol is applied for all laparoscopic cholecystectomy procedures in our department. Briefly, all patients are informed about ESPB and offered its application pre-operatively. Patients who refuse pre-operative ESPB are also informed regarding the post-operative analgesic alternatives which are ESPB or meperidine, if needed. Following the premedication with 2 mg midazolam intravenously, patients are transferred to the operating room. Anesthesia is induced with 2 mcg/kg fentanyl, 2 mg/kg propofol, and 0.6 mg/kg rocuronium following the standard monetization. Anesthesia is maintained with sevoflurane (1-2%, 1 minimum alveolar concentration), remifentanil (0.05-0.2 mcg/kg/min) infusion and oxygen/air mixture (50%/50%), and remifentanil (0.05-0.3 mcg/kg/min) infusion to keep the heart rate and blood pressure within 20% of baseline. Isotonic saline solution (4 mL/kg/h) with 50 mg/kg magnesium sulfate is infused during the perioperative period. Patients receive 20 mg tenoxicam, 0.1 mg/kg dexamethasone, 1 g paracetamol, and 1.5 mg/kg tramadol intraoperatively for analgesia. After the surgery, 2 mg/kg sugammadex is used for the reversal of neuromuscular blockade and tracheal extubation occurs when adequate muscle strength is established. All patients are followed up for 60 min in the PACU.

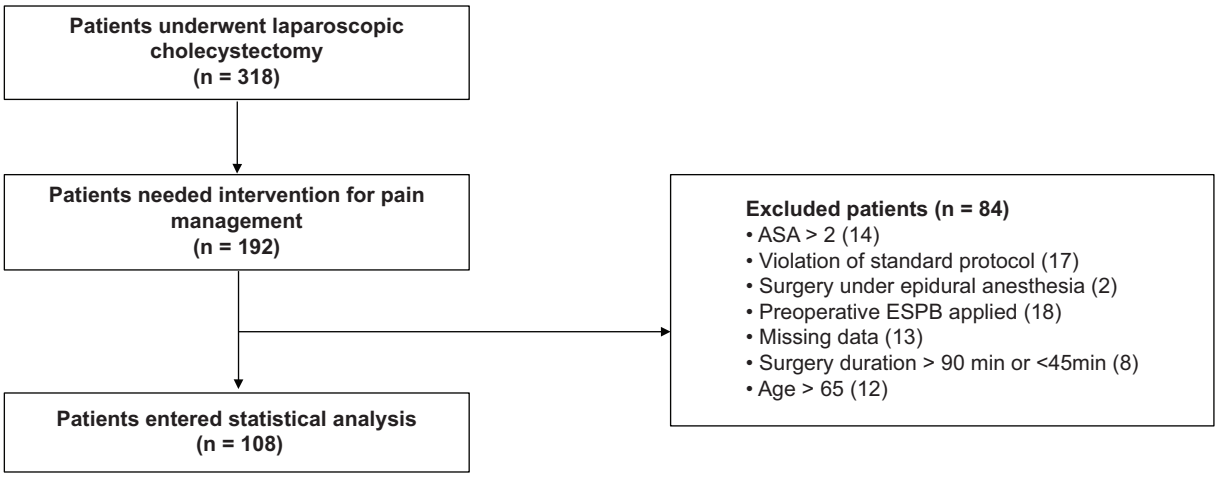

Figure 1. *Flow chart. Eighty-four patients were excluded in line with the exclusion criteria and 108 patients were included in the statistical analysis.*

Post-operative pain management

As part of the standardized perioperative care in our clinic, the pain management is routinely carried out as follows: Patients with a NRS score of > 3 receives either an IV meperidine bolus dose or ESPB in line with their selections. Following the initial intervention, patients are evaluated every 5 min in terms of their NRS scores until sufficient pain relief is secured (defined as NRS score of < 4). If the NRS score is not reduced by at least 20% when compared to the prior one, additional meperidine bolus is applied. All meperidine boluses are dosed in line with the pain intensity as follows: 10 mg if NRS score > 3, 20 mg if NRS score > 5, and 30 mg if NRS score > 8. NRS scores and meperidine boluses applied are recorded on the PACU follow-up form.

Ultrasound (USG)-guided ESPB

All blocks were performed by an anesthesiologist, who is in charge of post-operative pain control in the recovery room and is experienced in the application of truncal blocks. The patients are placed in the left lateral recumbent position following the intravenous administration of 10 mcg of remifentanil. Blocks are applied using a high-frequency (12-15 MHz) linear USG transducer (Hitachi Arietta 65 USG device) and a 22G, 80-mm, peripheral nerve block needle. After skin disinfection is ensured, the level of the lower end of the scapula is determined and accepted as T7 level and the probe is placed longitudinally 2.5-3 cm lateral to the T8 level. Transverse process and erector spinae muscle are visualized. The needle is advanced up to the transverse process at the T8 level with an out-of-plane approach. After negative aspiration and confirming the location with physiological saline, 5 cc 2% lidocaine and 20 cc 0.5% bupivacaine are injected and its spread is visualized under USG. The indicated doses are within the safe dose range for all patients to be used according to their weight. Blocks are applied unilaterally (right). The patients are evaluated every 5 min in terms of their NRS scores until NRS < 4 is achieved. Additional meperidine doses are applied when the target NRS is not achieved.

Data collection

Data regarding patients' sex, age, ASA score, body mass index, duration of surgery, and pre-operative/intraoperative use of regional techniques were obtained from intraoperative follow-up forms. Data regarding post-operative pain management (patients' NRS scores, number of meperidine boluses and cumulative meperidine doses applied, application of ESPB) and whether the patients had nausea and vomiting were obtained from PACU follow-up forms. Five time points were determined for data recording: admission to PACU (T0), and 5^{th}, 15^{th}, 30^{th}, and 60^{th} min in the PACU (T5, T15, T30, and T60, respectively).

Statistical analysis

Our primary outcome was to evaluate the effect of ESPB applied postoperatively on meperidine

Table 1. Characteristic of patients

Variables	ESP (62)	IV (46)	p-value
Age	43 ± 12	44 ± 11	0,37
Sex			0.96
Male	24 (39%)	18 (38%)	
Female	38 (61%)	30 (62%)	
ASA Score			0.66
1	20 (32%)	17 (35%)	
2	42 (68%)	31 (65%)	
BMI (kg/m^2)	26.4 ± 3.9	26.3 ± 4.2	0.85
Duration of Surgery (min)	68 ± 14	65 ± 14	0.64

Values are expressed as mean ± SD, or frequency (percentage). Chi-square and Student's t-tests were used for the comparison of categorical and continuous variables, respectively. BMI: body mass index

Table 2. NRS scores in rest at the post-operative time points

Groups	T0	T5	T15	T30	T60	p intragroup
ESP	8 (7-9)	6 (5-8)	4 (3-5)	3 (2-3)	2 (1-3)	$p_i < 0.001$
IV	8 (6-9)	6 (5-7)	4 (3-6)	3 (2-4)	2 (2-3)	$p_i < 0.001$
p intergroup	p: 0.4	p: 0.5	p: 0.12	p: 0.03	p < 0.007	

Values are expressed as median (25th-75th percentile). Friedman test and Mann–Whitney U-test were used for intergroup and intragroup comparisons, respectively. Statistically significant *post hoc* analyses: p_i; statistical significance was observed between all-time points ($p < 0.05$).

consumption in PACU. We expected at least a 20 mg reduction in the cumulative meperidine dose applied. A sample size of 89 patients was calculated to reveal this reduction assuming α of 5% (two-tailed) and β of 10% using the power analysis program (G-Power, P.S. version 3.1.2).

Data distribution was evaluated by Shapiro–Wilk test. Normally distributed data were presented as mean ± standard deviation and compared with Student's t-test. Non-normally distributed data were presented as median (25th percentile-75th percentile) unless stated otherwise. Categorical data were presented as frequency (percentage) and compared with a Chi-square test. NRS scores and cumulative meperidine consumption were compared between and within the groups using the Mann–Whitney U-test and Friedman/Wilcoxon test, respectively.

Results

A total of 318 patients underwent laparoscopic cholecystectomy between February 2022 and May 2022, and 192 of them had a NRS score > 3 at admission to the PACU. Eighty-four patients were excluded in line with the exclusion criteria and 108 patients were included in the statistical analysis (Fig. 1). The patients were allocated into two groups: 62 (57%) patients received ESPB postoperatively (pESPB group) and 46 (43%) patients were managed with IV meperidine boluses only (IV group). Data regarding the patients' demographic characteristics, ASA scores, and surgery durations are given in Table 1.

There was no statistically significant difference in terms of NRS scores between the groups on T0, T5, and T15 while the NRS scores of the pESPB group were significantly lower than those of the IV group on T30 and T60 (Table 2). Trends of the groups' NRS scores

Table 3. Frequencies of analgesic doses at post-operative time points

Patients received a meperidine dose	T0	T15	T30	Total
ESP	n/a	12 (19%)	4 (6%)	12 (19%)
IV	46	28 (58%)	11 (23%)	46 (100%)
p intergroup	n/a	p < 0.001	p: 0.009	p < 0.001

Values are expressed as frequency (percentage) and compared with the Chi-square test

Table 4. Post-operative analgesic requirements

Use of meperidine	T0	T15	T30	p intragroup
Cumulative dose administered (mg)				
ESP	ESP	0 (0-40)	0 (0-40)	p: 0.06
IV	20 (10-30)	30 (10-60)	30 (10-80)	$p_1 < 0.001$
p intergroup	n/a	p < 0.001	p < 0.001	

Values are expressed as median (minimum - maximum). Mann–Whitney U-test was used for intergroup comparisons. In accordance with the number of paired groups compared, the Wilcoxon/Friedman test was used for intragroup comparisons. Statistically significant *post hoc* analyses: p_1; statistical significance was observed between all subgroup comparisons ($p < 0.05$)

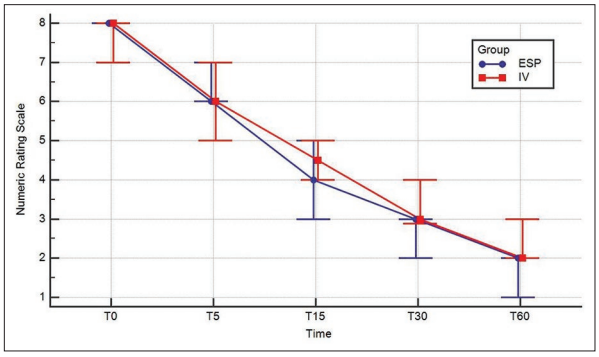

Figure 2. *NRS scores over time. Trends of the groups' NRS scores over time.*

over time were placed in figure 2. In the pESPB group, 12 (19%) patients needed at least one meperidine bolus while 50 (81%) patients recovered without the need for any additional meperidine application (Table 3). Cumulative doses of meperidine used between and within the groups are shown in Table 4. In the pESPB group, 58 (94%) patients had a NRS score < 4 on T30 while 35 (77%) patients in the IV group reached this outcome at the same time point (p = 0.009). There was no patient with a NRS score > 3 on T60.

Three patients (4.8%) in the pESPB group and 9 (19.5%) patients in the IV group had nausea at T60 (p = 0.02). One patient in the pESPB group and one patient in the IV group suffered from vomiting during the follow-up (1.6% and 2.2%, respectively, p = 0.61).

No major complications occurred due to the block application.

Discussion

The current study shows that in patients undergoing laparoscopic cholecystectomy, USG-guided unilateral ESPB reduces both the number of patients requiring opioid administration and the total dose of opioids used when applied as rescue therapy in the PACU. NRS scores are statistically lower in patients who receive ESPB. Furthermore, ESPB is related to lower time duration for achieving a NRS score < 4. These results are in line with recent studies showing that ESPB application reduces opioid consumption in the post-operative period[7–11]. Several meta-analyses have shown that ESP block reduces the 24-h consumption of opioids in different surgical settings[12,13]. In a study conducted in laparoscopic cholecystectomy patients, Cesur et al.[14] reported a 26% reduction in 24-h morphine consumption due to the unilateral application of ESP block. However, in these studies, ESP block was performed preoperatively or after the completion of surgery but before the termination of general anesthesia. To the best of our knowledge, this is the first study in which ESP block was applied as a post-operative rescue therapy.

There is no gold standard for the application level of the ESP block, as well as for the concentration, volume, and type of local anesthetics used in patients undergoing laparoscopic cholecystectomy. ESPB has been applied successfully from the levels between T7-T9 in different studies for this patient group[7-9,11]. We applied ESP at the T8 level and visualized local anesthetic spread in the craniocaudal direction in each patient under USG guidance. There are studies indicating that the ESP block only shows ipsilateral efficacy because it does not spread to the paravertebral/epidural spaces.[15,16] Therefore, it has been performed bilaterally in many studies for laparoscopic cholecystectomy.[7,8,12,17] However, we performed the ESPB unilaterally to avoid double injection in awake patients, as it has been shown that ESPB can result in bilateral sensory blockage with local anesthetic spread when applied unilaterally[6,14,18]. We preferred 0.5% as the bupivacaine concentration since there are studies in the literature showing that the duration of sensory block is longer when the local anesthetic concentration is higher[19,20]. One of the reasons for the unilateral application of the block was the need to divide the maximum dose of local anesthetic administered when the block was applied bilaterally, which would lead to a decrease in concentration. In this study, ESPB was used as a rescue therapy in the post-operative period. Therefore, we needed to initiate the analgesic effect as quick as possible. In line with this aim, we chose to use lidocaine along with bupivacaine due to its shorter onset of action[21].

Opioids might be insufficient in somatic pain control and are associated with many post-operative complications, including nausea and vomiting[2,22]. Therefore, it is clear that we need strategies that will relieve patients of their opioid overload. Compared with the IV group, the number of patients who suffered from post-operative nausea was lower in the pESPB group (p: 0.02 at T60). This difference can be explained by the lower total opioid consumption in the pESPB group. There was no significant difference in terms of post-operative vomiting. These data are consistent with studies showing that ESP block reduces the incidence of PONV when applied in spinal surgery and breast surgery[23,24].

This study has some limitations. First, the study was conducted retrospectively with a relatively small sample size. In the future, multi-center, prospective randomized controlled studies with larger sample sizes are needed to evaluate any possible advantages and disadvantages of post-operative ESPB for patients undergoing laparoscopic cholecystectomy. Second, the pain follow-up of the patients was performed only in the recovery room, and long-term results were not evaluated due to the absence of NRS score documentation in the clinics. Third, ESPB was applied unilaterally from the T8 level using both lidocaine and bupivacaine. Different interventional approaches might result in different outcomes.

Conclusion

When ESPB is applied as a post-operative rescue analgesic technique, the frequency of opioid administration and the amount of opioids administered are both reduced in the early post-operative period. Therefore, in case ESPB is not performed preoperatively, it is rational to apply the block postoperatively. This approach should be considered before opioid administration in terms of avoiding systemic side effects and ensuring a faster and stronger analgesic efficacy.

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Conflicts of interest

The authors declare that there are no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

References

1. Chin KJ, McDonnell JG, Carvalho B, Sharkey A, Pawa A, Gadsden J. Essentials of our current understanding: abdominal wall blocks. Reg Anesth Pain Med. 2017;42(2):133-83.
2. Sinha S, Munikrishnan V, Montgomery J, Mitchell SJ. The impact of patient-controlled analgesia on laparoscopic cholecystectomy. Ann R Coll Surg Engl. 2007;89(4):374-8.
3. Jesus RR, Leite AM, Leite SS, Vieira MC, Villela NR. Anesthetic therapy for acute pain relief after laparoscopic cholecystectomy: systematic review. Rev Col Bras Cir. 2018;45(4):e1885.
4. Barazanchi AWH, MacFater WS, Rahiri JL, Tutone S, Hill AG, Joshi GP; PROSPECT collaboration. Evidence-based management of pain after laparoscopic cholecystectomy: a PROSPECT review update. Br J Anaesth. 2018;121(4):787-803.
5. De Cassai A, Bonvicini D, Correale C, Sandei L, Tulgar S, Tonetti T. Erector spinae plane block: a systematic qualitative review. Minerva Anestesiol. 2019;85(3):308-19.
6. Schwartzmann A, Peng P, Maciel MA, Forero M. Mechanism of the erector spinae plane block: insights from a magnetic resonance imaging study. Can J Anaesth. 2018;65(10):1165-1166.
7. Hannig KE, Jessen C, Soni UK, Børglum J, Bendtsen TF. Erector spinae plane block for elective laparoscopic cholecystectomy in the ambulatory durgical setting. Case Rep Anesthesiol. 2018;2018:5492527.
8. Tulgar S, Kapakli MS, Senturk O, Selvi O, Serifsoy TE, Ozer Z. Evaluation of ultrasound-guided erector spinae plane block for postoperative analgesia in laparoscopic cholecystectomy: a prospective, randomized, controlled clinical trial. J Clin Anesth. 2018;49:101-6.
9. Vrsajkov V, Ilić N, Uvelin A, Ilić R, Lukić-Šarkanović M, Plećaš-Đurić A. Erector spinae plane block reduces pain after laparoscopic cholecystectomy. Anaesthesist. 2021;70(Suppl 1):48-52.
10. Canıtez A, Kozanhan B, Aksoy N, Yildiz M, Tutar MS. Effect of erector spinae plane block on the postoperative quality of recovery after laparoscopic cholecystectomy: a prospective double-blind study. Br J Anaesth. 2021;127(4):629-635.
11. Altiparmak B, Toker MK, Uysal Aİ, Kuşçu Y, Demirbilek SG. Eficácia do bloqueio do plano do músculo eretor da espinha guiado por ultrassom para analgesia após colecistectomia laparoscópica: um estudo controlado randômico. Braz J Anesthesiol. 2019;69(6):561-8.
12. Koo CH, Hwang JY, Shin HJ, Ryu JH. The effects of erector spinae plane block in terms of postoperative analgesia in patients undergoing laparoscopic cholecystectomy: a meta-analysis of randomized controlled trials. J Clin Med. 2020;9(9):2928.
13. Huang J, Liu JC. Ultrasound-guided erector spinae plane block for postoperative analgesia: a meta-analysis of randomized controlled trials. BMC Anesthesiol. 2020;20(1):83.
14. Cesur S, Y R Ko Lu HU, Aksu C, Ku A. Bilateral versus unilateral erector spinae plane block for postoperative analgesia in laparoscopic cholecystectomy: a randomized controlled study. Braz J Anesthesiol. 2023;73(1):72-7.
15. Ivanusic J, Konishi Y, Barrington MJ. A cadaveric study investigating the mechanism of action of erector spinae blockade. Reg Anesth Pain Med. 2018;43(6):567-71.
16. Chin KJ, Adhikary S, Sarwani N, Forero M. The analgesic efficacy of pre-operative bilateral erector spinae plane (ESP) blocks in patients having ventral hernia repair. Anaesthesia. 2017;72(4):452-460.
17. Yildiz M, Kozanhan B, Iyisoy MS, Canıtez A, Aksoy N, Eryigit A. The effect of erector spinae plane block on postoperative analgesia and respiratory function in patients undergoing laparoscopic cholecystectomy: A double-blind randomized controlled trial. J Clin Anesth. 2021;74:110403.
18. Tulgar S, Selvi O, Ahiskalioglu A, Ozer Z. Can unilateral erector spinae plane block result in bilateral sensory blockade? Can J Anaesth. 2019;66(8):1001-2.
19. Huang L, Zheng L, Wu B, Chen Z, Chen J, Xu X, Shi K. Effects of ropivacaine concentration on analgesia after ultrasound-guided serratus anterior plane block: a randomized double-blind trial. J Pain Res. 2020;13:57-64.
20. Mulroy MF, Larkin KL, Batra MS, Hodgson PS, Owens BD. Femoral nerve block with 0.25% or 0.5% bupivacaine improves postoperative analgesia following outpatient arthroscopic anterior cruciate ligament repair. Reg Anesth Pain Med. 2001;26(1):24-9.
21. Day TK, Skarda RT. The pharmacology of local anesthetics. Vet Clin North Am Equine Pract. 1991;7(3):489-500.
22. Macintyre PE. Safety and efficacy of patient-controlled analgesia. Br J Anaesth. 2001;87(1):36-46.
23. Gürkan Y, Aksu C, Kuş A, Yörükoğlu UH. Erector spinae plane block and thoracic paravertebral block for breast surgery compared to IV-morphine: A randomized controlled trial. J Clin Anesth. 2020;59:84-8.
24. Liang X, Zhou W, Fan Y. Erector spinae plane block for spinal surgery: a systematic review and meta-analysis. Korean J Pain. 2021;34(4):487-500.

ORIGINAL ARTICLE

Effect of stainless-steel wire internal fixation on intracapsular condylar fracture

Efecto de la fijación interna de alambre de acero inoxidable en la fractura condilar intracapsular

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Abstract

Objectives: *The aim of the study was to investigate the clinical effect of stainless-steel wire fixation on the early mouth-opening movement of an intracapsular fracture involving the condylar process.* **Materials and methods:** *In this study, patients who underwent mandibular condylar intracapsular fracture surgery in our hospital from 2012 to 2020 were selected as research subjects. A total of 44 patients received steel wire internal fixation treatment, 32 patients received titanium plate-and-nail rigid internal fixation, and 28 patients underwent conservative non-surgical treatment.* **Results:** *For the patients in the stainless-steel wire group, the degree of mouth opening reached normal levels of 3.7 cm approximately 10 days after surgery. The recovery time for the patients in the titanium plate-and-nail rigid internal-fixation group was 21 days, while the patients in the conservative treatment group needed 60 days to recover.* **Conclusion:** *The treatment of fixation with a stainless-steel wire for intracapsular condylar fracture reduced the time taken to perform mouth-opening exercises and improved the recovery rate of patients.*

Keywords: *Fixation method. Intracapsular condyle fracture. Fixation with stainless-steel wire. Fixation with titanium plate and titanium nail. Conservative treatment.*

Resumen

Objetivo: *Explorar el efecto clínico de la fijación de alambre de acero inoxidable en el movimiento temprano de apertura de la boca en la fractura interna del cóndilo.* **Método:** *Este estudio seleccionó a pacientes que se sometieron a cirugía de fractura intracapsular de cóndilo en nuestro hospital de 2012 a 2020 como sujetos de investigación. Un total de 44 pacientes recibieron tratamiento de fijación interna de alambre de acero, 32 recibieron placa de titanio y fijación interna con clavos, y 28 recibieron tratamiento conservador no quirúrgico.* **Resultados:** *En los pacientes del grupo de alambre de acero inoxidable, alrededor de 10 días después de la cirugía el grado de apertura de la boca alcanzó un valor normal de 3.7 cm. El tiempo de recuperación de los pacientes en el grupo de fijación interna con clavos y placa de titanio fue de 21 días, mientras que los pacientes en el grupo de tratamiento conservador tardaron 60 días en recuperarse.* **Conclusiones:** *La fijación con alambre de acero inoxidable para el tratamiento de la fractura intracapsular del cóndilo acorta el tiempo hasta la apertura de la boca y mejora la tasa de recuperación de los pacientes.*

Palabras clave: *Método de fijación. Fractura interna de la cápsula del cóndilo. Fijación con alambre de acero inoxidable. Fijación con placa de titanio y clavos. Tratamiento conservador.*

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Introduction

Condylar fracture is a common mandible break with a high incidence, accounting for approximately 30% of mandibular fractures[1-4]. Patients with a condylar fracture experience pain in the temporomandibular joint, localized tenderness in the jaw area, limited mouth movement, prominent local swelling, and occlusion of the teeth. Other symptoms of a condylar fracture include pathological changes of the temporomandibular joint, osteonecrosis, a skewed lower facial area, and true ankylosis of the temporomandibular joint[5]. The clinical treatment of a condylar fracture requires anatomical structural healing and functional reconstruction. On the one hand, after surgical treatment or non-surgical conservative treatment, the condylar fracture site heals anatomically at the temporomandibular joint. Conversely, the dislocation of the two fractured ends of the condylar break relocates due to the action of the lateral pterygoid muscle, necessitating local structural function reconstruction[6,7]. Hlawitschka and Eckelt[8] divided intracondylar cyst fractures into the following three types: Type A: a condylar cyst fracture with no displacement, where the height of the ascending ramus of the mandible remains unchanged. Type B: The intracondylar fracture breaks through the joint capsule, and the height of the ascending ramus of the mandible decreases. Type M: Comminuted fractures in the condyle are associated with damage to the joint capsule and disc[9-11].

If the correct treatment is not applied following a condylar fracture, the patient will experience dyskinesia related to the opening and closing of the mouth as well as condylar malunion; furthermore, the growth of the mandible will be affected[12]. Due to the complex anatomical structure of the area near the temporomandibular joint, surgery can easily cause a series of complications, such as intraoperative bleeding and postoperative facial paralysis; therefore, most doctors recommend non-surgical conservative treatment[13]. Other oral and maxillofacial surgeons prefer surgical treatment of intracapsular condylar fractures. During surgery, the displaced fracture piece is relocated to its original position by the accurate anatomical reduction of soft and hard tissue, reliable fixation, and minimal injury. At present, the main fixation methods for the clinical surgical treatment of intracapsular condylar fracture are lag screws, steel wires, and miniature titanium plates[14,15], with different fixation methods having their own advantages and disadvantages. As for the choice between reduction and internal fixation, there is no research showing which fixation method has the best effect. In addition, different types of condylar fractures have different clinical symptoms and treatment plans[16]. Therefore, the treatment plan should be determined according to the type of condylar fracture. Different types of condylar fractures can be treated differently. At present, the treatment of intracondylar type-B fractures remains controversial in both research and clinical contexts.

This study aimed to compare the effects of two different fixation methods (stainless-steel wire internal fixation and titanium plate-and-nail rigid internal fixation) and non-surgical conservative treatment on Type-B intracapsular condylar fractures of the mandible and explore the effects of the two different fixation methods in the surgical treatment of intracapsular condylar fractures to provide a reference for the treatment of such injuries.

Materials and methods

Research subjects

Patients with unilateral intracondylar capsular Type-B fractures who were admitted to the oral and maxillofacial surgery ward of our hospital between 2012 and 2020 were analysed retrospectively. Of these, 104 patients met the inclusion criteria of this study, and their complete clinical data were obtained. A total of 44 patients received steel wire internal fixation treatment, 32 patients received rigid internal fixation with a titanium plate/titanium nail, and 28 patients undertook conservative non-surgical treatment. Oral mandibular computed tomography images or curved mandibular tomography images were obtained for all the participants with intracapsular condylar fractures before surgery to identify the location of the fracture and the subsequent displacement resulting from the break. This study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the ethics committee of our hospital. All participants signed an informed consent form for inclusion in the study.

Inclusion and exclusion criteria

The inclusion criteria were as follows: (1) Patients who were diagnosed with an intracapsular condylar fracture, (2) patients who had stable vital signs without other surgical contraindications, (3) patients who were older than 18 years, and (4) patients with complete medical records and available relevant imaging data.

The exclusion criteria were as follows: (1) patients with severe heart, liver, or kidney dysfunction, (2) patients with an advanced malignant tumor, (3) patients with incomplete data, and (4) patients with other surgical or non-surgical treatment failures before admission.

Treatment protocols

Steel wire internal fixation

The procedure for intracapsular condylar fracture with stainless-steel wire fixation was as follows. The skin was incised along the fracture site, the subcutaneous tissue was separated, and the joint capsule was exposed. The exposure range of the surgical field was up to the zygomatic temporal process and down to the sigmoid notch. The fracture fragment was looked for intraoperatively, and the reduction was accompanied by a repair of the joint disc. Holes were drilled with a high-speed power handpiece at two broken end-to-end marks and fixed with a 0.2-cm stainless-steel wire. The teeth were examined to be in good apposition and were sutured in layers, and drainage was maintained for 24-48 h after surgery.

Titanium plate-and-nail internal fixation

The procedure for the titanium plate-and-nail rigid internal fixation for the treatment of intracapsular condylar fractures was as follows. An incision in the skin and subcutaneous tissue was made at the fracture site. The condylar tissue structure was anatomically separated, and on reaching the outside of the condylar joint capsule, the adhesion of the joint disc and the ends of the fracture were peeled. The ends of the intracapsular condylar fracture were fixed using small or miniature titanium plates (0.2 mm) and nails (6, 8, and 10 mm). After surgery, it was important to suture the tear or the joint disc that had been cut during the operation.

Conservative non-surgical treatment

The conservative non-surgical treatment of intracapsular fractures was as follows: rather than using the open reduction method, local anti-inflammatory and detumescence drugs were applied to the fracture. The maxillary and mandibular teeth were tractioned and fixed using circular rubber wire to maintain the occlusion function and stabilize the mandible. The typical traction time was 2-3 weeks. At the end of the elastic intermaxillary traction period, the patient was guided to perform mouth-opening exercises.

Early postoperative mouth-opening exercise

The mouth-opening exercise procedure was as follows: mandibular opening and closing training began on day 4 after surgery for an intracapsular condylar fracture using the stainless-steel wire internal-fixation method. Mouth-opening training was performed using a mouth-opening device from day 4 until day 7 after surgery. Five to seven days after mouth-opening training, the extent of mouth opening and the occlusion function of all patients were examined. A curved mandibular tomogram was obtained after surgery to determine the fixation of the condylar structure for the intracapsular condylar fracture and determine whether the mandibular ascending height was normal.

Observational indicators

The main observational indicators included condylar function, the degree of mouth opening and the time required to reach the mouth-opening exercise standard.

The secondary outcome indicator included postoperative complications. For the observation of complication indicators, the presence of infection and facial paralysis was observed within 1 week after surgery, and the presence of occlusal relationship disorder, joint popping, joint pressure pain, and joint ankylosis complications were examined 6 months after surgery.

Statistical analysis

We used the SPSS Statistics 20.0 (IBM, Chicago, USA) software program for the statistical analysis. The continuous variables of a normal distribution were expressed as mean ± standard deviations, the continuous variables of a non-normal distribution were expressed as medians (interquartile range), and the categorical variables were expressed as frequencies (percentage). For multiple comparisons, each value was compared using a one-way analysis of variance following Dunnett's test when each datum conformed to a normal distribution; non-normally distributed continuous data were compared using non-parametric tests. Count data were tested using the Chi-squared test or Fisher's exact test. A value of $p < 0.05$ was considered statistically significant.

Table 1. Information of all patients in the groups of Stainless steel-wire internal fixation, titanium-plate and nail rigid internal fixation, and conservative treatment

Index	Stainless steel-wire internal fixation group (n = 44)	Titanium plate and nail rigid internal fixation group (n = 32)	Conservative non-surgical treatment group (n = 28)	p-value
Type of fracture				0.052
Intracapsular condyle fractures (left)	14	14	14	
Intracapsular condyle fractures (right)	18	18	14	
Intracapsular condyle fractures (bilateral)	12	0	0	
Gender				0.700
Male	30	18	16	
Female	14	14	12	
Age	19-58	22-45	11-36	
Average age	31.8	29.7	22.6	0.447

Results

General characteristics

The characteristics of the study participants are listed in table 1. There were 44 patients in the stainless-steel wire internal-fixation group, 32 patients in the titanium plate-and-nail rigid internal-fixation group and 28 patients in the conservative non-surgical treatment group.

In the stainless-steel wire internal-fixation group, there were 44 cases of intracapsular condylar fractures, of which 32 were unilateral fractures, and 12 were bilateral fractures. Among the 32 patients with unilateral intracapsular condylar fractures, 14 had left intracapsular fractures, and 18 had right intracapsular fractures. The patients ranged in age from 19 to 58 years, with an average age of 31.8 years.

In the intracapsular condylar fracture with a titanium plate-and-nail treatment group, 32 patients had a unilateral intracapsular condylar fracture. Among them, 18 were male, and 14 were female; there were 14 cases of a fracture in the left condylar sac and 18 cases of a fracture in the right condylar sac. The age of the patients ranged from 22 to 45 years, with an average age of 29.7 years.

In the non-surgical conservative treatment group, all 28 patients had a unilateral intracondylar fracture; 14 were on the left, and 14 were on the right side of the temporomandibular joint. Among these 28 patients, 16 were male, and 12 were female; their ages ranged between 11 and 36 years, with a mean age of 22.6 years.

Comparison of the degree of mouth opening between different groups

The degree of mouth opening of the patients is shown in table 2. The results reveal that the degree of mouth opening for the patients treated with stainless-steel wire fixation reached 3.7 cm, which is the normal extent, after only 10 days after surgery, while the titanium plate-and-nail fixation group required 21 days to achieve the same result. The conservative treatment group required the longest time, with patients needing 60 days to recover. The best postoperative bone reconstruction results of the condylar fractures were in the stainless-steel wire internal-fixation group compared with the other two treatment methods.

Comparison of recovery at 8 months after surgery between different groups

Of the patients, 90.9% (40/44) were healed within 8 months after surgery in the stainless-steel wire fixation group. A total of 62.5% (20/32) of patients in the titanium plate-and-nail group and 50.0% (14/28) of patients in the conservative treatment group were healed within 8 months after surgery. The stainless-steel wire internal-fixation group had a much higher cure rate than the other two groups ($p = 0.016$) (Table 3). The incidence rate of temporomandibular joint ankyloses was 0% after surgery for all three treatment methods.

Table 2. Comparison of the effectiveness of three groups

Number of days after the clinical treatment	Extent of mouth opening (mm) for stainless steel wire internal fixation	Extent of mouth opening (mm) for titanium plate and nail rigid internal fixation	Extent of mouth opening (mm) for conservative non-surgical treatment
3	15.12 ± 2.12	0	0
7	25.32 ± 1.98	15.62 ± 0.54	0
10	35.52 ± 1.76	21.16 ± 0.84	0
14	37.62 ± 1.72	25.52 ± 0.54	15.06 ± 0.50
21	37.58 ± 2.08	37.55 ± 0.48	32.74 ± 0.26
30	37.08 ± 1.78	36.85 ± 0.64	36.32 ± 0.24
60	37.42 ± 1.92	37.22 ± 1.96	37.02 ± 0.22

Table 3. Comparison of recovery at 8 months after operation between different groups

Index	Stainless steel-wire internal fixation group (n = 44)	Titanium plate and nail rigid internal fixation group (n = 32)	Conservative non-surgical treatment group (n = 28)	p-value
Number of healing cases (n [%])	40 (90.9%)	20 (62.5%)	14 (50.0%)	0.016

Comparison of mouth-opening degree and lateral mandibular shift at 30 days after treatment

After 30 days of treatment with the three methods, the measurement results for the degree of mouth opening and the lateral mandibular shift during mouth opening in the stainless-steel wire internal-fixation group were 37.08 ± 1.78 mm and 7.04 ± 1.08 mm, respectively. In the titanium plate-and-nail rigid internal-fixation group, the extent of mouth opening was 36.85 ± 0.64 mm, and the lateral mandibular shift was 6.76 ± 0.32 mm. In the conservative treatment group, the extent of mouth opening was 36.32 ± 0.24 mm, and the lateral mandibular shift was 6.27 ± 0.32 mm. These details are listed in table 4.

Comparison of the incidence of post-operative complications

In this study, two cases in each of the stainless-steel wire internal-fixation group and the titanium plate-and-nail rigid internal-fixation group developed infections, eight cases in the stainless-steel wire internal-fixation group had joint popping, 10 cases in the titanium plate-and-nail rigid internal-fixation group had joint popping, and six cases in the conservative non-surgical treatment group had joint popping. Two cases of facial palsy were observed in each of the three groups. There was no statistically significant difference in the incidence of postoperative infection, joint popping, joint tenderness and facial palsy among the three groups ($p > 0.05$), and no joint ankylosis or disturbed occlusal relationship occurred in any of the three groups (Table 5).

Discussion

For the surgical treatment of intracapsular condylar fractures, based on the condylar and extrapteral muscles in the joint capsule, it is necessary to perform a surgical reduction of the fracture in the joint capsule to ensure the stability of the biomechanical functioning of the temporomandibular joint[17-19]. For the surgical reduction of the ends of the intracapsular fracture, efforts should be made to minimise damage to the temporomandibular joint capsule and the mandibular joint disc during surgery and achieve the safest and most effective treatment for each patient[20].

The results of this study showed that the new stainless-steel wire internal-fixation method is an effective treatment for intercapsular condylar fractures, with less trauma, earlier recovery of mouth opening and no temporomandibular joint ankyloses. The performance of this method exceeded that of the titanium plate-and

Table 4. Comparison of the mouth opening degree and the lateral mandibular shift during mouth opening at 30 days after the treatments between different groups

Index	Stainless steel wire internal fixation group (n = 44)	Titanium plate and nail rigid internal fixation group (n = 32)	Conservative non-surgical treatment group (n = 28)	p-value
Extent of mouth opening	37.08 ± 1.78 mm	36.85 ± 0.64 mm	36.32 ± 0.24 mm	0.039
Lateral mandibular shift	7.04 ± 1.08 mm	6.76 ± 0.32 mm	6.27 ± 0.32 mm	<0.001

Table 5. Comparison of the incidence of post-operative complications

Index	Stainless steel-wire internal fixation group (n = 44)	Titanium plate and nail rigid internal fixation group (n = 32)	Conservative non-surgical treatment group (n = 28)	p-value
Infection (n [%])	2 (4.55%)	2 (6.25%)	0	0.657
Facial paralysis (n [%])	2 (4.55%)	2 (6.25%)	2 (7.14%)	0.944
Occlusal relationship disorder (n [%])	0	0	0	/
Joint pressure pain	4 (9.09%)	6 (18.75%)	4 (14.29%)	0.686
Joint ankylosis	0	0	0	/
Joint popping	8 (18.18%)	10 (31.25%)	6 (21.43%)	0.631

nail rigid internal fixation and conservative treatment methods and is thus a promising candidate for the treatment of intracapsular condylar fractures. The new surgical method for the treatment of intracapsular condylar fractures with stainless-steel wire fixation is easy to perform and reduces surgery time compared with using titanium plates and nails in rigid internal-fixation procedures.

However, there is some controversy about the clinical treatment of intracapsular condyle fractures[21]. Some researchers believe that the actual fracture of an intracapsular condylar break cannot be treated with surgery and suggest that intracondylar fracture treatment is best applied using non-surgical conservative treatment, particularly in children[22,23]. However, in some cases, the non-surgical conservative treatment of these fractures can result in symptomatic temporomandibular joint ankylosis, such as restricted mouth opening[24]. Other researchers believe that surgical incision reduction should be performed in the early stages of treatment to prevent the development of temporomandibular joint stiffness[25]. In this study, we also examined the prognosis of the non-surgical conservative treatment of intracapsular condylar fractures. We observed a loss in the vertical mandibular height of the fracture side compared with the healthy side in patients undergoing conservative treatment, and a significant bulging deformity was observed on the affected side of the jaw. A recent study showed that there are many shortcomings in the non-surgical conservative treatment of intracapsular condylar fractures[26]. The conservative treatment of intracondylar fractures does not allow precise anatomical repositioning, and it may cause occlusal disorders, restricted opening, chronic joint pain, and joint popping[27].

The extensor pterygoid muscle is the mouth-opening muscle. The contraction of one side of the extensor pterygoid muscle turns the mandible to the opposite side, and the contraction of the posterior fibers of the temporalis muscle pulls the mandible backwards[28]. Occlusal disturbances and restricted opening, which are common sequelae of intracondylar capsule fractures, can occur after both surgical and conservative treatment[29]. Occlusal disorder after condylar fracture is caused by the fracture block being pulled forward medially by the extra-pterygoid muscle and the change in height of the mandibular ascending branch, which makes the affected posterior teeth contact early under the action of the ascending muscle group[30]. Moreover, following trauma, there may be varying degrees of opening restriction due to muscle spasm, edema and blood accumulation in the joint.

After 30 days of treatment, the degree of mouth opening and the lateral shift were examined for all

three treatment methods (titanium plate-and-nail rigid internal fixation, conservative treatment, and stainless-steel wire internal fixation). There were no differences in the average degree of mouth opening and the lateral shift between the three treatments. This may have been due to the selection of the treatment methods, which strictly followed the symptoms of the fractures in our department. It can be seen that the different methods had little influence on opening tension.

Surgical treatment is performed with stainless-steel wire fixation, and the fracture fragment can produce a micro-movement under the traction of the extensor pterygoid muscle, stimulating the periosteum to form a fibrous crust and cartilage crust, thus promoting fracture healing. The small size of the wire causes less damage to the articular disc, which has the unique advantage of fixation in the case of small fracture fragments, and the degree of tightening of the wire can be controlled during fixation. In practice, the choice of fixation method sometimes depends on the actual situation of the patient. For the treatment of condylar fractures, a treatment plan is determined according to the location of the condylar fracture, the vital signs of the patient and the degree of displacement of the ends of the condylar fracture caused by external force or local muscle traction.

There were several limitations in this study. First, this trial was not a randomized controlled trial. Second, the sample size of this study was limited; therefore, larger trials with more participants should be conducted in the future. Third, the clinical follow-up time was short. In the future, we need to collect data on different fixation methods of intracondylar capsule fractures and study the clinical treatment effects of different fixation methods for intracondylar capsule fractures of the mandible according to the typology of such fractures. In addition, we need to discuss the choice of fixation methods for intracondylar capsule fractures, summarize the advantages and disadvantages of different fixation methods, and provide a reference basis for the treatment of intracondylar capsule fractures.

Conclusion

The treatment of intracondylar capsule fractures with stainless-steel wire fixation facilitates improvement in the degree of opening and promotes patient recovery.

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Conflicts of interest

All the authors had no personal, financial, commercial, or academic conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

References

1. Kumaran A, Soh HL. Management of non-union and malunion after primary mandibular condyle fracture treatment: a review and recommendations. J Oral Maxillofac Surg. 2020;78:2267-72.
2. Marwan H, Sawatari Y. What is the most stable fixation technique for mandibular condyle fracture? J Oral Maxillofac Surg. 2019;77:2522.e1-12.
3. Fathimani K. The case of the irretrievable mandibular condyle: my experience with utilization of an extraoral vertical ramus osteotomy in managing severely medially displaced or dislocated mandibular condyle fractures. J Maxillofac Oral Surg. 2023;22:49-53.
4. Nogami S, Yamauchi K, Bottini GB, Morishima H, Sai Y, Otake Y, et al. Mandibular fractures and dental injuries sustained during baseball and softball over 14 years in a Japanese population: a retrospective multicentre study. Dent Traumatol. 2020;36:156-60.
5. Liu K, Zhi Y, Wang Z, Zhang W, Shi J. Simple way of facilitating reduction the fragment for fractures with condyle. J Craniofac Surg. 2020;31:568-9.
6. Masquijo JJ, Ferreyra A, Torres-Gomez A, Allende V. Medial epicondyle fractures: current practices and preferences between SLAOTI members (sociedad latinoamericana de ortopedia y traumatología infantil). J Pediatr Orthop. 2020;40:267-70.
7. Samieirad S, Eshghpour M, Dashti R, Tohidi E, Javan AR, Mianbandi V. Correlation between lower third molar impaction types and mandibular angle and condylar fractures: a retrospective study. J Oral Maxillofac Surg. 2019;77:556-64.
8. Hlawitschka M, Eckelt U. Assessment of patients treated for intracapsular fractures of the mandibular condyle by closed techniques. J Oral Maxillofac Surg. 2002;60:784-91.
9. Ellis E, Throckmorton G. Treatment of mandibular condylar process fractures: biological considerations. J Oral Maxillofac Surg. 2005;63:115-34.
10. Boe RR, Ward Booth RP, de Bont LG. Mandiblar condyle fractures: a consensus. Br J Oral Maxillofac Surg. 1999;37:87-9.
11. Haug RH, Brandt MT. Closed reduction, open reduction, and endoscopic assistance: current thoughts on the management of mandibular condyle fractures. Plast Reconstr Surg. 2007;120:90S-102.
12. Liu S, Tian L, Ding M, Liu Y, Li G, Chen J, et al. The effect of extracapsular injuries on growth and development of the mandible condyle: an experimental study in growing dogs. Oral Surg Oral Med Oral Pathol Oral Radiol. 2016;122:e131-45.
13. Xu P, Jin A, Dai B, Li R, Li Y. Surgical timing for facial paralysis after temporal bone trauma. Am J Otolaryngol. 2017;38:269-71.
14. Costa FW, Bezerra MF, Ribeiro TR, Pouchain EC, Sabóia VP, Soares EC. Biomechanical analysis of titanium plate systems in mandibular condyle fractures: a systematized literature review. Acta Cir Bras. 2012;27:424-9.
15. Sahoo N, Boruah D, Thakral A, Kumar R, Roy ID. Comparative histomorphometric evaluation of healthy and ankylosed mandibular condylar process. J Maxillofac Oral Surg. 2018;17:248-53.
16. Yao S, Zhou J, Li Z. Contrast analysis of open reduction and internal fixation and non-surgical treatment of condylar fracture: a meta-analysis. J Craniofac Surg. 2014;25:2077-80.

17. Riu GD, Gamba U, Anghinoni M, Sesenna E. A comparison of open and closed treatment of condylar fractures: a change in philosophy. Int J Oral Maxillofac Surg. 2001;30:384-9.
18. Zhang H, Liu C, Hou M. Clinical treatment of high condylar fracture through intraoral approach. J Oral Maxillofac Surg. 2009;17:61-4.
19. Giannakopoulos HE, Quinn PD, Granquist E, Chou JC. Posttraumatic temporomandibular joint disorders. Craniomaxillofac Trauma Reconstr. 2009;2:91-101.
20. Liu W. Clinical features and treatment of mandibular condylar fracture. J Nanchang Univ. 2014;54:52-5.
21. Wu Y, Long X, Fang W, Li B, Cheng Y, Deng M, et al. Management of paediatric man dibular condylar fractures with screw-based semi-rigid inter maxillary fixation. Int J Oral Maxillofac Surg. 2012;41:55-60.
22. Guven O, Keskin A. Remodelling following condylar fractures in children. J Craniomaxillofac Surg. 2001;29:232-7.
23. Zhou Q. Clinical analysis of 36 cases of mandibular condylar fracture treated by endoscope. Minim Invas Med. 2009;4:177-8.
24. Deng S, Zhong F, Guan S, Zhao J, Guo Y. Clinical study of surgical treatment of condylar fracture. J Clin Stomatol. 2011;27:307-9.
25. Jiang R, Li J, Shen N, Dong H. Application of medical ear brain glue in the operation of old condylar comminuted fracture. Guangxi Med J. 2013;35:564-5.
26. Luo S, Li B, Long X, Deng M, Cai H, Cheng Y. Surgical treatment of sagittal fracture of mandibular condyle using long-screw osteosynthesis. J Oral Maxillofac Surg. 2011;69:1988-94.
27. Cuéllar J, Santana J, Núñez C, Villanueva J. Surgical or conservative treatment for mandibular condyle fractures. Tratamiento quirúrgico o conservador para fracturas de cóndilo mandibular. Medwave. 2018;18:e7352.
28. Pae EK. Response of masticatory muscles to passive stretch stimulus - from perspectives of functional appliances. Korean J Orthod. 2012;42:64-72.
29. Vincent AG, Ducic Y, Kellman R. Fractures of the mandibular condyle. Facial Plast Surg. 2019;35:623-6.
30. Ortiz-Gutiérrez AL, Beltrán-Salinas B, Cienfuegos R. Mandibular condyle fractures: a diagnosis with controversial treatment. Fracturas del cóndilo mandibular: un diagnóstico con tratamiento controversial. Cir Cir. 2019;87:587-94.

ARTÍCULO ORIGINAL

Utilidad diagnóstica de la escala de Alvarado en adultos mayores con sospecha de apendicitis aguda

Diagnostic utility of the Alvarado scale in older adults with suspected acute appendicitis

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Resumen

Antecedentes: *La apendicitis aguda es un diagnóstico diferencial en el adulto mayor con dolor abdominal. La escala de Alvarado se utiliza para orientar el diagnóstico y el tratamiento. Las características operativas de la escala son poco conocidas en este grupo de pacientes.* **Método:** *Revisión sistemática de estudios originales publicados entre 1986 y 2022 que evaluaron el rendimiento diagnóstico de la escala de Alvarado en adultos mayores con sospecha de apendicitis aguda, con base en la declaración PRISMA. La evaluación de la calidad metodológica de los estudios se realizó con los criterios ROBINS-I.* **Resultados:** *Se identificaron cuatro estudios originales de diseño retrospectivo que incluyen 480 pacientes. La heterogeneidad y la baja calidad metodológica limitaron un análisis estadístico agregado (metaanálisis). El valor de la curva ROC de la escala varía entre 0.799 y 0.969. En los estudios disponibles, el valor de la curva ROC es inferior al de la escala RIPASA y similar al de la escala de Lintula.* **Conclusiones:** *La evidencia que sustenta el rendimiento diagnóstico de la escala de Alvarado en los adultos mayores es limitada. La pobre calidad de los estudios disponibles advierte sobre el uso prudente de esta herramienta en este grupo poblacional. Los hallazgos identificados ofrecen oportunidades de investigación futura.*

Palabras clave: *Apendicitis aguda. Escala de Alvarado. Predicción. Adulto mayor. Dolor abdominal agudo.*

Abstract

Background: *Acute appendicitis remains as a differential diagnosis in older patients with abdominal pain. The Alvarado scale may assist to guide the diagnosis and treatment of this entity. The operative characteristics of the scale are little known in this population.* **Method:** *We conducted a systematic review of original studies published between 1986 and 2022 evaluating the diagnostic performance of the Alvarado scale in older adults with suspected acute appendicitis. The review was conducted according to the PRISMA statement. The evaluation of the methodological quality of the studies was performed according to the ROBINS-I criteria.* **Results:** *Four original studies of retrospective design including 480 patients were identified. The heterogeneity and poor methodological quality limited an aggregate statistical analysis (meta-analysis). The value of the ROC curve of the scale varies between 0.799 and 0.969. From the available studies, the value of the ROC curve is lower in comparison to the RIPASA scale and comparable to the Lintula scale.* **Conclusions:** *The evidence on the diagnostic performance of the Alvarado scale in older adults is limited. The poor methodological quality of the available studies calls for a prudent use of this tool in this population. Our findings offer opportunities for future research.*

Keywords: *Acute appendicitis. Alvarado score. Prediction. Elderly. Acute abdominal pain.*

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Introducción

La prevalencia de apendicitis aguda a lo largo de la vida se encuentra en un 7-8%[1]. Con el crecimiento de la expectativa de vida también ha aumentado la prevalencia de la apendicitis aguda en la población mayor de 65 años[2,3]. En este grupo de pacientes, la prevalencia es similar a la de la población general, pero la tasa de perforación es mayor (35% vs. 13%)[4]. Además, es bien sabido que con la edad incrementa la ocurrencia de patologías abdominales de tipo inflamatorio, vascular y oncológico, entre otras, y el número de adultos mayores ocupa una proporción significativa de los pacientes que consultan a los servicios de urgencias[5]. La apendicitis aguda continúa siendo una causa de dolor abdominal agudo cercana al 15% y representa la segunda causa de dolor abdominal luego de la enfermedad biliar[4]. Por estas razones, es recomendable que en todos los pacientes se estratifique la probabilidad de apendicitis aguda para orientar el diagnóstico y el tratamiento[6]. En general, quienes presentan alta probabilidad de apendicitis deben ser operados, quienes presentan baja probabilidad deben ser observados ambulatoriamente y quienes se encuentran en una zona gris, o de incertidumbre diagnóstica, deben ser estudiados con técnicas de imagen, idealmente con tomografía computarizada contrastada abdominal. Este tipo de estratificación se realiza mediante escalas diagnósticas que combinan síntomas, hallazgos de la exploración física y pruebas bioquímicas. Las más recomendadas son la de Alvarado y la *Appendicitis Inflammatory Response* (AIR)[6]. La escala de Alvarado, en particular, es aceptada entre la comunidad científica por el extenso cuerpo de evidencia empírica que la respalda desde la década de 1980[7]. En su versión original, la escala fue desarrollada para evaluar la probabilidad de apendicitis aguda en la población general[8]. Sin embargo, el rendimiento de la escala de Alvarado no es completamente conocido en los adultos mayores. Estos pacientes representan una población especial, junto con los niños, las mujeres en embarazo y los pacientes con inmunosupresión. Por tal motivo, se recomienda una evaluación cuidadosa ante la posibilidad de otras patologías abdominales, así como por la coexistencia de enfermedades crónicas, uso medicamentos, fragilidad, cambios cognitivos y alteraciones en la funcionalidad, entre otros. Estas razones llevan a que muchos cirujanos e instituciones, como parte de la atención segura, evalúen a todos los adultos mayores con imágenes diagnósticas, independientemente del puntaje, o incluso sin aplicar ninguna escala diagnóstica. No obstante, en la práctica diaria es habitual que los adultos mayores continúen estratificándose con escalas de la misma forma que la población general. Frente a esta controversia en el abordaje diagnóstico del adulto mayor con dolor abdominal agudo, el objetivo de este estudio fue revisar la evidencia disponible sobre el rendimiento de la escala de Alvarado en la probabilidad de apendicitis aguda en esta población.

Método

Se realizó una revisión sistemática de la literatura de pruebas diagnósticas, de acuerdo con la declaración PRISMA *(Preferid Reporting Items for Systematic reviews and Meta- Analyses)*[9]. Este estudio fue aprobado por la Comisión de Investigación de la Facultad de Medicina de la Universidad de La Sabana (MEDEsp-41-2020).

Selección de los estudios

Los criterios de inclusión fueron ser estudios originales publicados en inglés o español que evaluaran el rendimiento diagnóstico de la escala de Alvarado (individual o en comparación con otras escalas) en adultos mayores de 65 años con sospecha clínica o diagnóstico de apendicitis aguda. Para este propósito se seleccionaron ensayos clínicos, estudios de cohorte prospectiva y retrospectiva, y series de casos, publicados desde enero de 1986 hasta diciembre de 2022. Se excluyeron revisiones narrativas de la literatura, cartas al editor, resúmenes, pósteres y presentaciones en congresos.

La búsqueda se realizó en las bases de datos PubMed, Scopus, LILACS, Cochrane y BIREME. Se utilizaron los siguientes términos clave en inglés: “Alvarado scale”, “Alvarado score”, “acute apendicitis”, “elderly”, “older adults”, “diagnostic scale”, “predictive scale” y “appendectomy”. Se utilizaron los siguientes términos clave en español: “escala de Alvarado”, “puntaje de Alvarado”, “apendicitis aguda”, “ancianos”, “adultos mayores”, “escala diagnóstica”, “escala predictiva” y “apendicectomía”. La búsqueda también incluyó referencias cruzadas. Los títulos y los resúmenes de todos los artículos fueron evaluados independientemente por cada autor y luego seleccionados en consenso.

Desenlaces

– Primarios: características operativas de la escala de Alvarado. Se evaluaron los puntos de corte ideales, los valores de la curva ROC *(Receiver*

Operating Characteristics), la sensibilidad, la especificidad, el valor predictivo positivo, el valor predictivo negativo, la razón de verosimilitud positiva, la razón de verosimilitud negativa, la exactitud diagnóstica y la capacidad discriminativa.
- Secundarios: morbilidad, mortalidad, readmisión, estancia hospitalaria y costos.

Extracción de los datos de los estudios

Se obtuvieron los siguientes datos demográficos de cada estudio: autor, año de publicación, país, diseño del estudio, objetivo, método, población, sexo, edad, tiempo de evolución de los síntomas, promedio en la escala de Alvarado, distribución de la población en la escala de Alvarado, estudio histopatológico y uso de pruebas diagnósticas complementarias. Luego se realizó la extracción de los datos correspondientes a los desenlaces propuestos.

Evaluación de la calidad de la evidencia

Se realizó por consenso entre los dos autores de la revisión siguiendo los criterios ROBINS-I *(Risk Of Bias In Non-randomized Studies - of Interventions)*[10].

En cada estudio se identificaron los siguientes tipos de sesgos: confusión, selección de los participantes en el estudio, clasificación de las intervenciones, desviaciones de las intervenciones previstas, falta de datos, medición de los resultados y selección del resultado informado.

Análisis estadístico

Se calcularon las estadísticas descriptivas para las variables demográficas. Las variables continuas se expresaron en promedios, desviaciones estándar y rangos. Las variables categóricas se expresaron en frecuencias y porcentajes. De acuerdo con los resultados de evaluación de la calidad metodológica, en caso de identificar homogeneidad en los estudios, se planeó un análisis estadístico agregado de los datos (metaanálisis).

Resultados

Características de los estudios y aspectos demográficos

Cuatro estudios cumplieron los criterios para ser incluidos en la revisión sistemática de la literatura[11-14]. El diagrama de flujo para la selección de los estudios se presenta en la figura 1. Dos estudios (50%) fueron realizados en Turquía[11,12] y los otros dos en los Estados Unidos de América[13,14]. Todos son de diseño retrospectivo; dos de ellos corresponden a estudios de cohorte y los otros dos a series de casos. Dos estudios comparan el rendimiento de la escala de Alvarado frente a las escalas de Raja Isteri Pengiran Anak Saleha Appendicitis (RIPASA)[11] y Lintula[12]. En todos los estudios, el computo del puntaje de la escala de Alvarado fue realizado retrospectivamente.

Los estudios seleccionados incluyen un total de 480 pacientes. El porcentaje de mujeres varió entre el 42% y el 58.3%. En dos estudios, el diagnóstico de apendicitis aguda fue realizado por tomografía computarizada en más del 95% de los pacientes[13,14]. Otros aspectos demográficos de la población se muestran en la tabla 1.

La evaluación de la calidad metodológica de los estudios se encuentra en la figura 2. En general, los estudios incluidos demostraron un alto riesgo de sesgos y heterogeneidad metodológica, que limitan conducir un análisis estadístico agregado (metaanálisis).

Características diagnósticas operativas de la escala de Alvarado

Dos estudios reportaron la curva ROC de la escala de Alvarado, en comparación con otras escalas. El valor de la curva ROC de la escala de Alvarado, con un punto de corte > 4, en comparación con la de RIPASA, fue 0.799 versus 0.886[11]. Con un punto de corte > 5, en comparación con la escala de Lintula, el valor de la curva ROC fue 0.969 versus 0.92[12]. La exactitud diagnóstica solo fue reportada por un estudio y correspondió al 88.7%[12]. Otras características operativas se encuentran descritas en la tabla 2.

Con respecto a la capacidad de discriminación de la escala, independientemente de la gravedad de la apendicitis aguda, un estudio reportó que la distribución de los pacientes fue similar cuando el puntaje fue ≥ 7 (complicada = 61.8, no complicada = 63.2; p no significativa)[13]. No obstante, las características diagnósticas operativas de la escala con respecto a la gravedad de la apendicitis no fueron reportadas en ningún estudio.

Desenlaces secundarios

De acuerdo con la información disponible en dos estudios, la tasa de complicaciones varió entre el

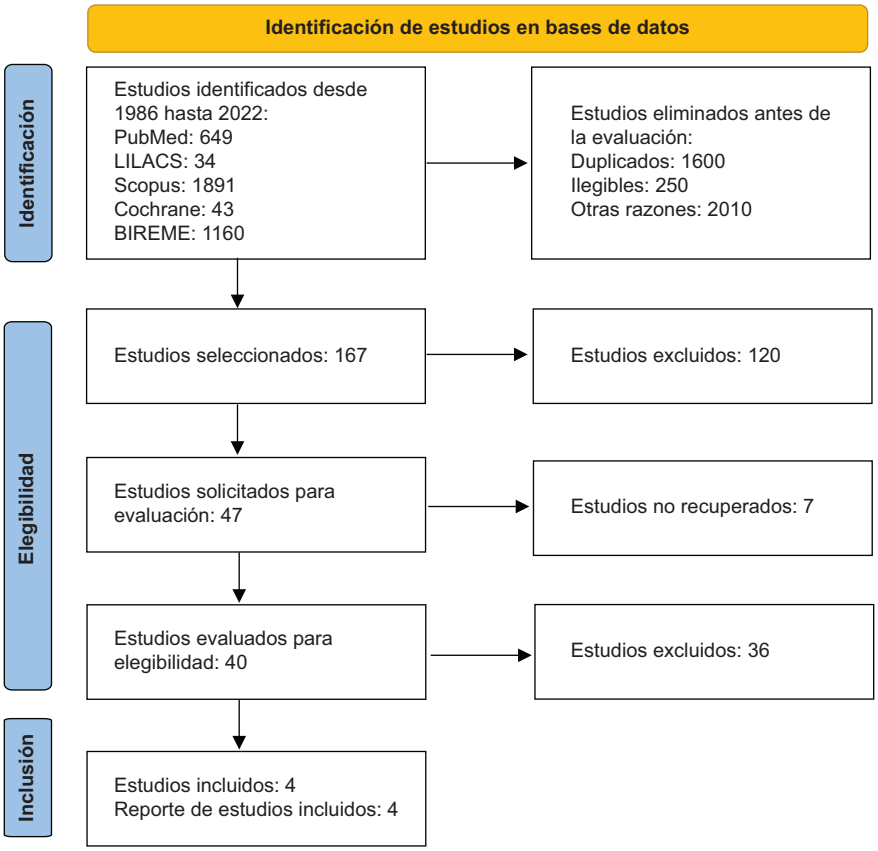

Figura 1. *Diagrama de flujo siguiendo la declaración PRISMA.*

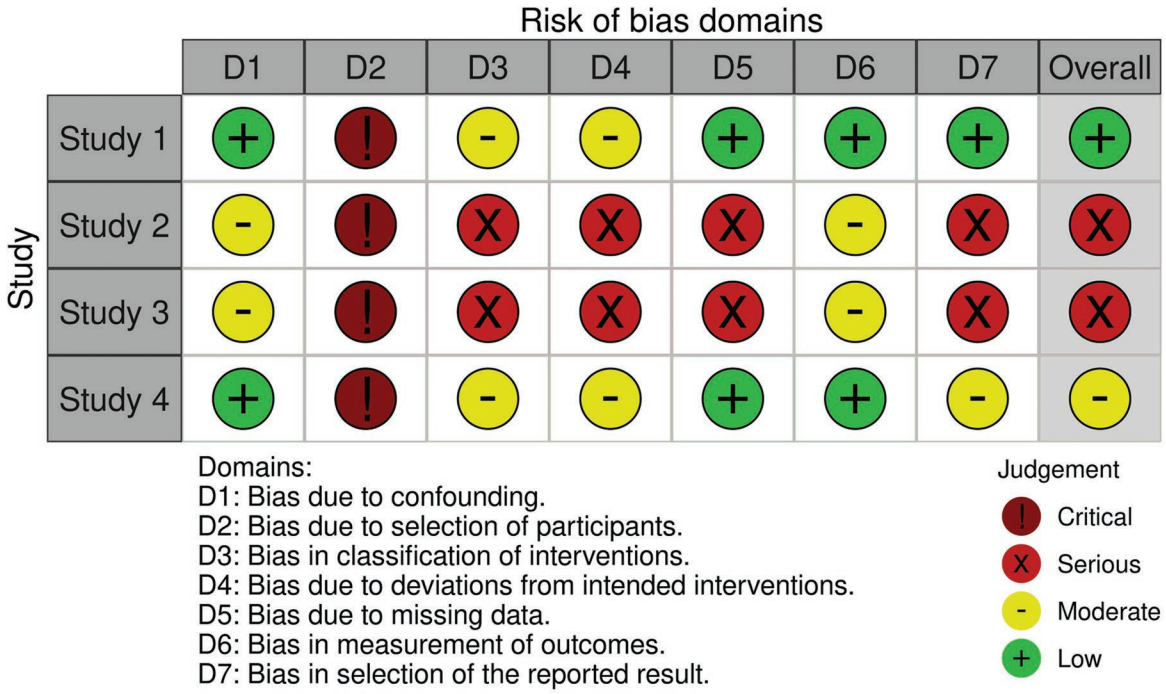

Figura 2. *Evaluación de la calidad metodológica de los estudios incluidos.*

Tabla 1. Características de los estudios incluidos en la revisión

Autores	País/año	Diseño	Objetivo	Métodos	Población	Edad (años)	Mujeres (%)	Tiempo de evolución (días)	Promedio escala	Distribución escala	IMC	Comorbilidad (%)	Patología positiva (%)	Imágenes diagnósticas (%)
Tekyol et al.[11]	Turquía, 2022	Cohorte retrospectiva (2018-2021)	Evaluar la precisión diagnóstica de RIPASA y Alvarado en adultos mayores operados por apendicitis aguda	Los investigadores identificaron pacientes > 65 años operados (con o sin confirmación patológica) Calcularon retrospectivamente Alvarado y RIPASA	86	71.2 ± 5.9	53.5	ND	3.48-5.29	ND	ND	ND	75.6	ND
Deiters et al.[13]	EE.UU., 2019	Serie de casos retrospectiva (2012-2016)	Determinar la utilidad de la escala de Alvarado para identificar apendicitis aguda complicada vs. no complicada	Los investigadores identificaron pacientes > 65 años operados y con diagnóstico patológico Calcularon retrospectivamente Alvarado	100 complicada	72.9 ± 6.9	49	2.70 ± 3.41	6.96 ± 1.99	≥ 7: 61.8%	28.5 ± 6.3	26.2	100	99,1% (TC)
					106 no complicada	73.0 ± 6.7	42	2.09 ± 3.08	6.72 ± 1.85	≥ 7: 63.2%	28.7 ± 5.3	31.6		
Shchatsko et al.[14]	EE.UU., 2017	Serie de casos retrospectiva (2000-2010)	Evaluar la utilidad de la escala de Alvarado en la predicción de la apendicitis aguda en adultos > 65 años	Los investigadores identificaron reportes patológicos Calcularon retrospectivamente Alvarado Compararon la distribución en los puntajes de la escala con los de la cohorte de Alvarado (1986)	96	73.7 ± 1.5	58.3	2.8 ± 0.8	6.9 ± 0.33	1-4: 3.7% 5-8: 86,6% 9-10: 9.7%	ND	ND	100	97.9% (TC)
Konan et al.[12]	Turquía, 2011	Serie de casos retrospectiva (fecha ND)	Evaluar el rendimiento de las escalas de Alvarado y Lintula en pacientes > 65 años	A pacientes con diagnóstico patológico se les calculó retrospectivamente Alvarado y Lintula Luego fueron comparados con un grupo de pacientes con dolor abdominal no específico	41 apendicitis 41 dolor abdominal	69	43	ND	ND	ND	ND	ND	100	ND

IMC: índice de masa corporal; ND: no descrito; RIPASA: *Raja Isteri Pengiran Anak Saleha Appendicitis*; TC: tomografía computarizada.

Tabla 2. Características operativas de la escala de Alvarado en pacientes mayores de 65 años

Autores	Escala	Puntos de corte ideales	ROC global (IC95%)	Índice Youden	Sensibilidad (IC95%)	Especificidad (IC95%)	VPP	VPN	RVP	RVN	Exactitud	Capacidad para diferenciar apendicitis complicada de no complicada
Tekyol et al.[11]	Alvarado	> 4	0.799 (0.698-0.877)	0.549	69.2 (56.6-80.1)	85.7 (63.7-97.0)	93.7	47.4	4.85	0.36	ND	ND
	RIPASA	> 8	0.886 (0.799-0.944)	0.642	78.5 (66.5-87.7)	85.7 (63.7-97.0)	94.4	56.2	5.49	0.25	ND	ND
Deiters et al.[13]	Alvarado	ND	ND	ND	ND	ND	ND	ND	ND	ND		Alvarado ≥ 7 Complicada 61.8 No complicada 63.2 No diferencia entre pacientes < 70 años, 71-75 años o > 76 años con apendicitis complicada y no complicada
Shchatsko et al.[14]	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	Alvarado 5-8 se correlacionó mas frecuentemente con apendicitis aguda, independientemente del tipo patológico Con respecto al estudio original (1986) se encontraron diferencias en la distribución de los puntajes entre 5-6 (37.8% vs. 15%; p = 0.001) y 9-10 (9.7% vs. 32.1%; p = 0.001)
Konan et al.[12]	Alvarado	5	0,969 (0,94-0,998)	ND	87.8	89.7	90.0	87.5	ND	ND	88.7	ND
	Lintula	12	0.928 (0,874-0.982)	ND	87.8	87.2	88	87	ND	ND	87,5	ND

IC95%: intervalo de confianza del 95%; ND: no descrito; RIPASA: *Raja Isteri Pengiran Anak Saleha Appendicitis*; ROC: *Receiver Operating Characteristics*; RVN: razón de verosimilitud negativa; RVP: razón de verosimilitud positiva; VPN: valor predictivo negativo; VPP: valor predictivo positivo.

22% y el 37%[13,14]. Las tasas de reoperación y de mortalidad reportadas en un estudio fueron del 1.2% y el 5.3%, respectivamente[14]. La tasa de apendicectomía negativa fue reportada en un estudio (24.4%)[11]. Ningún estudio incluye información relacionada con los costos. Asimismo, ningún estudio informó sobre el comportamiento de los desenlaces secundarios en función del puntaje en la escala de Alvarado. En la tabla 3 se muestran otros hallazgos.

Discusión

Los resultados de la presente revisión indican que existe un número limitado de estudios originales, de pobre calidad metodológica, sobre la utilidad de la escala de Alvarado en la predicción de apendicitis aguda en el adulto mayor. Dos estudios comparan el rendimiento diagnóstico frente a las escalas de RIPASA y Lintula, respectivamente; en estos el valor de la curva ROC de la escala de Alvarado fue inferior al de la RIPASA y prácticamente igual al de la Lintula.

Esta es la primera revisión sistemática de la literatura que ofrece una síntesis clara y estructurada de la información disponible sobre este tema. Estudios previos dan cuenta del aceptable rendimiento diagnóstico de la escala en pacientes pediátricos, embarazadas y población general, y soportan su uso en la práctica clínica[6,15,16]. Con respecto a los hallazgos, esta revisión identifica varias limitaciones de la evidencia disponible, que en su conjunto dan cuenta de los sesgos de estudios publicados en las dos décadas anteriores, las cuales ofrecen oportunidades de nuevos estudios. A continuación, se enumeran algunas de las limitaciones más importantes, así como algunas propuestas para la agenda de investigación:

- Todos los estudios primarios disponibles sobre el rendimiento diagnóstico y las características operativas de la escala de Alvarado en adultos mayores son de diseño retrospectivo. La validación de pruebas diagnósticas con base en diseños retrospectivos representa una amenaza para la confiabilidad de los resultados[17]. Los nuevos estudios deben enfocarse en la validación prospectiva de la escala.
- El principal criterio de validez de una prueba diagnóstica es su capacidad para clasificar correctamente si un paciente tiene la enfermedad (sensibilidad) o no la tiene (especificidad). Es frecuente una «sobreestimación» del resultado de la prueba diagnóstica en estudios cuando se conoce previamente el desenlace y se asignan de esta

Tabla 3. Desenlaces posoperatorios y costos

Autores	Abordaje quirúrgico	Complicaciones	Mortalidad	Estancia hospitalaria	Reoperación	Apendicetomía negativa (%)	Costos
Tekyol et al.[11]	ND	ND	ND	ND	ND	24,4	ND
Deiters et al.[13]	Laparoscópico: 88.8% Conversión: 8.8%	Apendicitis complicada: 37%	1	5.34 ± 5.56	ND	-	ND
		Apendicitis no complicada: 22%	0	3.12 ± 2.86			
Shchatsko et al.[14]	ND	33	1.2	5.88 ± 1.02	5,3	-	ND
Konan et al.[12]	ND	ND	ND	ND	ND	-	ND

ND: no descrito.

forma componentes de la prueba a los enfermos[18]. En todos los estudios incluidos en esta revisión, el cómputo del puntaje de Alvarado se realizó *a posteriori* sobre datos disponibles en registros clínicos. Por la naturaleza del diseño de investigación, algunos hallazgos clínicos en la exploración física (por ejemplo, el signo de Blumberg) pueden ser difíciles de evaluar de forma retrospectiva, a menos que estén adecuadamente consignados en la historia clínica, y ser interpretados como positivos. En estrecha relación con el diseño prospectivo, es necesario que en los nuevos estudios el cálculo del puntaje de la escala se realice en tiempo real con base en los hallazgos clínicos observados por el examinador.

– En tres de los cuatro estudios incluidos en esta revisión, la población correspondió a sujetos que presentaron apendicitis aguda confirmada por estudio histopatológico, considerado el método de referencia. Por lo tanto, estos estudios cuentan con un importante sesgo de medición relacionado con la exclusión de sujetos no enfermos, es decir, sin apendicitis aguda. Debido a ello, el cómputo de la sensibilidad y la especificidad podría sobre- o subestimarse. Aunque el método de referencia es crucial en cualquier estudio de pruebas diagnósticas, los nuevos estudios deben incluir pacientes con dolor abdominal agudo con y sin apendicitis aguda. Con este tipo de población, la sensibilidad y la especificidad podrían ser confiables. Además, este tipo de análisis permitiría conocer el comportamiento de los falsos positivos (por ejemplo, qué otras patologías abdominales se encuentran en la población). Este sesgo también afecta otras características operativas de la escala; por ejemplo, el computo de la razón de verosimilitud positiva, entendida como la razón entre la tasa de verdaderos positivos y la tasa de falsos positivos, e igualmente la razón de verosimilitud negativa.
– Los estudios incluidos en esta revisión informan pobremente sobre el espectro de gravedad de la enfermedad en la población. El comportamiento de la escala debe tenerse en cuenta en pacientes con apendicitis complicada y no complicada. Aunque dos estudios informan sobre la gravedad de la apendicitis, no reportan las características operativas de la escala en cada grupo. Estos estudios únicamente ofrecen porcentajes sobre la positividad de la escala por encima de determinados puntos de corte en individuos con diferentes tipos de apendicitis. Un estudio adecuadamente diseñado debería incluir pacientes con diferente gravedad de la apendicitis e informar sobre las características operativas en cada uno de ellos.
– La comparación disponible sobre la validez predictiva de la escala de Alvarado con otras escalas es limitada. Dos estudios fueron realizados con las escalas RIPASA y Lintula. Existen limitaciones metodológicas en estos estudios propias del cálculo retrospectivo de los puntajes. Adicionalmente, la escala de Lintula fue diseñada para la población pediátrica[19]. Es necesario conducir estudios que comparen la validez predictiva frente a escalas de uso creciente y adecuado rendimiento diagnóstico en adultos, como AIR[20], RIPASA[21] y *Diagnostic Score*[22]. Llamativamente, no existen estudios que evalúen el rendimiento de estas últimas escalas en población geriátrica.

– Las limitaciones anteriores afectan la estimación de los puntos de corte óptimos de la escala con los cuales se obtienen las mejores sensibilidad y especificidad. En los estudios incluidos, los cálculos de estas características operativas fueron realizados basándose en los puntos de corte de la escala para la población general. Adicionalmente, los adultos mayores con sospecha de apendicitis aguda presentan comorbilidad cercana al 44%, así como otras patologías abdominales concomitantes cercanas al 85%, que podrían afectar los puntos de corte y el rendimiento de la escala[5]. En la práctica, estos aspectos indican la necesidad de explorar cuidadosamente al paciente y no atenerse únicamente a los ítems de la escala. Si bien la escala de Alvarado puede tener utilidad en el tamizaje, es necesario que los nuevos estudios ajusten dinámicamente los puntos de corte para mejorar las características operativas de la prueba.
– En tres estudios incluidos en la revisión, el diagnóstico de apendicitis aguda fue confirmado por técnicas de imagen. Aunque el diseño de los estudios fue retrospectivo y el puntaje de la escala no contribuyó a orientar la solicitud de pruebas diagnósticas, los nuevos estudios deben tener en cuenta este aspecto.
– Aunque dos estudios informan sobre la morbilidad, la mortalidad y la estancia hospitalaria de la población, se desconoce el impacto de la escala de Alvarado sobre estos indicadores. Los nuevos estudios deben analizar cuidadosamente el comportamiento de la escala de Alvarado en la reducción de la morbilidad asociada al tratamiento de la apendicitis aguda.
– Se desconoce el impacto de la escala de Alvarado en los costos directos e indirectos del cuidado clínico. Los nuevos estudios también deben considerar este aspecto.
– Los estudios disponibles incluidos en esta revisión fueron realizados en los Estados Unidos de América y en Turquía. Se desconoce el rendimiento de la escala en otros contextos de asistencia clínica (por ejemplo, Europa y Latinoamérica).

Conclusión

El dolor abdominal agudo es un reto diagnóstico en el adulto mayor. De acuerdo con los aspectos mencionados, y pese a algunas limitaciones propias de las revisiones sistemáticas de la literatura relacionadas con la cantidad y la calidad de los estudios, así como la falta de evaluación de literatura gris, la escala de Alvarado tiene una utilidad limitada en esta población. Una alta concurrencia de patologías que confunden el diagnóstico en estos pacientes, una mayor posibilidad de una respuesta inflamatoria modificada (ingesta crónica de medicamentos, condición de fragilidad, etc.) y la pertinencia de efectuar pruebas de alto rendimiento diagnóstico para otras condiciones inflamatorias intraabdominales (tomografía computarizada o resonancia magnética)[23,24] limitan la utilidad de la escala de Alvarado como un elemento diagnóstico determinante de una conducta quirúrgica o expectante. La presente revisión sistemática de la literatura identifica algunos vacíos de conocimiento relacionados con este tema y contribuye con algunas propuestas para la investigación futura.

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Conflicto de intereses

Los autores declaran no tener ningún conflicto de intereses.

Responsabilidades éticas

Protección de personas y animales. Los autores declaran que para esta investigación no se han realizado experimentos en seres humanos ni en animales.

Confidencialidad de los datos. Los autores declaran que en este artículo no aparecen datos de pacientes.

Derecho a la privacidad y consentimiento informado. Los autores declaran que en este artículo no aparecen datos de pacientes.

Bibliografía

1. Stewart B, Khanduri P, McCord C, Ohene-Yeboah M, Uranues S, Vega Rivera F, et al. Global disease burden of conditions requiring emergency surgery. Br J Surg;2014;101:e9-22.
2. Storm-Dickerson TL, Horattas MC. What have we learned over the past 20 years about appendicitis in the elderly? Am J Surg. 2003;185:198-201.
3. Horattas MC, Guyton DP, Wu D. A reappraisal of appendicitis in the elderly. Am J Surg. 1990;160:291-3.
4. Kraemer M, Franke C, Ohmann C, Yang Q. Acute appendicitis in late adulthood: incidence, presentation, and outcome. Results of a prospective multicenter acute abdominal pain study and a review of the literature. Langenbeck's Arch Surg. 2000;385:470-81.
5. Lapsa S, Ozolins A, Strumfa I, Gardovskis J. Acute appendicitis in the elderly: a literature review on an increasingly frequent surgical problem. Geriatrics (Basel). 2021;6:93.

6. Di Saverio S, Podda M, De Simone B, Ceresoli M, Augustin G, Gori A, et al. Diagnosis and treatment of acute appendicitis: 2020 update of the WSES Jerusalem guidelines. World J Emerg Surg. 2020;15:27.
7. Ohle R, O'Reilly F, O'Brien KK, Fahey T, Dimitrov BD. The Alvarado score for predicting acute appendicitis: a systematic review. BMC Med. 2011;9:139.
8. Alvarado A. A practical score for the early diagnosis of acute appendicitis. Ann Emerg Med. 1986;15:557-64.
9. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews [Internet]. BMJ. 2021;372:n71.
10. Sterne JA, Hernán MA, Reeves BC, Savović J, Berkman ND, Viswanathan M, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ. 2016;355:i4919.
11. Tekyol D, Ak R, Hökenek NM, Kılıç M, Tekyol KK, Erdoğan D. A comparative study of the RIPASA and Alvarado scores in geriatric patients diagnosed with acute appendicitis. Rev Assoc Med Bras. 2022;68:1308-12.
12. Konan A, Hayran M, Kilic YA, Karakoc D, Kaynaroglu V. Scoring systems in the diagnosis of acute appendicitis in the elderly. Ulus Travma ve Acil Cerrahi Derg. 2011;17:396-400.
13. Deiters A, Drozd A, Parikh P, Markert R, Shim JK. Use of the Alvarado score in elderly patients with complicated and uncomplicated appendicitis. Am Surg; 2019;85:397-402.
14. Shchatsko A, Brown R, Reid T, Adams S, Alger A, Charles A. The utility of the Alvarado score in the diagnosis of acute appendicitis in the elderly. Am Surg. 2017;83:793-8.
15. Kulik DM, Uleryk EM, Maguire JL. Does this child have appendicitis? A systematic review of clinical prediction rules for children with acute abdominal pain. J Clin Epidemiol. 2013;66:95-104.
16. Tatli F, Yucel Y, Gozeneli O, Dirican A, Uzunkoy A, Yalçın HC, et al. The Alvarado Score is accurate in pregnancy: a retrospective case–control study. Eur J Trauma Emerg Surg. 2019;45:411-6.
17. Cohen JF, Korevaar DA, Altman DG, Bruns DE, Gatsonis CA, Hooft L, et al. STARD 2015 guidelines for reporting diagnostic accuracy studies: explanation and elaboration. BMJ Open. 2016;6:e012799.
18. Chassé M, Fergusson DA. Diagnostic accuracy studies [Internet]. Semin Nucl Med. 2019;49:87-93.
19. Lintula H, Pesonen E, Kokki H, Vanamo K, Eskelinen M. A diagnostic score for children with suspected appendicitis. Langenbeck's Arch Surg. 2005;390:164-70.
20. Andersson M, Kolodziej B, Andersson RE, Andersson RE, Andersson M, Eriksson T, et al. Randomized clinical trial of Appendicitis Inflammatory Response score-based management of patients with suspected appendicitis. Br J Surg. 2017;104:1451-61.
21. Chong CF, Adi MIW, Thien A, Suyoi A, Mackie AJ, Tin AS, et al. Development of the RIPASA score: a new appendicitis scoring system for the diagnosis of acute appendicitis. Singapore Med J. 2010; 51:220-5.
22. Eskelinen M, Meklin J, Syrjänen K, Eskelinen M. A diagnostic score (DS) is a powerful tool in diagnosis of acute appendicitis in elderly patients with acute abdominal pain. Anticancer Res. 2021;41:1459-69.
23. Mwinyogle AA, Bhatt A, Ogbuagu OU, Dhillon N, Sill A, Kowdley GC. Use of CT scans for abdominal pain in the ED: factors in choice. Am Surg. 2020;86:324-33.
24. Spangler R, Manning S. Disaster diagnoses in geriatric patients with abdominal pain. Emerg Med Clin North Am. 2021;39:347-60.

ARTÍCULO ORIGINAL

Discriminación de la cirujana en el ejercicio de su profesión

Discrimination against the female surgeon in the exercise of her profession

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Resumen

Objetivo: *Describir la discriminación que vive la cirujana general en México.* **Método:** *Estudio prospectivo, transversal y descriptivo, con una encuesta de 30 preguntas cerradas, de manera anónima, voluntaria y confidencial, distribuida a través de un enlace en el chat de WhatsApp en un grupo cerrado de cirujanas de todo el país que son miembros de la Asociación Mexicana de Cirugía General.* **Resultados:** *Participaron 146 cirujanas, con un porcentaje de respuesta del 58.4%. La discriminación percibida por las cirujanas en formación fue de 86 (58.9%), frente a 28 (19.2%) cuando ya son cirujanas, al no permitirles realizar los mismos procedimientos que sus pares. La discriminación por parte de los pacientes fue de 72 (49.3%). No las llaman doctoras sino «señoritas» en 126 (86.3%) y les solicitan hacer funciones de enfermería en 120 (82.2%). También existe discriminación hacia las cirujanas por el personal de enfermería en 87 (59.6%).* **Conclusiones:** *La discriminación hacia las cirujanas es frecuente en los tres ámbitos: pares, pacientes y personal de enfermería. Este es un trabajo inicial, donde se realiza la cuantificación de la discriminación en México. Se deberán implementar las estrategias para evitar la discriminación a las cirujanas y estar en un ambiente de igualdad.*

Palabras clave: *Cirujanas. Discriminación. Género.*

Abstract

Objective: *To describe the discrimination experienced by the general female surgeon.* **Method:** *Prospective, cross-sectional and descriptive study, with a survey of 30 questions, closed, anonymous, voluntary and confidential, distributed through a link in the WhatsApp chat in a closed group of female surgeons who are members of the Asociación Mexicana de Cirugía General.* **Results:** *146 female surgeons participated, with a response rate of 58.4%. The discrimination perceived by female surgeons in training was 86 (58.9%), and 28 (19.2%) when they are already surgeons by not allowing them to perform the same procedures as their peers. Regarding the patients, discrimination against female surgeons was 72 (49.3%). They do not call them doctors, but "ladies", in 126 (86.3%), and they are asked to perform nursing duties in 120 (82.2%). On the other hand, there is also discrimination against female surgeons by nursing staff in 87 (59.6%).* **Conclusions:** *Discrimination is common in the daily surgical practice of female surgeons in all three areas: peers, patients, and nursing staff. This is an initial work, where the quantification of discrimination in Mexico is carried out. Strategies must be implemented to avoid discrimination against female surgeons and be in an environment of equality.*

Keywords: *Female surgeons. Discrimination. Gender.*

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Introducción

La discriminación que sufre la mujer es un fenómeno social universal, que se manifiesta en los diferentes países de acuerdo con el grado educativo y económico, como lo documenta el Global Gender Gap Index de 2021[1].

La tendencia y el prejuicio directo contra médicos por diversos antecedentes, por parte de los pacientes, es frecuente que ocurra. Las doctoras tienen una larga experiencia de discriminación en el sistema de salud basada en su género[2].

Aunque hay reconocimiento de la contribución histórica en la práctica quirúrgica de la mujer, se sienten percibidas con desigualdad por su contraparte masculina; sin embargo, existe poca evidencia reportada[3].

A través de la historia, la mujer ha participado en la medicina y posteriormente en la cirugía, pero ha sido muy difícil la introducción al mundo del dominio del hombre en los diferentes siglos. Para ello se ha tenido que vestir como hombre para su aceptación como estudiante de la licenciatura de medicina y en el ejercicio de la medicina o de la cirugía. En la actualidad no requiere realizar esto, pero aún las cirujanas son objeto de discriminación. Por lo tanto, este grupo minoritario sigue siendo un grupo vulnerable, aunque ellas en algunos casos no lo perciban. La discriminación se origina en las distintas relaciones sociales, muchas veces desde la familia, a través de la formación de estereotipos y prejuicios[4].

Discriminar significa seleccionar excluyendo, esto es, dar un trato de inferioridad a personas o grupos a causa de su origen étnico o nacional, religión, edad, sexo, opiniones, preferencias políticas, preferencias sexuales, condiciones de salud, discapacidades, estado civil u otra causa. Se entiende como un trato injusto de unas personas hacia otras en virtud de la pertenencia a un grupo social sobre el cual existen prejuicios u opiniones negativas[5,6].

La desigualdad de género es un fenómeno social mundial, incluso en los países con mayor desarrollo educativo y económico. En el Global Gender Gap Index de 2021 se calificó a Suecia en el quinto lugar a pesar de ser un país de igualdades, y a México en el lugar 34 de 156 países en el mundo y el cuarto en Latinoamérica en cuanto a la igualdad de género[1].

La discriminación de la mujer en medicina está documentada desde que son estudiantes, residentes y cirujanas en los diferentes países como Suecia, el Reino Unido, los Estados Unidos de América, Kuwait y Corea, entre otros, siendo el porcentaje variable dependiendo del grado de desarrollo social y económico de cada país[2,3,7-9].

En Kuwait se realizó un estudio sobre microagresiones en el periodo de entrenamiento como residentes, siendo la más frecuente el insulto verbal (67%), seguido de la invalidación de su opinión (62.1%) y de actos de discriminación (56.4%)[8].

La discriminación en medicina es muy amplia y puede ser manifestada en varias formas, tanto por parte de pares como de los pacientes y del personal de salud[7].

El objetivo de este estudio fue describir la discriminación que vive la cirujana general en México en una muestra en el año 2022.

Método

Fue un estudio prospectivo, transversal y descriptivo. Se elaboró una encuesta con 30 preguntas cerradas y dos abiertas, que se dividió en dos secciones: la primera para los datos demográficos y la segunda acerca de la discriminación de la cirujana en su práctica diaria. La información que se recolectó fue de una muestra de cirujanas en México. La aplicación de la encuesta fue en forma anónima, voluntaria y confidencial. La distribución de la encuesta fue a través de una invitación a participar en el trabajo; se envió una liga para contestar el cuestionario de autoaplicación a través del chat de WhatsApp de un grupo cerrado de cirujanas de todo el país que son miembros de la Asociación Mexicana de Cirugía General (AMCG), durante un periodo de 6 meses (febrero a agosto de 2022). El criterio de inclusión fue ser cirujana y desear contestar la encuesta completa, y el criterio de exclusión fue ser médica no cirujana. Los datos fueron procesados en una computadora elaborando una base de datos. El análisis fue descriptivo, con la elaboración de tablas de contingencia y utilizando un paquete estadístico.

Resultados

Se invitó a 250 cirujanas a través del chat a responder una encuesta y la regresaron 146, siendo el porcentaje de respuesta del 58.4%. En cuanto a los datos demográficos, en lo que se refiere al lugar de nacimiento, 52 (35.6%) son originarias de la Ciudad de México, 11 (7.5%) de Michoacán, 9 (6.2%) de Veracruz, 8 (5.5%) de Puebla, 7 (4.8%) del Estado de México y 7 (4.8%) de Jalisco. La edad de las cirujanas

Tabla 1. Edad de las cirujanas distribuida por lustros

Edad (años)	n	%
25-30	4	2.7
31-35	16	11
36-40	32	21.9
41-45	24	16.4
46-50	25	17.1
51-55	22	15.1
56-60	7	4.8
61-65	8	5.5
> 65	8	5.5
Total	146	100

Tabla 2. Formación académica de las cirujanas

	n	%
Finalización de la licenciatura (década)		
1970 a 1979	7	4.8
1980 a 1989	12	8.2
1990 a 1999	43	29.5
2000 a 2009	47	32.2
2010 a 2019	24	16.4
2020 en adelante	13	8.9
Total	146	100.0
Años hasta entrar a la especialidad		
1	40	48.7
2	24	29.2
3	10	12.1
4	4	4.8
5	2	2.4
6	2	2.4
Total	82	

estuvo en mayor porcentaje en 36-40 años, con 32 (21.9%); le siguió el grupo de edad de 46-50 años con 25 (17.1%), y en tercer lugar las de 41-45 años con 24 (16.4%). (Tabla 1). En cuanto a su estado civil, 52 (35.6%) están casadas, 43 (29.5%) son solteras y 25 (17.1%) están en unión libre.

Con relación al año que terminaron la licenciatura, el mayor porcentaje fue entre 1990 y 1999, con 43 (29.5%), y entre 2000 y 2009 con 47 (32.2%) (Tabla 2). Como se puede observar, con el transcurrir del tiempo se ha ido incrementado el número de cirujanas; hay que esperar que se complete la década para ver su comportamiento.

La formación académica de las cirujanas continuó inmediatamente de la licenciatura a la especialidad en 64 (43.8%). Las que interrumpieron su formación de posgrado fueron 82 (56.1%), por diversas causas, siendo la principal no haber suficientes plazas de residencia, pues en 2020 solo existían 1646 lugares para todo México; la segunda causa fue por falta de recursos económicos, la tercera por el cuidado de los hijos y la última incluyó otras razones. Se analizó que cuantas más veces se presenta al Examen Nacional para Aspirantes a Residencias Médicas (ENARM) va disminuyendo la posibilidad de ingreso a la residencia de cirugía general (Tabla 2).

La institución donde realizaron la especialidad las cirujanas fue la Secretaría de Salud en 57 (39%), seguida del Instituto Mexicano del Seguro Social (IMSS) en 49 (33.6%) y del Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (ISSSTE) en 26 (17.8%) (Tabla 3). En todas estas instituciones, durante su formación como especialistas, 86 (58.9%) cirujanas sufrieron discriminación por sus pares al no darles las mismas oportunidades de realizar procedimientos quirúrgicos que a sus compañeros hombres.

Tabla 3. Desarrollo académico a través del tiempo de las cirujanas generales

	n	%
Institución donde realizaron la especialidad		
Secretaría de Salud	57	39
IMSS	49	33.5
ISSSTE	26	17.8
Pemex	5	3.4
Institutos	4	2.7
Hospital privado	3	2.05
Hospital universitario	2	1.36
Total	146	100
Rango de tiempo		
Antes de 1980	1	0.7
1980 a 1989	11	7.5
1990 a 1999	29	19.9
2000 a 2009	37	25.3
2010 a 2019	58	39.7
2020 en adelante	10	6.8
Total	146	99.9

El número de cirujanas que terminan la especialidad de cirugía general va aumentado a través del tiempo, como se observa en la tabla 3.

Al término de la especialidad obtuvieron su certificación por el Consejo Mexicano de Cirugía General (CMCG) 119 (81.5%) cirujanas. Por otra parte, 37 (25.3%)

Tabla 4. Instituciones públicas y del sector privado donde laboran las cirujanas

Un trabajo			Dos trabajos			Tres trabajos			Total
Sector	**n**	**%**	**Combinación**	**n**	**%**	**Combinación**	**n**	**%**	
IMSS	32	38	IMSS, Secretaría de Salud	11	21	IMSS, Secretaría de Salud, privado	5	56	
Secretaría de Salud	19	23	IMSS, ISSSTE	4	8	IMSS, SEMAR, privado	2	22	
ISSSTE	13	15	IMSS, otros	7	13	IMSS, ISSSTE, privado	2	22	
Otros	7	8	Secretaría de Salud, ISSSTE	2	4				
Privado	13	15	IMSS, privado	16	30				
			Secretaría de Salud, privado	9	17				
			ISSSTE, privado	4	8				
Total	84	100	Total	53	100	Total	9	100	146
	57.5			36.3			6.2		100

continuaron su entrenamiento con una alta especialidad, siendo endoscopia la principal, con 16 (43.2%) cirujanas.

En el ámbito laboral, las cirujanas ejercen su especialidad 102 (69.8%); de ellas, 36 (24.6%) como alta especialidad. Solo 8 (5%) ocupan puestos de directivos en el área hospitalaria, ya sea de directora, subdirectora médica, jefe de servicio y de enseñanza, o como investigadora. En cuanto a su función como cirujanas, siguen siendo discriminadas, ya que 28 (19.2%) no realizan los mismos procedimientos que sus pares; sin embargo, 118 (80.8%) sí los realizan.

De las cirujanas, 64 (43.8%) trabajan en una institución pública, 69 (47.2%) en la combinación de dos instituciones públicas o privadas, y solo 13 (8.9%) únicamente en el medio privado (Tabla 4). La práctica privada está limitada para las cirujanas, por lo que se infiere que sus ingresos económicos son menores que los de sus pares masculinos.

Al comparar cirujanas y cirujanos en un servicio de cirugía general, estas son un número mínimo, teniendo una distribución desde una (46 [31.5%]) hasta nueve cirujanas (3 [2.1%]), mientras los cirujanos hombres van de dos (1.4%) hasta 26-30 (2.1%), como se observa en la tabla 5.

La discriminación por los pacientes hacia las cirujanas es importante, ya que 72 (49.3%) no son igual de reconocidas que los cirujanos hombres, denominando a las cirujanas como «señoritas» 126 (86.3%) en vez de decirles «doctoras» como a sus compañeros varones. En el ámbito hospitalario, los pacientes tanto hombres como mujeres solicitan a las cirujanas hacer funciones de enfermería en 120 (82.2%), tales como que les pasen el cómodo o se lo retiren. También las mismas mujeres pacientes desean ser atendidas por un cirujano hombre en 64 (43.8%) en vez de una cirujana, aunque disminuye cuando un paciente hombre está en la misma condición a 40 (27.4%). Las pacientes mujeres llevan a sus esposos para presionar a la cirujana para su atención en 45 (30.8%).

Por otro lado, la discriminación hacia las cirujanas se presenta con el personal de enfermería en 87 (59.6%) cuando está en el quirófano; la cirujana que va a operar con un ayudante hombre, se dirigen a él como líder del equipo quirúrgico, a pesar de que la cirujana está programada como tal.

En lo que se refiere a dónde ejercen las cirujanas, principalmente es en la Ciudad de México con 41 (28%), seguida de Nuevo León con 11 (7.5%), Estado de México con 9 (6.1%) y Michoacán, Morelos, Quinta Roo y Veracruz con 8 (5.47 %) cada uno.

Por otro lado, las cirujanas tratan de compaginar su vida profesional y familiar, dividida en múltiples actividades como el cuidado de sus hijos en caso de tenerlos; en algunas ocasiones, en la práctica institucional muchas de ellas eligen el turno nocturno para no dejar a sus hijos solos durante el día, aunque manifestaron que tienen el apoyo de sus esposos y una red social. Sin embargo, se sienten abrumadas con tantas actividades y, por lo tanto, algunas expresaron que no es posible que se actualicen acudiendo a cursos o congresos. Más del 50% perciben que pueden compaginar su vida profesional con su vida familiar; expusieron que cuando son solteras sin hijos

Tabla 5. Comparación del número de cirujanas y de cirujanos que trabajan en un servicio de cirugía general

Número en servicio	Cirujanas		Cirujanos	
	n	%	n	%
1	46	31.5	2	1.37
2	16	11.0	4	2.74
3	20	13.7	4	2.74
4	18	12.3	8	5.48
5	18	12.3	5	3.42
6	14	9.6	11	7.53
7	5	3.4	2	1.37
8	6	4.1	8	5.48
9	3	2.1	12	8.22
10	0		14	9.59
11 a 15	0		43	29.5
16 a 20	0		20	13.7
21 a 25	0		9	6.2
26 a 30	0		3	2.1
31 o más	0		1	0.7
Total	146	100	146	100

Tabla 6. Combinación de la práctica quirúrgica y la vida familiar

Criterio	n	%
Felices de combinar ambas	87	59.5
Difícil de combinar	59	40.4
Total	146	100

o casadas sin hijos, y cuando cuentan con alta especialidad como endoscopia, es más fácil realizar su actividad como cirujana. Por otro lado, 59 (40.4%) que expresaron ser difícil de compaginar su vida como cirujana y su vida familiar laboran en el turno nocturno para poder realizar las actividades de madre y ama de casa, así como las que cursan con baja autoestima (Tabla 6).

Discusión

Tradicionalmente la cirugía ha sido considerada una especialidad «de hombres», pero eso está cambiando. La percepción de que la cirugía demanda demasiado tiempo, que el trabajo durante la residencia es extremo y que el estilo de vida de los cirujanos no es compatible con una vida familiar y social plena, desalienta a muchas mujeres para ser especialistas en cirugía general. La cirugía no requiere fuerza física, sino toma de decisiones, capacidad intelectual y habilidades motoras[10].

En el mundo, las mujeres siguen siendo discriminadas en cirugía a pesar de su crecimiento en todos los niveles de formación y laboral, tanto como estudiantes de medicina, médicas generales, residentes de cirugía, cirujanas y académicas[9].

En Corea se graduaron el 38.7% de mujeres de todas las escuelas de medicina con que cuenta, pero solo el 8.9% se graduaron de cirujanas en el año 2020[9]. En países como el Reino Unido, a pesar de que en las escuelas de medicina ingresan el 55% de estudiantes mujeres, solo el 28% optan por una especialidad quirúrgica[3]. En los Estados Unidos de América también ocurre lo mismo en las escuelas de medicina, donde ingresan más del 50% de mujeres, pero en las especialidades quirúrgicas el porcentaje aún es bajo, como urología, ortopedia y cardiotorácica; en cirugía general, se ha incrementado al 35.5%[11]. En México, en 2019, de acuerdo con INEGI e INMUJERES, el porcentaje de mujeres que ingresaron a la carrera de medicina fue del 6.9% de todas las estudiantes universitarias, frente al 6.1% de los estudiantes varones[4]. Así, también en las facultades de medicina un poco más del 50% son mujeres (el 64% en la de la Universidad Nacional Autónoma de México); sin embargo, para la especialidad de cirugía general aún es bajo el porcentaje[12,13].

Otro factor relevante para explicar este fenómeno de la tendencia al incremento de la matrícula femenina es que con la carrera de medicina se obtiene una retribución económica en general de nivel medio, y por ello muchos hombres buscan profesiones que potencialmente sean mejor remuneradas que la medicina; no obstante, esta afirmación debe ser sujeta a estudios posteriores[12].

Heizen et al.[14], en un estudio realizado en 2017, documentaron que había 147,910 médicos especialistas, de los cuales el 37.4% eran mujeres y el 62.6% eran hombres; la relación hombre: mujer fue de 1:7, dependiendo de la especialidad. De acuerdo con la Encuesta Nacional de Ocupación y Empleo del INEGI, al segundo semestre de 2021 México contaba con 305,418 personas ocupadas como médicos, de las cuales el 54% eran hombres y el 46% eran mujeres, entre las edades de 25 a 40 años[15].

En nuestro estudio se observó un incremento paulatino del egreso de la licenciatura de medicina; en la década de 1970 a 1979 solo habían terminado la licenciatura 7 (4.8%) y en la década de 2000 a 2009 fueron 47 (32.2%). Las médicas generales que ingresan a la especialidad de cirugía general son altamente competitivas, ya que casi la mitad (64 [43.32%]) ingresaron en la primera vez que se presentaron al ENARM, y el resto no fue por falta de capacitación, sino probablemente por falta de plazas para su formación, ya que en 2019 el ENARM lo presentaron 42,680 aspirantes y solo había ofertadas 9480 plazas, y de estas, 1646 eran para la especialidad de cirugía general. También se observó en nuestro estudio que, cuantas más veces se presentan al ENARM, menor es el número de médicas que ingresan a la especialidad; en el primer examen fueron 64 (43.8%), en el segundo fueron 40 (48.1%) y en el sexto solo 2 (2.4%) lo pasaron. También se ve cómo se ha incrementado el egreso de las cirujanas a lo largo del tiempo; en la década de 1970 a 1979 solo terminó 1 (0.7%) y para la década de 2010 a 2019 terminaron 58 (39.7%)[16].

En Kuwait se realizó un estudio de microagresiones en el periodo de entrenamiento como residentes, que es otra forma de discriminación, siendo la más frecuente el insulto verbal (67%), seguido de la invalidación[8]. Las microagresiones en México se pueden percibir cuando la residente de cirugía está en entrenamiento y el cirujano adscrito realiza un comentario estereotipado, como que estaría mejor «en la cocina de su casa» en vez de estar en el quirófano, siendo puesta en ridículo frente a todo el equipo quirúrgico[17].

Una de las formas de discriminación de género que tiene la cirujana es por sus pares al no permitirle realizar los mismos procedimientos quirúrgicos. La Dra. Katheryn Dorohty Duncan Anderson, cirujana pediatra, trabajó en el Georgetown University Hospital y solo le asignaron siete casos en 2 años, por lo que decidió cambiar a los hospitales comunitarios, donde en un periodo de 1 año opero 700 casos; cabe hacer mención que fue la primera cirujana en ser presidenta del American College of Surgeons (2005-2006)[11,18]. En nuestro estudio se documentó que no se permitió realizar los mismos procedimientos quirúrgicos a las mujeres que a los hombres, durante el periodo de adiestramiento, en 86 (58.9%), y cuando ya eran cirujanas en 28 (19.2%).

En un estudio de médicos especialistas en México, en 2017, se publicó que el 69% cuentan con certificación; de estos, las mujeres especialistas tienen un porcentaje más alto, del 73.5%[14]. Otra cifra importante al respecto de la certificación, que publicaron Zermeño et al.[19], es que por parte del CMCG hay certificados aproximadamente 10,232 cirujanos, de los cuales se ha calculado que el 10.5% son cirujanas. Esto se corrobora en nuestro trabajo, ya que 119 (81.5%) cirujanas cuentan con la certificación del CMCG, lo cual indica que las cirujanas siguen la normatividad y las hace más competitivas.

Dentro de los datos demográficos se observó que un gran porcentaje de cirujanas nacieron en la Ciudad de México (52 [35.6%]), probablemente debido a que todo el país está centralizado. Pocas emigran a los Estados, ya que 41 (28%) están trabajando en la Ciudad de México, probablemente por la infraestructura que ofrecen los hospitales.

La discriminación hacia las mujeres, en especial en las estudiantes de medicina y las cirujanas, se va a manifestar de diferentes formas de acuerdo con la cultura. En los países altamente desarrollados en igualdad, como Suecia, las estudiantes de medicina aún sufren discriminación de género, en el 41.7%, y quienes la producen son el personal médico en un 33.7%, los pacientes y los familiares de estos en un 29.7%, y otros estudiantes de medicina en un 14.9%. La discriminación se manifiesta en forma silenciosa, ignorándolas, menospreciándolas, no importando lo que digan en un contexto. Otra forma es ponerlas en ridículo. Los pacientes las tratan como un objeto o un juguete, diciéndoles *little girl* o *sweet girl,* no tomándolas en serio como a sus pares[7]. En Chile, a las cirujanas las llaman «señoritas», sin reconocimiento, y también las ignoran, a pesar de que la cirujana vaya a valorar a un paciente para realizarle un procedimiento quirúrgico de urgencias, y si acude con residentes varones les dan el crédito a ellos, como si fueran los cirujanos que van intervenir al paciente[20]. La manifestación de la discriminación en nuestro estudio por parte de los pacientes a las cirujanas en México es denominándolas «señoritas» en 126 (86.3%), como si fueran enfermeras, solicitándoles que realicen actividades de enfermería y no tomándolas en serio.

En un país como México, con tradición sexista milenaria, en nuestro estudio las cirujanas son discriminadas por los pacientes, ya que en el 50.7% no son igual de reconocidas como los cirujanos hombres. Por otro lado, las mismas mujeres dudan de las capacidades de sus congéneres cuando prefieren acudir a consultas médicas con hombres, por desconfiar de las especialistas o cirujanas[10]. En nuestro estudio, las pacientes mujeres desean ser atendidas por cirujanos

hombres en el 43.8%; en contraste, cuando un paciente hombre está en la misma condición, el porcentaje es del 27.4%. Las pacientes mujeres llevan a sus esposos para presionar a la cirujana para su atención en un 30.8%, como una manifestación de sexismo.

El personal de enfermería no considera que las cirujanas sean de mayor jerarquía que ellas, las consideran como pares y desean que realicen las mismas funciones, discriminado a las cirujanas. Cuando un paciente solicita el cómodo a una residente o a una cirujana, y esta informa a las enfermeras, les dicen «¿por qué no se lo lleva usted?», pero si fuera un hombre medico dirían «sí, en un momento se lo llevo»[17]. Otra forma de discriminación por el personal de enfermería es que no considera que la cirujana sea capaz de operar, por lo que, en nuestros resultados, el 59.6% (87), si están en el quirófano y hay un hombre, se dirigirán a él como líder del equipo quirúrgico a pesar de que la cirujana esté programada como tal.

En las academias y asociaciones, pocas cirujanas han alcanzado a representar estas. Así, en la Academia Nacional de Medicina, durante sus 158 años de existencia, solo ha habido una presidenta. En la Academia Mexicana de Cirugía, con sus 89 años de fundada, no ha habido ninguna presidenta. Y en lo que se refiere a la Asociación Mexicana de Cirugía General, con 49 años de existencia, ha habido dos presidentas. Pero este fenómeno no es exclusivo de México; también se observa los Estados Unidos de América, pues en el American College of Surgeons ha habido cuatro presidentas, Kathryn D. Anderson, Patricia J. Numann, Bárbara Lee Bass y Julie A. Freischlang, en los 109 años desde su fundación[18,21-23]. Falta promoción de las mujeres en posiciones directivas, que generalmente son ocupadas por hombres, ya que en nuestro estudio solo el 5% de todas ocupan puestos de mando medio como directoras, subdirectoras y jefas de servicio de cirugía general.

El estado civil es importante para el desarrollo holístico de la cirugía general, porque las puede limitar en cuanto a la actualización académica. En un estudio realizado por Sánchez[24] en 1995, el 40% eran casadas, y en nuestro estudio lo son 52 (35.6%); sin embargo, ha habido un incremento muy importante de unión libre, del 1% antes al actual del 17.1%. Existe un menor porcentaje de solteras, con una reducción del 46% al 29.2%. Ser casadas o en unión libre conlleva múltiples actividades, como el cuidado de los hijos (en caso de tenerlos), mantener limpia la casa o la preparación de la comida, entre otras, que hacen que algunas cirujanas laboren en el turno nocturno para poder ejercer la cirugía. A pesar de las múltiples actividades que ejercen, el 59.5% dicen ser felices y pueden compaginar la cirugía con su vida familiar; sin embargo, el 40.4% dijeron tener dificultad en compaginar las actividades de su hogar con la cirugía y se sienten abrumadas, y algunas manifestaron no tener la oportunidad de acudir a las actividades académicas por falta de tiempo y que no existe la posibilidad de guarderías para el cuidado de sus hijos mientras asisten a cursos o congresos. Las cirujanas casadas sin hijos sí pueden desarrollarse en forma holística.

La autodiscriminación también existe, pues las mujeres en ocasiones se discriminan, dudando de sus propias capacidades y su potencial[10], y en vez de llamarse a sí mismas cirujanas eligen la traducción *women's surgeons* como mujeres cirujanos, cuando en el idioma español está aceptado desde los años 1980 por la Real Academia Española que en todas las profesiones existe el femenino y, por lo tanto, es cirujana. Otras, cuando en vez de llamarlas «doctora» les dicen «señorita», se ponen contentas porque dicen que es «señora», y no se están reconociendo su capacidad intelectual. Por otro lado, a las cirujanas, cuando los pacientes se dirigen como doctora es por su nombre, como a las enfermeras, y no por el apellido, a diferencia de los hombres médicos, a quienes siempre se dirigen por su apellido.

Se deberán elaborar estrategias para que las cirujanas puedan desarrollarse en condiciones de igualdad con los cirujanos hombres, probablemente crear una infraestructura donde las cirujanas puedan tener el cuidado de sus hijos en un lugar seguro mientras ellas se desarrollan en el ámbito quirúrgico, así como contar en los eventos académicos con guarderías, mientras ellas asisten a estos. El camino es aún largo, y se deberá continuar trabajando día a día en ello.

Conclusiones

La discriminación es frecuente en la práctica quirúrgica diaria de las cirujanas en los tres ámbitos: pares, pacientes y personal de enfermería. Este es un trabajo inicial en el que se cuantifica la discriminación de las cirujanas en México. Consideramos que futuros estudios deberían explorar otros aspectos de la discriminación en las cirujanas y si influyen en su desempeño como tales. Se deberán implementar estrategias para evitar la discriminación de las cirujanas, para estar en un ambiente de igualdad.

La percepción de discriminación de las cirujanas durante su entrenamiento y como especialistas requiere muchos pasos para crear cambios de conducta en el personal de salud y en los pacientes, siendo cambios sociales y culturales que llevarán mucho tiempo para sean consideradas como sus pares varones.

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Conflicto de intereses

Todas las autoras declaran que no tienen ningún conflicto de intereses.

Responsabilidades éticas

Protección de personas y animales. Las autoras declaran que para esta investigación no se realizaron experimentos en seres humanos ni en animales.

Confidencialidad de los datos. Las autoras declaran que en este artículo no aparecen datos de pacientes.

Derecho de privacidad y consentimiento informado. Las autoras declaran que en este artículo no aparecen datos de pacientes.

Bibliografía

1. World Economic Forum. Global gender gap report 2021. Disponible en: https://www.weforum.org/publications/global-gender-gap-report-2021/.
2. Dellasega C, Aruma JF, Sood N, Andreae DA. The impact of patient prejudice on minoritized female physicians. Front Public Health. 2022;10:902294.
3. Bellini MI, Graham Y, Hayes C, Zakeri R, Parks R, Papalois V. A woman's place is in theatre: women's perceptions and experiences of working in surgery from the Association of Surgeons of Great Britain and Ireland Women in Surgery Working Group. BMJ Open. 2019;9:1-8.
4. Mujeres y hombres en México 2019. INEGI, Inmujeres. México; 2019.
5. Discr/Cart/002. La discriminación y el derecho a la no discriminación. Comisión Nacional de Derechos Humanos. México; 2012.
6. Tuñon JP. Mujeres en México. México: Planeta; 1987.
7. Velin L, Chew MS, Pompermaier L. Discrimitation in an "equal country" — a survey amongst Swedish final-year medical students. BMC Med Educ. 2022;22:503.
8. Al Rashed A, Al Yousef R, Alhoutl F. Microaggresions: prevalence and perspectives of residents and fellows in post-graduate medical education in Kuwait. Front Surg. 2022;9:9075441-7.
9. Choi J, Lee JE, Choi J, Lee SE. Experiences and perceptions of gender discrimination and equality among Korean surgeons: results of a survey of the Korean surgical society. J Korean Med Sci. 2021;36:e323.
10. Cortes-Flores AO, Fuentes-Orozco C, López-Ramírez MK, Velázquez-Ramírez GA, Farias-Llamas OA, Olivares-Becerra JJ, et al. Medicina académica y general. La mujer en especialidades quirúrgicas. Gac Med Mex. 2005;141:341-4.
11. Emamaullee JA, Lyons MV, Berdan E, Bazzarelli A. Women leaders in surgery: past, present and future. Bulletin ACS. 2012;97:41.
12. Álvarez GLL, Sánchez CVM, Piña BG, Martínez-González A, Zentella MM. Tendencia de la matrícula femenina en la educación superior. Un cuarto de siglo. El caso de la carrera de medicina. Rev Fac Med UNAM. 2006;49:151-5.
13. Facultad de Medicina UNAM. Informe Facultad de Medicina 2016-2020. Disponible en: http://www.facmed.unam.mx/_documentos/informe/2019/INFORME2016-2020-1.pdf
14. Heizen-Martin G, Olmedo Canchola VH, Bazán-Miranda G, Bernard-Fuentes NA, Guizar-Sánchez DP. Los médicos especialistas en México. Gac Med Mex. 2018;154:342-51.
15. Instituto Nacional de Estadística y Geografía (INEGI). Estadísticas a propósito de las personas ocupadas como médicos (23 de octubre). Disponible en: https://www.inegi.org.mx>EAP_Medico2021.
16. Secretaria de Salud. Examen nacional de aspirantes a residencias médicas XLIII: resultados 2019. Disponible en: https://www.gob.mx/salud/prensa/examen-nacional-de-aspirantes-a-residencias-medicas-xliii-224410?idiom=es.
17. Villanueva Lozano M. Discriminación, maltrato y acoso sexual en una institución total: la vida secreta de los hospitales escuela. Revista Interdisciplinaria de Estudios de Género de El Colegio de México. 2019;5:e366. Disponible en: https://estudiosdegenero.colmex.mx/index.php/eg/article/view/366.
18. Anderson KD. Presidential address. Crisis in humanity. Bull Am Coll Surg. 2005;90:10-6.
19. Zermeño GMG, Kobeh JJ, Moreno GA, Jiménez CE, Pantoja MJP, Noyola VH, et al. La certificación en cirugía general a 42 años de su fundación del Consejo Mexicano de Cirugía General. Cirujano General. 2019;41:314-21.
20. Valenzuela MV. La mujer cirujano: ¿todavía un "cuento para niñas rebeldes"? Rev Cir. 2020;72:7-8.
21. Numann P. Presidential address. Stewardship of our profession. Bull Am Coll Surg. 2011;96:24-8.
22. Bass LB. Presidential address. The joy and privilege of a surgical career. Bull Am Coll Surg. 2017;102:12-7.
23. Freischlag JA. Installed as president of ACS. Bull Am Coll Surg. 2021;106:55-7.
24. Sánchez MI. La mujer mexicana dentro de la cirugía en los 90's. Resultados de una muestra en el DF y área metropolitana. Tesina para obtener el Diploma de la especialización en Administración de Recursos Humanos. División de Estudios de Posgrado e Investigación. FCA, UNAM, México; 1995.

ARTÍCULO ORIGINAL

Supervisión de las acciones esenciales de seguridad del paciente en las unidades médicas en una institución de salud

Supervision of essential patient safety actions in medical units in a health institution

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Resumen

Objetivo: *Determinar la importancia de la supervisión de las acciones esenciales de seguridad del paciente (AESP) en las diferentes unidades médicas de los distintos niveles de atención en la Ciudad de México.* **Método:** *La preocupación por la calidad en la atención de salud, entendida como la seguridad de los pacientes, es un aspecto fundamental que involucra a las autoridades y al personal operativo. Se realizaron supervisiones en las diferentes unidades médicas de la Ciudad de México.* **Resultados:** *Se observaron correlaciones positivas entre la supervisión de las AESP y el número de daños, incidentes, eventos y errores existentes en las unidades médicas.* **Conclusiones:** *La supervisión del programa de AESP debe estar destinado a la prevención y gestión de los riesgos en la atención de salud, reconociendo la ocurrencia de eventos adversos como una realidad producto de un trabajo paulatino de todo un proceso de mejora continua.*

Palabras clave: *Acciones esenciales. Seguridad. Paciente.*

Abstract

Objective: *To determine the importance of the supervision of the essential patient safety actions (AESP) in the different Medical Units of the different levels of care in Mexico City.* **Method:** *The concern for quality in health care, understood as the safety of patients, is a fundamental aspect that involves the authorities and operational personnel. Supervisions were carried out in the different medical units of Mexico City.* **Results:** *Positive correlations were observed between the implementation of the AESP and the number of damages, incidents, events and errors existing in the medical units.* **Conclusions:** *The supervision of the AESP program should be aimed at the prevention and management of risks in health care, recognizing the occurrence of adverse events as a reality resulting from a gradual work of a whole process of continuous improvement.*

Keywords: *Essential actions. Safety. Patient.*

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Introducción

Es una realidad que la falta de seguridad en el proceso de atención a la salud produce daño a los pacientes, que en algunas ocasiones ha llegado a cobrar vidas y en otras ha dejado secuelas que llegan a ser muy graves, generando afectaciones, personales, familiares y laborales, cuya remediación representa un alto costo[1].

Los datos más recientes publicados muestran que la falta de seguridad del paciente en los Estados Unidos de América es la tercera causa de muerte en ese país, apoderándose de 220,000 vidas cada año, y en términos económicos se estima un costo de entre 17,000 y 29,000 millones de dólares anuales por eventos adversos prevenibles[2].

En México se estima que un 8% de los pacientes hospitalizados sufren algún tipo de daño y un 2% mueren, siendo la población más afectada la que se encuentra económicamente activa, situación que pone de manifiesto el hueco económico y las repercusiones sociales que tiene y que pocas veces nos detenemos a mirar. La ventana de oportunidad se encuentra en un 62% de los eventos adversos que son prevenibles, y es en ellos en los que se debe incidir para brindar una atención médica más segura.

Para atender este problema se han impulsado diversas acciones en el ámbito internacional, pero no se ha logrado avanzar lo suficiente, a pesar de las campañas, acciones, metas y demás estrategias que se han puesto en marcha[3,4].

La seguridad para el paciente durante los procesos de atención a la salud es prioritaria. De acuerdo con las estimaciones, en México, el 2% de los pacientes hospitalizados mueren y el 8% sufren algún daño a causa de eventos adversos relacionados con la seguridad del paciente[5]. Sin embargo, se calcula que un 62% de este tipo de eventos adversos son prevenibles, lo que plantea un área de oportunidad para brindar atención médica.

La Organización Mundial de la Salud (OMS) estima que, a escala mundial, cada año decenas de millones de pacientes sufren lesiones incapacitantes o mueren como consecuencia de prácticas médicas o atención insegura[6].

De acuerdo con los National Institutes of Health de los Estados Unidos de América, la seguridad del paciente se define como la atención libre de daño accidental, asegurando el establecimiento de sistemas y procesos operativos que minimicen la probabilidad del error y se maximice la probabilidad de su impedimento[7].

La OMS, en 2007, lanzó las soluciones para la seguridad del paciente, con la finalidad de ayudar a reducir el riesgo de daños innecesarios relacionados con la atención sanitaria, mediante la reformulación de los procedimientos de asistencia al enfermo para evitar los errores humanos y hacerlos más seguros. En los países desarrollados se estima que hasta uno de cada 10 pacientes hospitalizados sufre daños asociados al proceso de atención recibida, y en los países en desarrollo la cifra probablemente sea mucho mayor. Lo más importante en materia de seguridad de los pacientes es evitar que sufran daños durante el tratamiento y la atención[8,9].

La Joint Commission International (JCI) identifica, mide y comparte las mejores prácticas relacionadas con la calidad y la seguridad de los pacientes, y establece objetivos internacionales que ayudan a las organizaciones a abordar las áreas más problemáticas relacionadas con la seguridad de los pacientes[10-12].

El Sistema Nacional de Certificación de Establecimientos de Atención Médica (SiNaCEAM) del Consejo de Salubridad General promovió en 2009 las entonces Metas Internacionales de Seguridad del Paciente, las cuales son prioridad para la certificación de establecimientos de atención médica hasta la fecha. El trabajo conjunto con la Dirección General de Calidad y Educación en Salud (DGCES) y las diferentes instituciones de salud generó las actuales ocho acciones esenciales para la seguridad del paciente (AESP). La seguridad del paciente es una premisa fundamental de la calidad de la atención y se ha convertido en una estrategia prioritaria del Sistema Nacional de Salud.

Con el propósito de disminuir la ocurrencia de daños evitables en la atención médica, surge la estrategia «Seguridad del Paciente» establecida por la OMS, y en México se publicó en el Diario Oficial de la Federación del 8 de septiembre de 2017, determinando la obligatoriedad de la implementación para todos los integrantes del Sistema de Salud.

La selección de las acciones es resultado de la evaluación de años de implementación con excelentes resultados en el cuidado de los pacientes, el aprendizaje a base del análisis de los errores y la medición de la percepción de la cultura de seguridad del paciente.

En el Instituto de Seguridad y Servicios Sociales para los Trabajadores del Estado consideramos que

la calidad es la esencia de cualquier tipo de acción o actividad y la encontramos implícita en todas las áreas del desarrollo del individuo y de la sociedad, de tal modo que la salud y el acceso efectivo a los seguros, prestaciones y servicios no es una excepción. A pesar de todos los conocimientos, avances y esfuerzos realizados por la sociedad, la deficiencia de calidad o de garantía de la calidad es una constante que representa un reto para la sociedad misma, pero sobre todo para aquellos países cuyos niveles de desarrollo no han alcanzado estándares deseables y sostenidos que repercutan en su progreso sanitario y social. En contraparte, la ausencia de calidad se manifiesta de diferentes maneras: servicios inefectivos e ineficientes, acceso limitado a los servicios de salud, prestaciones y servicios, incremento de costos, quejas médicas y administrativas, insatisfacción de la población usuaria y de los profesionales de la salud, afectación de la credibilidad en la prestación de servicios por parte de los usuarios, deficiente imagen institucional y, lo peor, pérdidas humanas y financieras.

Las Metas Internacionales de Seguridad del Paciente, actualmente conocidas como Acciones Esenciales de Seguridad del Paciente (AESP) son:

- Correcta identificación del paciente.
- Comunicación efectiva.
- Seguridad en el proceso de medicación.
- Seguridad en los procedimientos.
- Reducción del riesgo de infecciones asociadas a la atención de la salud.
- Reducción del riesgo de daño al paciente por causa de caídas.
- Registro y análisis de eventos centinela, eventos adversos y cuasi fallas.
- Cultura de seguridad del paciente.

Método

Estudio descriptivo, transversal, para verificar la aplicación de las AESP en las unidades médicas de la Ciudad de México en beneficio de los derechohabientes y del propio personal de salud. Se estandarizaron los elementos medibles de verificación de aplicación de las AESP:

- Correcta identificación del paciente.
- Comunicación efectiva.
- Seguridad de los procesos de medicación.
- Seguridad en los procedimientos.
- Reducción del riesgo de infecciones asociadas a la atención.

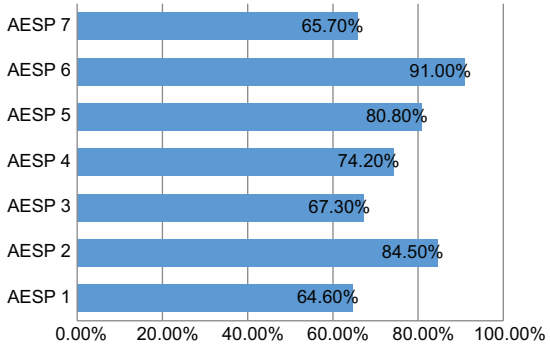

Figura 1. *Apego en clínicas de medicina familiar.*

- Reducción del riesgo de caídas.
- Registro y análisis de eventos adversos.
- Medición de la cultura de seguridad del paciente.

Como estrategia para la supervisión de las AESP, la Subdirección de Calidad de la Dirección Normativa de Supervisión y Calidad realizó la supervisión del personal operativo de las diferentes unidades en el primero, segundo y tercer nivel de atención de las cuatro delegaciones de la Ciudad de México. La primera ronda de seguridad se realizó durante el mes de enero, concluyendo el 31 de diciembre de 2021.

Se siguió una metodología estandarizada durante el trabajo en los procesos y las rondas de seguridad realizadas en las diferentes unidades médicas

Resultados

Al 31 de diciembre de 2021, la totalidad de las unidades médicas de la Ciudad de México concluyeron sus reportes, logrando sensibilizar a la totalidad de su población.

Se observaron correlaciones positivas entre la complejidad de la unidad médica y el apego a las AESP. El grado de apego es inversamente proporcional al nivel de atención médica y no necesariamente por la cantidad de recurso humano.

Los principales factores asociados a la falta de apego fueron la ausencia de supervisión y la carencia de una cultura de seguridad.

Los principales factores asociados a la letalidad fueron la falta de acceso a los servicios de salud, la vulnerabilidad por ingreso y la carencia social.

La evidencia generada debe llevar a decisiones tendentes al mejoramiento de la calidad de vida de la población con carencias y vulnerabilidades sociales, que necesita ser protegida contra las consecuencias de la pandemia de COVID-19.

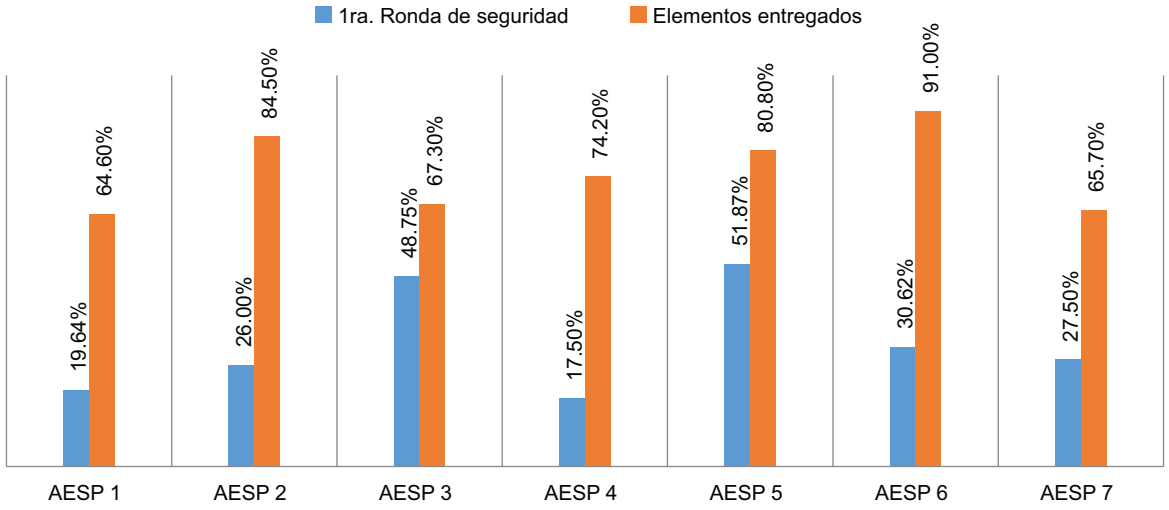

Figura 2. *Porcentaje de cumplimiento de elementos medibles y primera ronda de seguridad.*

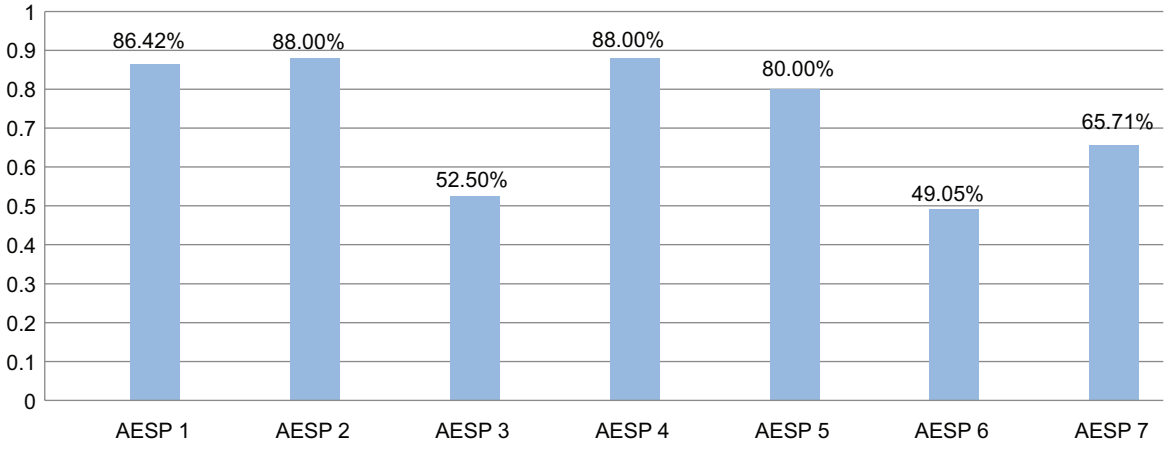

Figura 3. *Porcentaje de apego de clínicas de especialidad y hospitales generales.*

Referente al apego en las diversas clínicas de medicina familiar, en la figura 1 puede verse el porcentaje que alcanzó cada AESP derivado del cumplimiento por cada elemento medible, de lo cual destaca la reducción del riesgo de caídas (AESP 6), seguida por la comunicación efectiva (AESP 2) y la reducción del riesgo de infecciones en la atención a la salud con el programa de higiene de manos (AESP 5), dando un porcentaje por arriba del 80%; el resto de las acciones se estiman en una ascendencia por arriba del 60%.

El porcentaje de cumplimiento de elementos medibles y primera ronda de seguridad (Fig. 2) representó un avance importante, como lo demuestra el avance que se obtuvo tras la implementación del programa de las AESP, donde se observa de manera notoria un incremento significativo por arriba del 50% en cuatro de las acciones (identificación correcta del paciente, comunicación efectiva, procedimientos seguros y reducción de riesgo de caídas) y de un 35% las tres restantes (medicación segura, higiene de manos y notificación de eventos adversos), de acuerdo con los elementos que se deben cumplir por cada acción.

Al analizar el porcentaje de apego de clínicas de especialidad y hospitales generales (Fig. 3), observamos que aún existe un porcentaje inferior al 60% en riesgo de caídas y medicación segura, mientras que el incremento se presenta en un 80% en identificación correcta del paciente, comunicación efectiva,

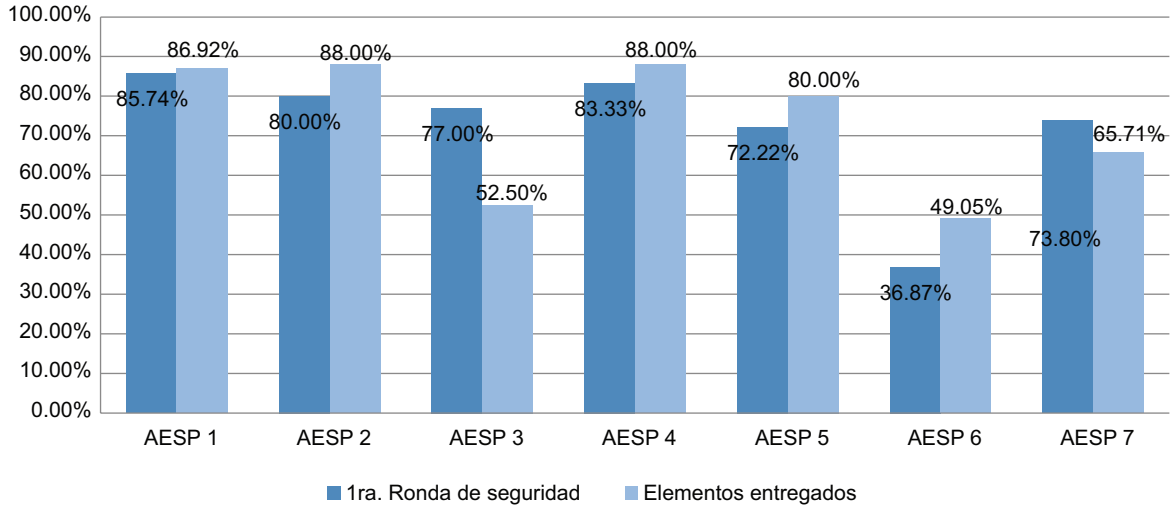

Figura 4. *Porcentaje de cumplimiento de elementos medibles y primera ronda de seguridad.*

procedimientos seguros y reducción del riesgo de infecciones asociadas a la atención a la salud. En un punto intermedio se encuentra la notificación de eventos adversos.

En cuanto a los avances obtenidos posterior a la implementación de las AESP con elementos medibles (Fig. 4), se observa un porcentaje de cumplimiento de elementos medibles y la primera ronda de seguridad por debajo del 90%, teniendo un incremento de un 8%, dado que en la primera ronda de seguridad se encontraban por arriba del 60% y del 80%.

Discusión

El presente trabajo de investigación fue diseñado para enmarcar que las unidades médicas y los profesionales de la salud requieren políticas de salud basadas en la calidad y la seguridad de los pacientes con continuos periodos de monitoreo para valorar los avances obtenidos e instaurar medidas de mejoramiento de la calidad, además de fomentar el desarrollo de una cultura de calidad y seguridad con el fin de concientizar sobre la necesidad de generar un ambiente seguro de calidad en todas las unidades.

Podemos decir que las acciones y los objetivos de la implementación de la AESP son:

- Identificación del paciente: mejorar la precisión de la identificación de pacientes, unificando este proceso en los establecimientos del sector salud, utilizando al menos dos datos que permitan prevenir errores que involucren al paciente equivocado.
- Comunicación efectiva: mejorar la comunicación entre los profesionales de la salud, los pacientes y los familiares, con el fin de obtener información correcta, oportuna y completa durante el proceso de atención y así reducir los errores relacionados con la emisión de órdenes verbales o telefónicas.
- Seguridad en el proceso de medicación: fortalecer las acciones relacionadas con el almacenamiento, la prescripción, la transcripción, la dispensación y la administración de medicamentos, para prevenir errores que puedan dañar a los pacientes.
- Seguridad en los procedimientos: reforzar las prácticas de seguridad ya aceptadas internacionalmente y reducir los eventos adversos para evitar la presencia de eventos centinela derivados de la práctica quirúrgica y de procedimientos de alto riesgo fuera del quirófano.
- Reducción del riesgo de infecciones asociadas a la atención de la salud: ayudar a reducirlas mediante la implementación de un programa integral de higiene de manos durante el proceso de atención.
- Reducción del riesgo de daño al paciente por causa de caídas: prevenir el daño al paciente asociado a las caídas en los establecimientos de atención médica del Sistema Nacional de Salud mediante la evaluación y la reducción del riesgo de caídas.
- Registro y análisis de eventos centinela, eventos adversos y cuasi fallas. Generar información sobre cuasi fallas, eventos adversos y centinela, mediante una herramienta de registro que permita el análisis y favorezca la toma de decisiones para que en el ámbito local se prevenga su ocurrencia.

– Cultura de seguridad del paciente: medir la cultura de seguridad del paciente en el ámbito hospitalario, con el propósito de favorecer la toma de decisiones para establecer acciones de mejora continua del clima de seguridad en los hospitales del Sistema Nacional de Salud.

Conclusiones

Se hace necesario desarrollar e implementar programas continuos e inquebrantables de educación y capacitación, con el objetivo de contar con personal capacitado y entrenado que disponga de conocimientos y formación, actualizando a todos los profesionales de la salud en los procesos de atención de la salud de calidad y seguridad bajo estándares que permitan desarrollar competencias evitando eventos adversos, en un ambiente de confianza en el sistema y de mejora de la comunicación. Resulta evidente que los compromisos de la institución con la calidad son ineludibles, por lo que la implementación de las AESP debe ocupar un lugar relevante en nuestro trabajo diario.

Financiamiento

Los autores declaran no haber recibido financiamiento.

Conflicto de intereses

Los autores declaran no tener ningún conflicto de intereses.

Responsabilidades éticas

Protección de personas y animales. Los autores declaran que para esta investigación no se han realizado experimentos en seres humanos ni en animales.

Confidencialidad de los datos. Los autores declaran que en este artículo no aparecen datos de pacientes.

Derecho a la privacidad y consentimiento informado. Los autores declaran que en este artículo no aparecen datos de pacientes.

Bibliografía

1. Rosenthal MM, Sutclifee KM. Medical error. What do we know? San Francisco: Jossey-Bass, Library of Congress; 2002. p. 3-35
2. Brenan TA, Leape LL, Laird N, Hebert L, Locadio AR, Barnes BA, et al. Incidence of adverse effects and negligence in hospitalized patients: results of the Harvard Medical Practice Study II. N Engl J Med. 1991;324:377-84.
3. Merry S, Mc Call A. Errors, medicine and law. Cambridge: Cambridge University Press; 2001.
4. Aranaz JM, Aibar C, Gea MT, Leon MT. Los efectos adversos en la asistencia hospitalaria. Una revisión crítica. Med Clin (Barc). 2004;123:21-5.
5. Makary MA. Medical error — the third leading cause of death in the US. BMJ. 2016;353:2139.
6. Aranaz JM, Aibar C, Villater J, Ruiz P. Estudio nacional sobre los efectos adversos ligados a la hospitalización. ENEAS 2005. Informe Ministerio de Sanidad; Madrid, España. 2006.
7. El Jardali F Dimassi H, Jamal D, Jaafar M, Hemadeh N. Predictors and outcomes of patient safety culture in hospitals. BMC Health Serv Res. 2011;11:45.
8. Ruelas E, Sarabia O, Tovar W. Seguridad del paciente hospitalizado. México: Instituto de Salud Pública, Médica Panamericana; 2007.
9. Weaver SJ, Lubomksi LH, Wilson RF, Pfoh ER, Martinez KA, Dy SM. Promoting a culture of safety as a patient safety strategy: a systematic review. Ann Intern Med. 2013;158:369-74.
10. Nora CRD, Beghetto MG. Patient safety challenges in primary health care: a scoping review. Rev Bras Enferm. 2020;73:e20190209.
11. Rosen CB, Kelz RR. Processes to create a culture of surgical patient safety. Surg Clin North Am. 2021;101:29-36.
12. Wu AW, Busch IM. Patient safety: a new basic science for professional education. GMS J Med Educ. 2019;36:Doc21.

ARTÍCULO ORIGINAL

Un nuevo dispositivo disector que separa y limpia las estructuras anatómicas durante la cirugía laparoscópica

A novel dissector device that separates anatomic structures during laparoscopic surgery

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Resumen

Objetivo: *Describir un nuevo dispositivo disector en laparoscopia, con una mejor definición de las estructuras anatómicas para obtener una mejor disección,separación y limpieza de las estructuras.* **Método:** *El disector endoscópico DisePad fue diseñado y desarrollado en el servicio de cirugía experimental del Centro Médico Nacional 20 de Noviembre, y patentado ante el Instituto Mexicano de la Propiedad Industrial (registro n.º 3512).* **Resultados:** *El componente más importante del disector es la punta que tiene contacto con los tejidos: es una tela de algodón-poliéster negra impregnada en un gel (patentado) que, al ser sumergido en un termo con solución salina caliente, permite retener la temperatura.* **Conclusiones:** *Este dispositivo ha sido utilizado en 364 procedimientos quirúrgicos por vía laparoscópica y ha demostrado ser útil para visualizar, separar y limpiar estructuras anatómicas sin producir daño por lesión térmica, desgarre, hemorragia ni perforación visceral.*

Palabras clave: *Cirugía laparoscópica. Disector laparoscópico. Separación de estructuras.*

Abstract

Objective: *To describe a novel dissector device useful in laparoscopy, better definition of anatomic structures to have a better dissection, separation, and cleaning of the structures.* **Method:** *The endoscopic dissector DisePad was designed and developed at the experimental surgery department of Centro Médico Nacional 20 de Noviembre, and properly patented at Instituto Mexicano de la Propiedad Industrial (title 3512).* **Results:** *The tip of the device is the most important component, by its direct contact with the different tissues, consists of a cotton-polyester black cloth impregnated with a special gel immersed into a hot saline solution. Once soaked the tip maintains the solution temperature on itself.* **Conclusions:** *This device has been used in 364 laparoscopic procedures demonstrating, its utility to visualize, separate and clean anatomical structures without thermal lesion, tear, hemorrhage or visceral perforation.*

Keywords: *Laparoscopic surgery. Laparoscopic dissector. Separate structures.*

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Introducción

Durante la cirugía laparoscópica puede ser útil contar con un instrumento, un disector endoscópico, que ayude a visualizar, separar y limpiar las estructuras anatómicas sin producir daño a los tejidos y órganos por lesión térmica, desgarre, hemorragia o perforación visceral (Fig. 1). Un disector endoscópico puede ser útil en varios procedimientos quirúrgicos, como colecistectomía[1,2], cualquier técnica de funduplicatura[3], esofagocardiomiotomía[4], colectomía[5], apendicectomía[6], adhesiólisis, histerectomía[7], adrenalectomía[8], etc. Es posible improvisar un disector endoscópico con una pequeña esfera de gasa tomada por una pinza laparoscópica y unida a una sutura larga de seguridad. En el comercio se cuenta con disectores laparoscópicos con esponjas en la punta, fabricados por Ethicon y Fabco, que nosotros como grupo hemos utilizado observando poca eficiencia en la disección; por ser blancos, al saturarse de sangre se pierden píxeles en el monitor, y además no cuentan con un mango ergonómico que facilite su utilización (Fig. 2). Hay disectores laparoscópicos que fueron patentados en los Estados Unidos de América, como el *Laparoscopic Surgical Gauze* (patente USA No. 5,817,121) y el *Christoudias Endodissector* (patente USA No. 6,391,040), que son instrumentos sofisticados, complicados de armar, esterilizables y de alto costo (Fig. 3).

Este artículo describe un nuevo disector endoscópico, el DisePad, diseñado y desarrollado en el servicio de cirugía experimental del Centro Médico Nacional 20 de Noviembre. El dispositivo fue presentado el 23 de septiembre de 2014 ante el Instituto Mexicano de la Propiedad Industrial, y después del análisis y una búsqueda nacional e internacional fue dictaminado como innovación quirúrgica, otorgándole el Registro de Modelo de Utilidad n.º 3512 con fecha 13 de julio de 2016, firmado por la Directora Divisional de Patentes (Fig. 4).

Las desventajas de los disectores laparoscópicos actuales son:

- *Endostik® Bullet* (Fabco): la punta del disector es de algodón hilado blanco, la experiencia es que se desliza resbalando sobre los tejidos sin lograr una disección eficiente, y debido a su color blanco se satura rápidamente de sangre y pierde píxeles en el monitor, y además no cuenta con un mango ergonómico.
- *Laparoscopic Surgical Gauze:* la punta del disector es de tela de algodón, unida a una base metálica que debe atornillarse a una varilla y desecharse después del procedimiento. Tampoco cuenta con mango ergonómico de sostén. La

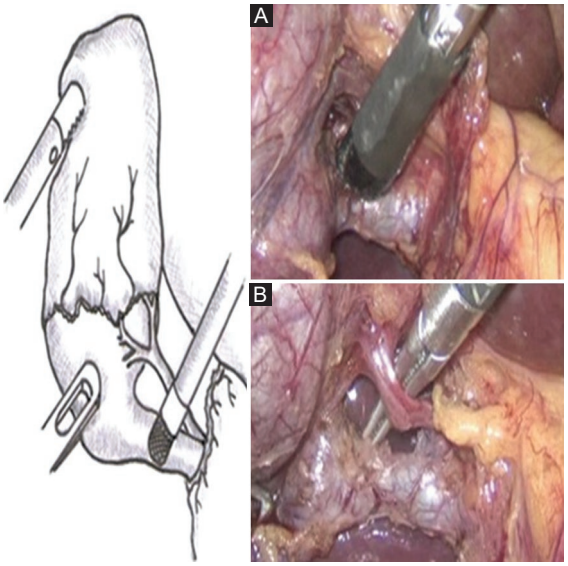

Figura 1. *Disector endoscópico DisePad en colecistectomía laparoscópica.* **A:** *disección del conducto cístico.* **B:** *visión crítica de la disección con el DisePad.*

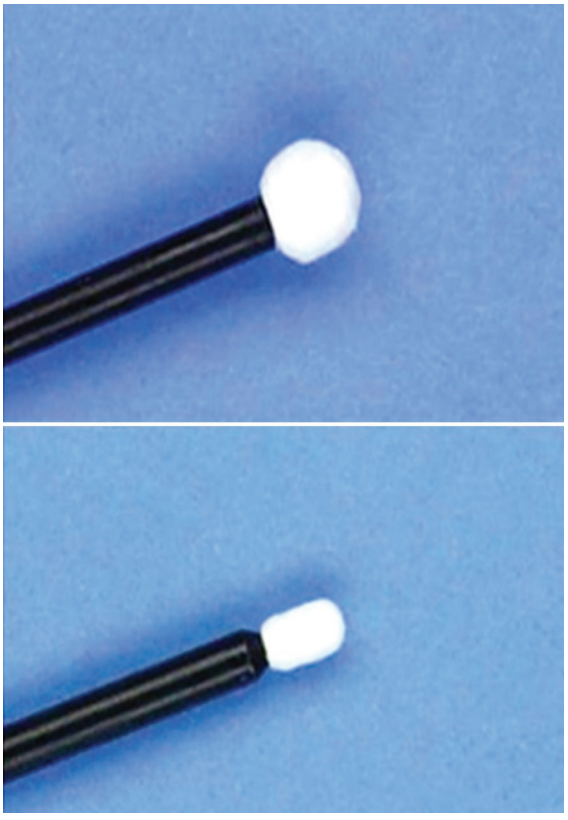

Figura 2. *Disectores laparoscópicos disponibles y patentados.*

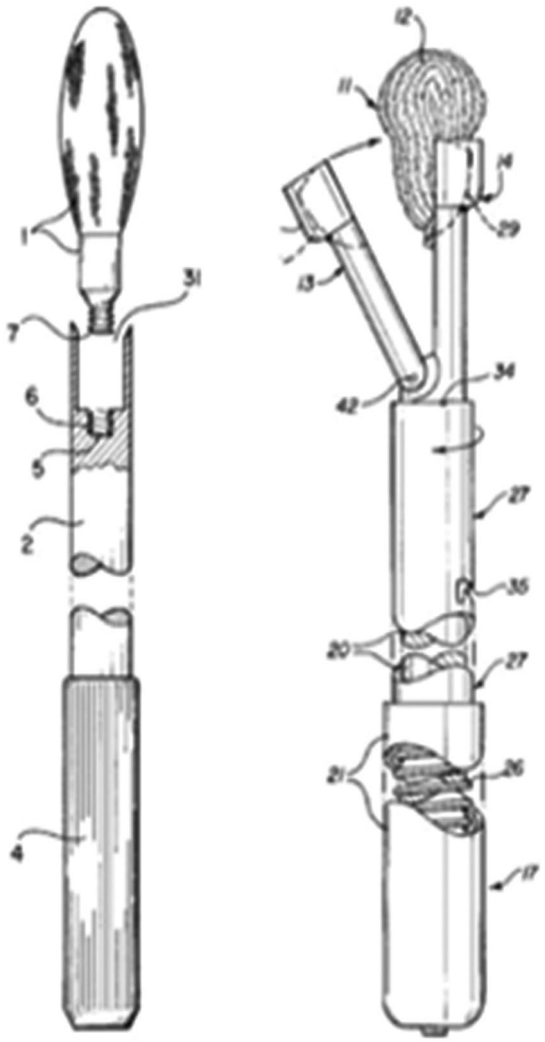

Figura 3. *Instrumentos patentados, sofisticados y de alto costo.*

varilla metálica debe limpiarse y esterilizarse., Tiene un alto costo.

– *Christoudias Endodissector:* con este tipo de disector el inconveniente es que la instrumentista tiene que preparar la punta disectora con gasa y colocar una sutura en la base. Esta punta disectora se introduce en la punta que se cierra con una pinza. Es un instrumento incómodo en la preparación y de elevado costo.

Las ventajas del disector laparoscópico DisePad son:

– Cuenta con una tela negra de algodón-poliéster impregnada en un gel, protegido por la patente, que tiene la particularidad de retener la temperatura al sumergirlo en solución estéril caliente en un termo, y por lo tanto la disección de los tejidos se realiza de forma fácil, con un mínimo sangrado y mayores eficiencia y seguridad.
– El color negro de la tela evita la pérdida de pixeles en el monitor, como sucede con las puntas blancas.
– Tiene un mango ergonómico que permite una manipulación fácil y cómoda por el cirujano.
– La segunda versión el disector tiene la misma punta de tela de algodón-poliéster impregnada en el gel patentado sobre una cinta fijadora *Thermofit,* con la gran ventaja de que es posible colocarlo de forma rápida en cualquier pinza laparoscópica sin afectar el instrumento. Esta segunda versión tiene un menor costo y supone un mayor cuidado al medio ambiente. (Véase en YouTube: *Dise-Pad Dissector Tip placement in reusable dissector forceps*. Luis Padilla MD.)

En nuestro grupo hemos utilizado el DisePad en 246 pacientes sometidos a diversos procedimientos de cirugía laparoscópica y observamos la ayuda y la seguridad que ofrece durante la disección. Estamos desarrollando un estudio comparativo en el procedimiento de colecistectomía laparoscópica con y sin el dispositivo, valorando el tiempo en que se logra tener una «visión crítica» con el conducto y la arteria císticos perfectamente disecados y visibles antes de la colocación de la grapa en cada una de las estructuras anatómicas. Con evidencia de vídeos comparativos, los resultados serán motivo de una futura publicación.

Método

El disector laparoscópico tiene dos versiones. La primera utiliza una varilla de aluminio sólido de 4.5 mm de diámetro y 35 cm de longitud. En uno de los extremos se rebaja a 3 mm de diámetro con una longitud de 2 cm. En el otro extremo se coloca un mango ergonómico de ácido poliláctico (PLA, *polylactic acid*), un material biodegradable, de 7 cm en el eje horizontal y 10 cm en el eje oblicuo. En el extremo rebajado de la varilla de aluminio se coloca una tela negra de algodón-poliéster tratada con un gel patentado que

SE
SECRETARÍA DE ECONOMÍA

Instituto Mexicano de la Propiedad Industrial

TÍTULO DE REGISTRO
DE MODELO DE UTILIDAD NO. 3512

Titular(es): Luis PADILLA SÁNCHEZ

Domicilio: Mayorazgo 130, Cons. 803, Col. Xoco, 03330, Deleg. Benito Juárez, Distrito Federal, MÉXICO

Denominación: DISECTOR ENDOSCÓPICO QUE SEPARA Y LIMPIA LAS ESTRUCTURAS ANATÓMICAS DURANTE LA CIRUGÍA ENDOSCÓPICA

Clasificación: Int.Cl.8: A61B17/32

Inventor(es): LUIS PADILLA SÁNCHEZ

SOLICITUD

Número:	Fecha de presentación:	Hora:
MX/u/2014/000462	23 de septiembre de 2014	10:33

PRIORIDAD

País:	Fecha:	Número:

Vigencia: Diez años

Fecha de Vencimiento: 23 de septiembre de 2024

El registro de referencia se otorga con fundamento en los artículos 1º, 2º fracción V, 6º fracción III, y 59 de la Ley de la Propiedad Industrial.

De conformidad con el artículo 29 de la Ley de la Propiedad Industrial, el presente registro tiene una vigencia de diez años improrrogables, contados a partir de la fecha de presentación de la solicitud y estará sujeta al pago de la tarifa para mantener vigentes los derechos.

Quien suscribe el presente título lo hace con fundamento en lo dispuesto por los artículos 6º fracciones III y 7º bis 2 de la Ley de la Propiedad Industrial (Diario Oficial de la Federación (D.O.F.) 27/06/1991, reformada el 02/08/1994, 25/10/1996, 26/12/1997, 17/05/1999, 26/01/2004, 16/06/2005, 25/01/2006, 06/05/2009,06/01/2010, 18/06/2010, 28/06/2010, 27/01/2012 y 09/04/2012); artículos 1º, 3º fracción V inciso a), 4º y 12º fracciones I y III del Reglamento del Instituto Mexicano de la Propiedad Industrial (D.O.F. 14/12/1999, reformado el 01/07/2002, 15/07/2004, 28/07/2004 y 7/09/2007); artículos 1º, 3º, 4º, 5º fracción V inciso a), 16 fracciones I y III y 30 del Estatuto Orgánico del Instituto Mexicano de la Propiedad Industrial (D.O.F. 27/12/1999, reformado el 10/10/2002, 29/07/2004, 04/08/2004 y 13/09/2007), 1º, 3º y 5º inciso a) del Acuerdo que delega facultades en los Directores Generales Adjuntos, Coordinador, Directores Divisionales, Titulares de las Oficinas Regionales, Subdirectores Divisionales, Coordinadores Departamentales y otros subalternos del Instituto Mexicano de la Propiedad Industrial (D.O.F. 15/12/1999, reformado el 04/02/2000, 29/07/2004, 04/08/2004 y 13/09/2007).

Fecha de expedición: 13 de julio de 2016

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MX/2016/58774

Figura 4. *Título de Registro número 3512, firmado por la Directora Divisional de Patentes, México.*

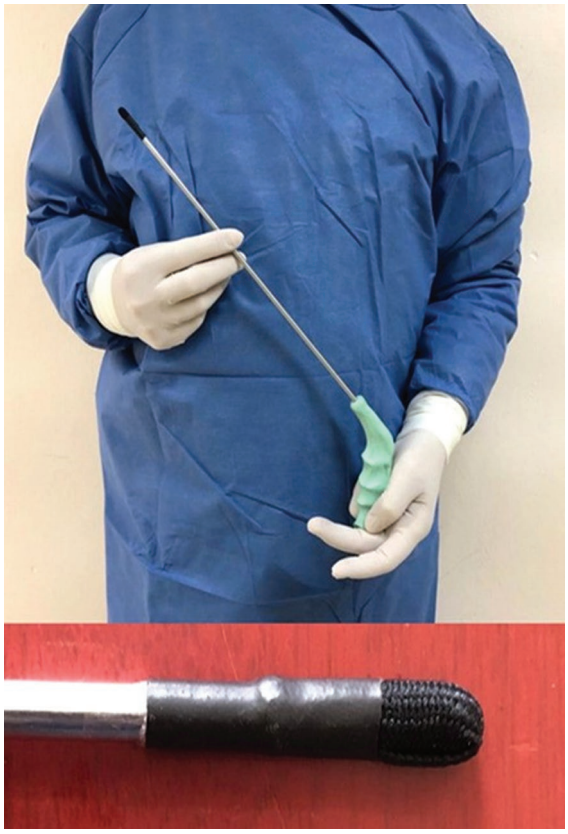

Figura 5. *Con el fin de fijar y retener la tela en la varilla de aluminio se coloca un tubo fijador termocontráctil de color negro (polímero olefínico-polietilénico), y al final se logra una punta disectora de 1 cm de longitud y 5 mm de diámetro.*

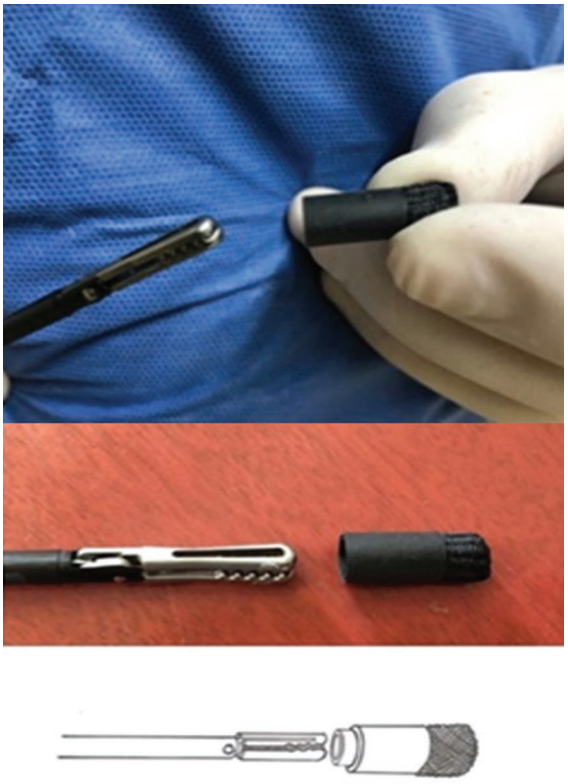

Figura 6. *La segunda versión es solo la punta disectora de tela negra de algodón-poliéster tratada con el mismo gel patentado que retiene alta la temperatura, con la cinta fijadora negra doble, y presenta la ventaja de que se puede colocar en cualquier pinza laparoscópica y desecharla al terminar el procedimiento quirúrgico sin afectar al instrumento.*

permite retener una alta temperatura para mayor eficiencia en la disección de tejidos. Para fijar y retener la tela en la varilla de aluminio se coloca un tubo fijador termocontráctil *(Thermofit)* negro (polímero olefínico-polietilénico), y al final se logra una punta disectora de 1 cm de longitud y 5 mm de diámetro (Fig. 5). La segunda versión es solo la punta disectora de tela negra de algodón-poliéster tratada con el mismo gel patentado que retiene alta la temperatura, y contiene también la cinta fijadora de *Thermofit* negra doble, pero la ventaja es que se puede colocar en cualquier pinza laparoscópica y desecharla al terminar el procedimiento quirúrgico sin afectar al instrumento (Fig. 6). Para fijar la punta disectora en la pinza, la enfermera instrumentista deberá sumergir la punta en el mismo termo con solución salina caliente que se usa para desempañar la lente laparoscópica siempre que el cirujano solicite el instrumento. (Véase en YouTube: *DisePad – Dissector tip placement in reusable dissector forceps*). Se cuenta con dos calibres: uno para trocar de 10 mm y otro para trocar de 5 mm.

Resultados

Desde el primer prototipo utilizado el 23 de septiembre de 2008 en una colecistectomía laparoscópica hasta la fecha, nuestro grupo ha utilizado exitosamente el DisePad en 246 colecistectomías laparoscópicas, 114 funduplicaturas laparoscópicas y 4 colectomías laparoscópicas. (Véase en YouTube: *Laparoscopic cholecystectomy with DisePad, Laparoscopic Nissen fundoplication with DisePad, Laparoscopic sigmoidectomy with DisePad* y *Laparoscopic Right Colectomy with DisePad*.)

Discusión

El dispositivo, al ser calentado en solución salina a 70 °C, diseca y separa los tejidos con mayor facilidad y menor trauma, logrando una mejor visualización de estructuras como los vasos sanguíneos, los conductos o los órganos intraabdominales. La punta disectora,

por ser negra, evita que el color rojo de la sangre produzca pérdida de píxeles en el monitor, como sucede con las gasas blancas impregnadas de sangre. Cuenta con un mango ergonómico de PLA que permite una fácil manipulación de entrada a través del trocar y un fácil movimiento de disección al estar sujeto firmemente a la varilla de aluminio. Es de fácil manufactura, económico y desechable, y además puede ser utilizado como instrumento de tracción quirúrgica. La segunda versión es solo la punta disectora colocada en una pinza laparoscópica, teniendo todas las ventajas anteriores, pero con un concepto de mayor cuidado al medio ambiente al no tener que desechar la varilla y el mango.

Conclusiones

Este dispositivo, diseñado y patentado por el servicio de cirugía experimental del Centro Médico Nacional 20 de Noviembre, cumple con el objetivo de disecar y separar los tejidos con mayor facilidad y menor trauma, logrando una mejor visualización de estructuras como los vasos sanguíneos, los conductos y los órganos intraabdominales. En la primera versión, que cuenta con mango ergonómico, este facilita la manipulación al entrar por el trocar y efectuar con firmeza los movimientos de disección dentro de la cavidad abdominal. La segunda versión tiene la misma eficiencia en la disección, pero como factor agregado se encuentra que, al ser solo una punta disectora adaptable a una pinza laparoscópica reutilizable, simplifica su uso, resulta más económica y protege el medio ambiente al no tener que desechar la varilla de aluminio y el mango de PLA de la primera versión. Es un dispositivo seguro y fácil de usar, y creemos que puede lograr una mejor visualización y disección de las estructuras. Estamos desarrollando un estudio comparativo en colecistectomía laparoscópica con y sin dispositivo, valorando el tiempo en que se logra tener la «visión crítica» con el conducto cístico y la arteria cística perfectamente disecados antes del grapeo. Con evidencia de vídeos comparativos, los resultados serán motivo de otra publicación.

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Responsabilidades éticas

Protección de personas y animales. Los autores declaran que los procedimientos seguidos se conformaron a las normas éticas del comité de experimentación humana responsable y de acuerdo con la Asociación Médica Mundial y la Declaración de Helsinki.

Confidencialidad de los datos. Los autores declaran que en este artículo no aparecen datos de pacientes.

Derecho a la privacidad y consentimiento informado. Los autores declaran que en este artículo no aparecen datos de pacientes.

Bibliografía

1. Reynolds W Jr. The first laparoscopic cholecystectomy. JSLS. 2001;5: 89-94.
2. Coccolini F, Catena F, Pisano M, Gheza F, Fagiuoli S, Di Saverio S, et al. Open versus laparoscopic cholecystectomy in acute cholecystitis. Systematic review and meta-analysis. Int J Surg. 2015;18:196-204.
3. Dallemagne B, Weerts JM, Jehaes C, Markiewicz S, Lombard R. Laparoscopic Nissen fundoplication: preliminary report. Surg Laparosc Endosc. 1991;1:138-43.
4. Cuschieri A, Shimi SM, Nathanson LK. Laparoscopic cardiomyotomy for achalasia. En: Cuschieri A, Buess G, Périssat J, editores. Operative manual of endoscopic surgery. Berlin, Heidelberg: Springer; 1992. p. 298-302.
5. Jacobs M, Verdeja JC, Goldstein HS. Minimally invasive colon resection (laparoscopic colectomy). Surg Laparosc Endosc. 1991;1:144-50.
6. Semm K. Endoscopic appendectomy. Endoscopy. 1983;15:59-64.
7. Seminario J. Histerectomia laparoscópica. (Primer caso Reich 1988). Rev Per Gin Obst. 2009;55:93-9.
8. Gagner M, Lacroix A, Bolté E. Laparoscopic adrenalectomy in Cushing's syndrome and pheochromocytoma. N Engl J Med. 1992;327:1033.

ARTÍCULO ORIGINAL

Discoidectomía lumbar por abordaje tubular vs. *mini-open:* resultados clínico-quirúrgicos

Tubular vs. mini-open lumbar discoidectomy: surgical-clinical outcome

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Resumen

Objetivo: *Evaluar los resultados clínico-quirúrgicos del abordaje tipo tubular en comparación con el mini-open en la discoidectomía lumbar. El abordaje tubular promete reducir el número de días de reposo y una reincorporación más temprana a las actividades diarias y laborales.* **Método:** *Se realizó un estudio de casos y controles de pacientes operados por hernia discal mediante cirugía tubular (casos) o mini-open (controles). Las variables investigadas fueron: dolor radicular y lumbar, sexo, edad, falla en el tratamiento conservador, hernia lumbar de un solo nivel, tiempo quirúrgico, sangrado, tiempo de estancia hospitalaria, persistencia de síntomas, complicaciones, tipo de actividad ocupacional y reinserción a las actividades cotidianas.* **Resultados:** *Se realizaron 100 cirugías y se crearon dos grupos, tubular y mini-open, con 50 pacientes cada uno, con hernia discal de L4-L5 o L5-S1, respectivamente. El nivel más afectado fue L4-L5 (69%). Del total de los casos, se encontró mejoría significativa ($p < 0.05$) a los 15 días posquirúrgicos en la escala EVA y ODI en el grupo tubular con respecto al mini-open. Ocurrieron complicaciones como infección de herida quirúrgica, durotomía y dolor persistente.* **Conclusiones:** *El abordaje tubular es una opción segura y efectiva para hernias discales del segmento lumbar, y reduce los tiempos quirúrgicos, el sangrado y el tiempo de reinserción a las actividades cotidianas del paciente.*

Palabras clave: *Discoidectomía. Cirugía tubular. Mini-open. Cirugía lumbar.*

Abstract

Objective: *To evaluate the clinical-surgical results of the tubular vs. mini-open approach in lumbar discoidectomy. The tubular approach promises to reduce the number of rest days and an earlier return to daily activities and work.* **Method:** *A case-control study of patients operated on for disc herniation using tubular surgery (case) and mini-open (control) was carried out. The variables investigated were as follow: radicular and lumbar pain, sex, age, failure in conservative treatment, single-level lumbar hernia, surgical time, bleeding, length of hospital stay, persistence of symptoms, complications, occupational activity, and reintegration into everyday activities.* **Results:** *Through 100 surgeries performed, two groups were created, tubular and mini-open, with 50 patients each, with L4-L5 or L5-S1 disc herniation, respectively. The most affected level was L4-L5 (69%). Of the total cases, a significant improvement was found ($p < 0.05$) at 15 postoperative days in the VAS and ODI scale in the tubular group with respect to mini-open. Complications such as surgical wound infection, durotomy, and persistent pain occurred.* **Conclusions:** *The tubular approach is a safe and effective option for herniated discs of the lumbar segment, and reduces surgical times, bleeding, and the time of reinsertion to daily activities of the patient.*

Keywords: *Discectomy. Tubular surgery. Mini-Open. Lumbar Surgery.*

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Introducción

Actualmente, la lumbalgia afecta al 85% de las personas en algún momento de su vida. Cada año se generan alrededor de 300,000 consultas en México por esta condición. Se considera la primera causa de consulta en edad laboral, y la incomodidad y la molestia generadas pueden conducir a limitación funcional e incapacidad de 10 días o más. Todo esto se traduce en una mala calidad de vida[1,2].

La degeneración de los discos intervertebrales se produce por una serie de factores que tienen como desenlace dolor lumbar e inestabilidad en la anatomía axial de la columna. Los factores que intervienen pueden ser estructurales, bioquímicos y biomecánicos. Debido al proceso de degeneración discal se encuentra un decrecimiento anormal de la vasculatura que irriga al núcleo pulposo y al anillo fibroso. Este estrés provocado llega a formar tejido de granulación que activa citocinas, interleucinas (IL-1β, IL-6, IL-8) y prostaglandinas (PGE2). Por último, los mediadores inflamatorios y los nociceptores bajan el umbral del dolor. Con esto se agrega hipermovilidad del disco intervertebral y se altera la biomecánica lumbar, así como las articulaciones facetarias, los músculos paraespinales y los ligamentos[3-5].

El proceso degenerativo inicia en los niveles que tienen mayor movimiento y carga/soporte de peso axial. Los niveles mayormente afectados son L5-S1 y L4-L5. Entendemos como hernia discal la salida del núcleo pulposo de su localización normal. Esta migración podrá ser hacia la periferia, a través de un anillo fibroso roto, o craneocaudal (hernias de Schmorl). Los niveles más frecuentemente implicados son L4-L5 y L5-S1[1,6,7].

Desde el año 1829 se tiene registro de la primera laminectomía, realizada por A.G. Smith en los Estados Unidos de América. La forma convencional para resolver una hernia discal de un solo nivel permanece vigente. Consiste en una laminectomía convencional con abordaje en la línea media para eliminar la apófisis espinosa, poder acceder al conducto y realizar la discectomía del disco afectado. Desde entonces, las técnicas y las formas de abordar esta patología han evolucionado, desde el uso de retractores pequeños para realizar una microdiscectomía realizado por Williams hasta el uso de dilatadores tubulares introducidos por Faubert y Caspart en 1991. En el año 2002, al acceso a microscopios transquirúrgicos se sumó a perfeccionar la técnica tubular gracias al grupo de Fessler y Palmer[8].

El abordaje *mini-open* para el tratamiento quirúrgico de hernias de discos lumbares se remonta a los inicios de los años 1990. Consiste en realizar una incisión en la línea media, de una longitud promedio de 3-5 cm, e involucra laminectomía bilateral amplia con facetectomía medial con o sin foraminotomía[9]. Las ventajas que la literatura mundial menciona para el abordaje tipo cirugía mínimamente invasiva de la columna vertebral (MISS, por sus siglas en inglés) tubular respecto al acceso clásico convencional son que se lesiona menos el grupo de músculos paraespinales y con ello la inestabilidad que pueda conducir a una listesis futura, con reducción del tiempo quirúrgico, del sangrado (< 50 ml) y del dolor lumbar y radicular que presenta el paciente, el tiempo de estancia intrahospitalaria, las complicaciones quirúrgicas (debido al menor diámetro de la herida quirúrgica) y el tiempo de reinserción laboral y a las actividades cotidianas del paciente[8-15]. En el presente artículo se discuten las diferencias significativas entre el abordaje tubular y el abordaje *mini-open,* así como los resultados clínicos.

Método

En este estudio de casos y controles se analizaron 100 pacientes (50 por grupo) con hernia discal tratados mediante cirugía tubular (casos) o *mini-open* (controles) (Figs. 1 y 2). Todos los pacientes fueron intervenidos por un mismo equipo quirúrgico en el periodo comprendido de enero de 2015 a enero de 2021. Las variables de estudio fueron sexo, edad, uso de escalas EVA (Escala Visual Análoga)[16-18] y ODI *(Oswestry Disability Index)*[7,19-21] para evaluar el dolor y la incapacidad, localización de la hernia, tipo de abordaje quirúrgico (tubular o *mini-open*), promedio de sangrado, tiempo quirúrgico, complicaciones posquirúrgicas, tiempo promedio de estancia hospitalaria y actividad ocupacional de los pacientes. La escala EVA, descrita por Hyanes y Patterson[16,17], va de 1 al 10, siendo 0 sin dolor y 10 dolor máximo. La escala ODI, descrita en 1976 por John O'Brien[18,19] para evaluar el dolor crónico, gradúa de 0 a 50 con las siguientes categorías: 0-10 mínimo, 11-20 moderado, 21-30 intenso, 31-40 incapacidad y 41-50 disfunción máxima. Se establecieron los siguientes momentos de evaluación y reevaluación del paciente con ambas escalas: revisión prequirúrgica y luego posquirúrgica a las 24 horas, 15 días, 1 mes, 3 meses y 6 meses.

Abordaje tubular

Bajo anestesia general, el paciente es colocado en posición prono-supina en una mesa quirúrgica

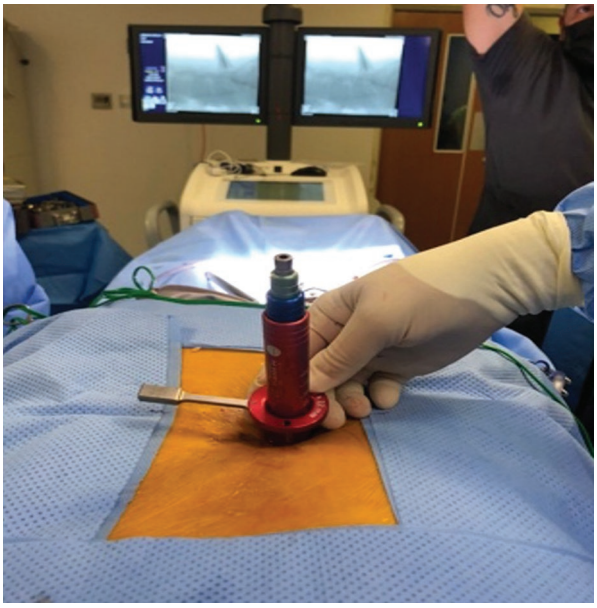

Figura 1. *Abordaje con técnica tubular.*

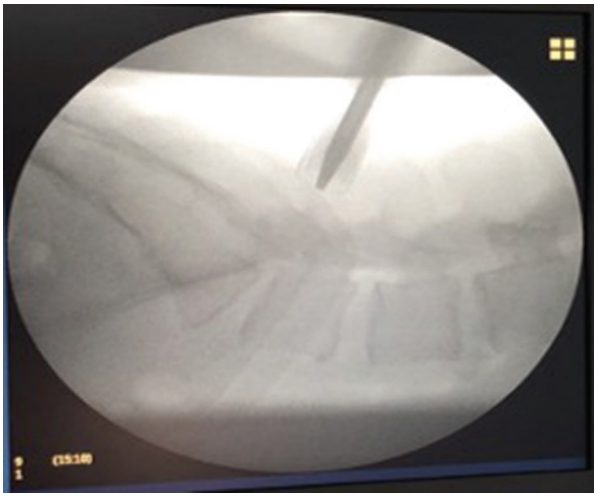

Figura 3. *Vista lateral L5-S1 por fluoroscopía.*

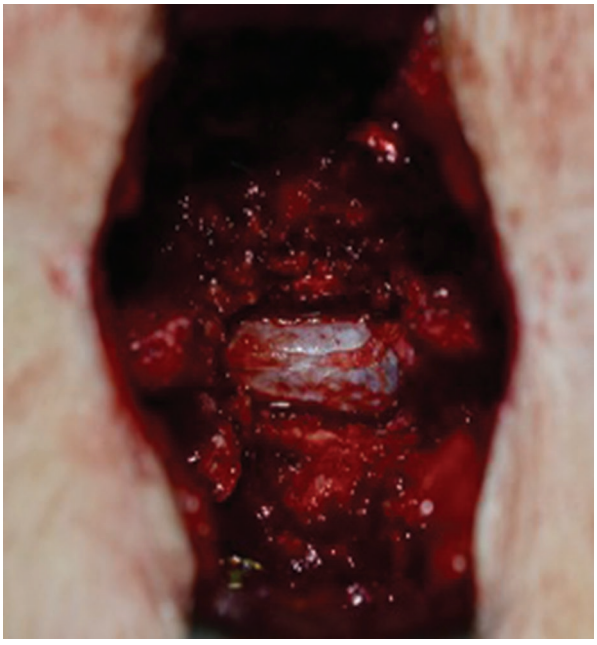

Figura 2. *Abordaje con técnica mini-open.*

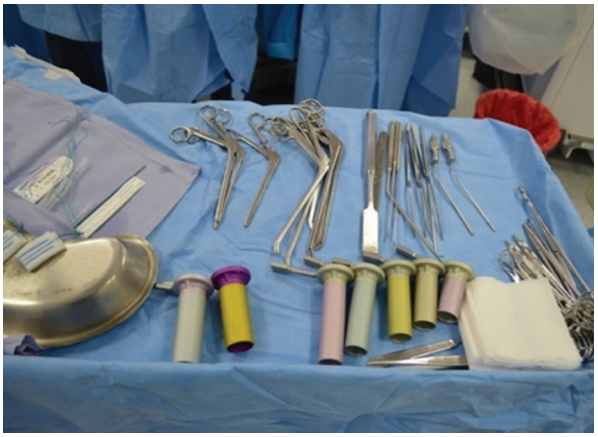

Figura 4. *Sistema de dilatación tubular Phantom.*

radiolúcida (Steris Amsco 3085). Después del protocolo quirúrgico de asepsia-antisepsia se realiza una incisión lineal paramedial (1 cm) de L5-S1, con previa visualización por fluoroscopía (Siemens-Cios Alpha) (Fig. 3). La incisión se profundiza más allá del tejido celular subcutáneo, el cual se incide con electrocauterio. Se localiza la fascia muscular ileocostal y se incide 1 cm lateral a la línea media, en donde con ayuda de dilatadores tubulares se inserta en los músculos erectores de la columna (*multifidus* y *longissimus*), hasta colocar un canal de trabajo de 20 mm (PHANTOM Tubular ML-2008) (Fig. 4) y exponer la lámina de L4-L5 o L5-S1. Se coloca un microscopio transquirúrgico Pentero 900 Zeiss. Se inicia la laminectomía de L4-L5 o L5-S1 con ayuda de craneotomo y Kerrison, así como flavectomía, lateralización medial del nervio espinal y exposición del disco intervertebral. Se realizan discectomía y foraminotomía, se verifica la hemostasia y se cierra la fascia muscular ileocostal lumbar con puntos en cruz con Vicryl® del n.º 1 (Fig. 5). Se infiltra el tejido celular subcutáneo con ropivacaína (7.5 mg/ml, 20 ml). Se afronta el tejido

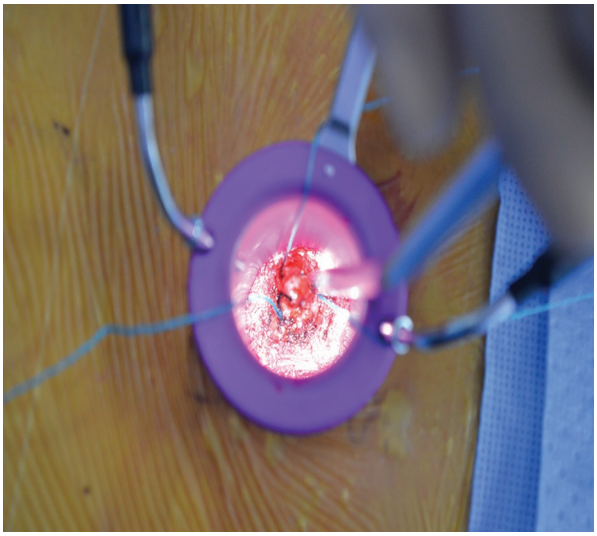

Figura 5. *Acceso tubular con fuente de luz.*

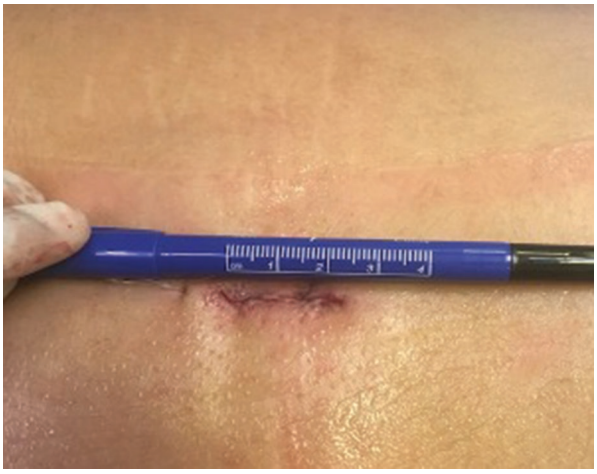

Figura 6. *Herida quirúrgica con la técnica tubular.*

celular subcutáneo con puntos simples separados con Vicryl® 2-0 y la piel con puntos simples con nailon 2-0 (Fig. 6).

Abordaje mini-open

Bajo anestesia general, el paciente es colocado en posición prono-supina en una mesa quirúrgica radiolúcida (Steris Amsco 3085). Después del protocolo quirúrgico de asepsia-antisepsia, se realiza una incisión en la línea media (1 cm) de L4-L5 o L5-S1, con previa visualización por fluoroscopía (Siemens-Cios Alpha). La incisión se profundiza mas allá del tejido celular subcutáneo, el cual se incide con electrocauterio. Se localiza la fascia muscular ileocostal y se incide en forma de C. Se procede a la disección muscular (interespinosos, intertransverso y espinosos, así como rotadores, multífidos y semiespinosos) hasta exponer las apófisis espinosas con ayuda de un separador de hemiláminas en L4-L5 o L5- S1. Se coloca un microscopio Pentero 900 y se procede a realizar laminotomía de L5 con ayuda de craneotomo y Kerrison, así como flavectomía, lateralización medial de nervio espinal y exposición del disco intervertebral. Se realizan discectomía y foraminotomía, se verifica la hemostasia y se cierra la fascia muscular ileocostal lumbar con puntos cruzados con Vicryl® 1. Se infiltra el tejido celular subcutáneo con ropivacaína (7.5 mg/ml, 20 ml). Se afronta el tejido celular subcutáneo con puntos simples separados con Vicryl® 2-0 y la piel con puntos simples de nailon 2-0.

Resultados

De los 100 pacientes estudiados, 45 fueron mujeres (45%) y 55 hombres (55%). La edad promedio fue de 41 años para las mujeres y de 40 años para los hombres; el rango de edad fue de 18 a 60 años, con una media de 41 años. Los dos niveles con mayor incidencia de hernias discales en la columna lumbar fueron L4-L5 y L5-S1. Hubo 33 pacientes (66%) con hernia en L4-L5 en el grupo *mini-open* y 36 pacientes (72%) en el grupo de abordaje tubular. Con hernia en L5-S1 se encontraron 17 pacientes (44%) en el grupo *mini-open* y 14 pacientes (28%) en el grupo de abordaje tubular. Implementando la escala EVA en la valoración prequirúrgica, en el grupo tubular se obtuvo una media de 8.40 y en el grupo *mini-open* de 8.56. A las 24 horas de la cirugía se evidenció un decremento a 3.12 en el grupo tubular y a 3.30 en el grupo *mini-open*. A los 15 días siguió el decremento del dolor a 1.48 en el grupo tubular y a 2.24 en el grupo *mini-open*. Al mes, 1.2 en el grupo tubular y 1.56 en el grupo *mini-open*. A los 3 meses, 0.94 en el grupo tubular y 1.2 en el grupo *mini-open*. En la última evaluación, a los 6 meses, 0.68 en el grupo tubular y 0.9 en el grupo *mini-open*. Con la escala ODI, en el grupo tubular se obtuvo una media de 33.14 y en el grupo *mini-open* de 34-54. A las 24 horas de la cirugía se encontró un decremento a 6.04 en el grupo tubular y a 6.70 en el grupo *mini-open*. A los 15 días, continuó una disminución del dolor a 10.08 en el grupo tubular y 15.40 en el grupo *mini-open*. Al mes, 6.22 en el grupo tubular y 7.60 en el grupo *mini-open*. A los 3 meses, 5.92 en el grupo tubular y 6.38 en el grupo *mini-open*. En la

última evaluación, a los 6 meses, 4.82 en el grupo tubular y 5.78 en el grupo *mini-open*.

El tiempo quirúrgico promedio fue de 53.50 minutos en el grupo tubular y de 60.70 minutos en el grupo *mini-open*. La media de sangrado transquirúrgico fue de 38.90 ml en el grupo tubular y de 70.90 ml en el grupo *mini-open* ($p > 0.05$). Entre las complicaciones que se presentaron, se observó un triple empate de frecuencia en el grupo tubular: dolor residual persistente en el 2% (n = 1), dehiscencia de herida en el 2% (n = 1) e infección de la herida quirúrgica en el 2% (n = 1). En el grupo *mini-open* se observó, en primer lugar de frecuencia, infección de la herida quirúrgica en el 6% (n = 3), y en segundo lugar durotomía, en el 2% (n = 1), que se resolvieron de manera transquirúrgica con puntos de sutura y sellado posterior con tejido muscular y aplicación de sello biológico de adhesivo tisular (Tisseel®). Estos pacientes se mantuvieron en vigilancia y reposo absoluto, presentando resolución y mejoría total una semana posterior al procedimiento quirúrgico, corroborado por ultrasonido Doppler de la región lumbar descartando colección de líquido cefalorraquídeo.

El promedio del tiempo de estancia hospitalaria fue de 20.64 horas para el grupo tubular y de 33.84 horas para el grupo *mini-open*.

En relación con la ocupación, encontramos que en el grupo tubular el 74% (n = 37) realizaban actividades de oficina, el 22% (n = 11) se dedicaban a la construcción y el 6% (n = 3) eran estudiantes, mientras que en el grupo *mini-open* el 76% (n = 38) realizaban actividades de oficina, el 12% (n = 6) se dedicaban a la construcción y el 12% (n = 6) eran estudiantes (Tabla 1).

Tabla 1. Resultados clínico-quirúrgicos

Variables de estudio	Abordaje tubular	Abordaje mini-open
Pacientes	n = 50	n = 50
Hombres	n = 31 (62%)	n = 24 (48%)
Mujeres	n = 19 (38%)	n = 26 (52%)
Nivel quirúrgico		
L4-L5	n = 36 (72%)	n = 33 (66%)
L5-S1	n = 14 (28%)	n = 17(44%)
EVA		
Prequirúrgico	8.40	8.56
Posquirúrgico (24 h)	3.12	3.30
15 días	1.48	2.24
1 mes	1.2	1.56
3 meses	0.94	1.20
6 meses	0.68	0.90
ODI		
Prequirúrgico	33.14	34.54
Posquirúrgico (24 h)	6.04	6.70
15 días	10.08	15.40
1 mes	6.22	7.60
3 meses	5.92	6.38
6 meses	4.82	5.78
Sangrado	38.90 ml	70.90 ml
Estancia hospitalaria	20.64 h	33.84 h
Tiempo quirúrgico	53.50 min	67.70 min
Actividad del paciente		
Oficina	n = 38 (76%)	n = 37 (74%)
Construcción	n = 6 (12%)	n = 11 (22%)
Estudiante	n = 6 (12%)	n = 2 (4%)
Complicaciones		
Dolor persistente	n = 0 (0%)	n = 1 (2%)
Dehiscencia de herida	n = 1 (2%)	n = 0 (0%)
Durotomía	n = 1 (2%)	n =0 (0%)
Infección de herida	n = 1 (2%)	n = 3 (6%)
Sin complicaciones	n = 47 (94%)	n = 46 (92%)

Discusión

El abordaje quirúrgico para la resolución de hernia de disco en un solo nivel lumbar con técnicas de mínima invasión, como la tubular y la *mini-open,* está descrito desde 1991. La mínima invasión ha abierto un panorama diverso para la pronta recuperación y la reinserción del paciente a sus actividades diarias[8]. En la búsqueda continua de poder ofrecer al paciente un procedimiento seguro, actual y que implique un abordaje de menor impacto a las estructuras anatómicas de la columna lumbar y su reinserción pronta a las actividades que desarrollaba, se evaluaron dos abordajes quirúrgicos para identificar el que ofrece los mejores resultados clínico-quirúrgicos.

Como fue descrito por Grainger & Allison[22] y Overdevest GM et al[23], este estudio no encontró una diferencia significativa a los 6 meses de seguimiento posoperatorio entre los abordajes tubular y *mini-open*. Sin embargo, se identificaron las siguientes diferencias que nos parece relevante resaltar. Los resultados de evaluación de dolor posquirúrgico a los 15 días, realizados con las escalas EVA y ODI, demostraron una diferencia estadísticamente significativa ($p < 0.05$) en el grupo tubular en comparación con el grupo *mini-open,* pero no hubo diferencia en el seguimiento a 1, 3 y 6 meses. Esta diferencia coincide con los estudios arriba mencionados[23,24]. Es decir, después del mes de seguimiento, los dos grupos no presentan una diferencia independientemente del abordaje quirúrgico.

Uno de los factores cruciales en el transquirúrgico en ambos tipos de abordaje es el sangrado. Aquí se encontró una diferencia significativa ($p < 0.05$), siendo menor el sangrado en el grupo tubular que en el grupo *mini-open,* como ha sido reportado por Grainger & Allison[22] y Overdevest GM et al[23]. De la misma manera, se encontró una diferencia significativa en los tiempos quirúrgicos al comparar el grupo tubular con el grupo *mini-open* ($p < 0.05$). Se esperaría una diferencia entre las dos técnicas debido a la experiencia del cirujano e incluso a la preferencia por alguna de ellas. En cuanto a la estancia intrahospitalaria, aunque sin diferencia significativa ($p > 0.05$), fue menor en el grupo tubular que en el grupo *mini-open*.

Por otro lado, no encontramos diferencia significativa en las complicaciones. En el grupo mini-open la complicación más prevalente fue la infección del sitio quirúrgico, que fue resuelta con antibioticoterapia. En el grupo tubular, el dolor persistente, la dehiscencia de herida quirúrgica y la durotomía fueron las complicaciones más frecuentes y pudieron haber influido en la diferencia de estancia hospitalaria del paciente, justo como ha sido descrito en la literatura[22,23].

Conclusiones

Actualmente persiste la búsqueda de la técnica quirúrgica más adecuada por abordaje de mínima invasión para corregir patologías de hernia discal lumbar, siendo las técnicas tubular y *mini-open* las dos con mayor beneficio clínico. Los resultados obtenidos en el presente estudio coinciden con la literatura mundial, habiendo obtenido una mejoría significativa del dolor a los 15 días de la cirugía, tanto en la escala EVA como en la ODI, con el abordaje tubular con respecto al *mini-open,* y sin diferencia significativa alguna en las revisiones clínicas subsecuentes. Ambas técnicas obtuvieron resultados similares, siendo ambas seguras y confiables.

Limitaciones del estudio

Dentro de las limitaciones del presente artículo cabe señalar el tiempo de seguimiento de los pacientes, que fue de 6 meses, a diferencia de lo realizado por Grainger & Allison[22] y Overdevest GM et al[23], quienes en estudios de largo seguimiento no encontraron diferencias significativas en los pacientes intervenidos por abordaje tubular. A diferencia de los trabajos antes mencionados, las intervenciones fueron realizadas por un mismo equipo quirúrgico, lo cual pudiera representar una mejora en los tiempos quirúrgicos del abordaje tubular. No se dio seguimiento al porcentaje de pacientes con reincidencia de hernia discal de los niveles intervenidos debido a que el periodo de seguimiento fue menor que el mencionado por las publicaciones antes descritas como tiempo de probable reincidencia.

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Conflicto de intereses

Los autores declaran no tener conflicto de intereses.

Responsabilidades éticas

Protección de personas y animales. Los autores declaran que para esta investigación no se han realizado experimentos en seres humanos ni en animales.

Confidencialidad de los datos. Los autores declaran que han seguido los protocolos de su centro de trabajo sobre la publicación de datos de pacientes.

Derecho a la privacidad y consentimiento informado. Los autores han obtenido el consentimiento informado de los pacientes y/o sujetos referidos en el artículo. Este documento obra en poder del autor de correspondencia.

Bibliografía

1. Smith LJ, Nerurkar NL, Choi K-S, Harfe BD, Elliott DM. Degeneration and regeneration of the intervertebral disc: lessons from development. Dis Model Mech. 2011;4:31-41.
2. IMSS. En el IMSS, más de 300 mil consultas por lumbalgia en 2017. Disponible en: https://imss.gob.mx/prensa/archivo/201810/246.
3. Gause PR, Godinsky RJ, Burns KS, Dohring EJ. Lumbar disk herniations and radiculopathy in athletes. Clin Sports Med. 2021;40:501-11.
4. Kim H, Hong JY, Lee J, Jeon W-J, Ha I-H. IL-1 promotes disc degeneration and inflammation through direct injection of intervertebral disc in a rat lumbar disc herniation model. Spine J. 2021;21:1031-41.
5. Modic MT, Ross JS. Lumbar degenerative disk disease. Radiology. 2007;245:43-61.
6. Maroon JC. Current concepts in minimally invasive discectomy. Neurosurgery. 2002;51(Suppl 2):S2-137-45.

7. Ropper AH, Zafonte RD. Sciatica. N Engl J Med. 2015;372:1240-8.
8. Yoon JW, Wang MY. The evolution of minimally invasive spine surgery: JNSPG 75th Anniversary Invited Review Article. J Neurosurg Spine. 2019;30:149-58.
9. Deyo RA, Mirza Sk. Clinical practice. Herniated lumbar intervertebral disk. N Engl J Med. 2016;374:1763-72.
10. Bridwell KH, Gupta M, editores. Bridwell and DeWald's textbook of spinal surgery. 4th ed. Philadelphia, PA: Lippincott Williams and Wilkins; 2019.
11. Oppenheimer JH, DeCastro I, McDonnell DE. Minimally invasive spine technology and minimally invasive spine surgery: a historical review. Neurosurg Focus. 2009;27:E9.
12. Lau D, Han SJ, Lee JG, Lu DC, Chou D. Minimally invasive compared to open microdisectomy for lumbar disc herniation. J Clin Neurosci. 2011;18:81-4.
13. Palmer S. Use of a tubular retractor system in microscopic lumbar discectomy: 1 year prospective results in 135 patients. Neurosurg Focus 2002;13:E5.
14. Clark AJ, Safaee MM, Khan NR, Brown MT, Foley KT. Tubular microdiscectomy: techniques, complication avoidance, and review of the literature. Neurosurg Focus. 2017;43:E7.
15. Bisson EF, Rajakumar DV, Mummaneni PV. Introduction. Minimally invasive spine surgery. Neurosurg Focus. 2017;43:E1.
16. Delgado DA, Lambert BS, Boutris N, McCulloch PC, Robbins AB, Moreno MR, et al. Validation of digital visual analog scale pain scoring with a traditional paper-based visual analog scale in adults. J Am Acad Orthop Surg Glob Res Rev. 2018;2:e088.
17. Zanoli G, Strömqvist B, Jönsson B. Visual analog scales for interpretation of back and leg pain intensity in patients operated for degenerative lumbar spine disorders. Spine. 2001;26:2375-80.
18. Huskisson EC. Measurement of pain. Lancet. 1974;304:1127-31.
19. Virk S, Vaishnav AS, Mok JK, McAnany S, Iyer S, Albert TJ, et al. How do high preoperative pain scores impact the clinical course and outcomes for patients undergoing lumbar microdiscectomy? J Neurosurg Spine. 2020;33:772-8.
20. Kim D. Surgical anatomy and techniques to the spine: expert consult. 2nd ed. London: W.B. Saunders; 2013.
21. Roberti F, Arsenault KL. Minimally invasive tubular laminectomies in multilevel spine surgery — an illustrative case-based review of techniques and combined approaches. J Spine Surg. 2021; 7:83-99.
22. Adam A, editor. Grainger & Allison's Diagnostic radiology. 6th ed. London: Churchill Livingstone; 2014.
23. Overdevest GM, Peul WC, Brand R, Koes BW, Bartels RH, Tan WF, et al.; Leiden-The Hague Spine Intervention Prognostic Study Group. Tubular discectomy versus conventional microdiscectomy for the treatment of lumbar disc herniation: long-term results of a randomised controlled trial. J Neurol Neurosurg Psychiatry. 2017;88:1008-16.

ARTÍCULO ORIGINAL

Comparación de la calidad de vida tras el tratamiento radical en cáncer de próstata: prostatectomía radical frente a radioterapia externa

Comparison of quality of life after radical treatment in prostate cancer: radical prostatectomy versus external radiotherapy

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Resumen

Objetivo: *Determinar y comparar los resultados funcionales y de calidad de vida de pacientes con cáncer de próstata tratados con intención curativa durante el año 2015 en nuestro centro.* **Método:** *Se incluyeron 77 pacientes sometidos a prostatectomía radical (PR) o radioterapia externa con terapia de deprivación androgénica (TDA). Se realizaron el Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) tras 3 años de seguimiento y el Cuestionario Español de Calidad de Vida en Pacientes con Cáncer de Próstata (CAVIPRES-30) al diagnóstico y a los 3 años.* **Resultados:** *Se incluyeron 68 pacientes, 39 con PR y 29 con radioterapia más TDA. De los pacientes intervenidos, el 61.5% están secos y el 17.9% usan tres o más compresas, diarias frente al 72.4% y el 6.8%, respectivamente, en el grupo de radioterapia. El 48.7% de los prostatectomizados refieren erecciones muy malas o ninguna, frente al 69% de los radiados. Tras la cirugía, el 43.6% refieren mala o muy mala calidad de vida, frente al 68.9% de los radiados. En la comparación de los datos del cuestionario pre- y postratamiento, los pacientes tenían una percepción superior antes del procedimiento.* **Conclusiones:** *Los pacientes tratados mediante cirugía tienen una mejor percepción de su calidad de vida relacionada con la salud que los radiados.*

Palabras clave: *Cáncer de próstata. Prostatectomía radical. Radioterapia externa. Calidad de vida. Cuestionario.*

Abstract

Objective: *To assess and compare the functional and quality of life results in patients treated with curative intent for localized prostate cancer during 2015 in our hospital.* ***Method:*** *77 patients treated by radical prostatectomy or external radiotherapy with androgen deprivation were prospective enrolled. Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP) questionnaire at 3-year follow-up and Spanish Questionnaire on Quality of Life in Patients with Prostate Cancer (CAVIPRES-30) at diagnosis and at 3-year follow-up were registered.* ***Results:*** *68 patients were included, 39 patients treated by radical prostatectomy and 29 received external radiotherapy with androgen deprivation. Among the operated patients, 61.5% were dry and 17.9% use three or more daily pads, compared to 72.4% and 6.8%, respectively, in the radiotherapy group. 48.7% of prostatectomized patients reported very poor or no capacity to have a sufficiently rigid erection, compared to 69% of the radiated group.*

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After surgery, 43.6% considered bad or very bad quality-of-life, compared to 68.9% in the radiotherapy group. In the comparison of the data of the pre- and post-treatment questionnaire can be seen that the patients had a superior perception before the procedure. ***Conclusions:*** *Patients treated by surgery have a better perception of quality-of-life compared to those treated by radiotherapy.*

Keywords: *Prostate cancer. Radical prostatectomy. External radiotherapy. Quality of life. Questionnaire.*

Introducción

El cáncer de próstata (CP) es el segundo tipo de cáncer más frecuente y la quinta causa de muerte relacionada con cáncer entre los varones[1]. La incidencia se ha incrementado en los últimos años y se espera que su elevada prevalencia haga del tratamiento de este tumor un importante problema en su manejo, por la merma en la calidad de vida (CV) que supone en los pacientes con una favorable supervivencia global y específica de cáncer a largo plazo[2].

La esperanza de vida media para el CP confinado al órgano es de 13.8 años, y por ello la evaluación de la CV es crucial por el prolongado tiempo que se pueden sufrir las secuelas del tratamiento: incontinencia urinaria, sangrado, toxicidad gastrointestinal y la disfunción eréctil, entre otras[3].

Una evaluación de los resultados funcionales es fundamental para comprender la situación de los hombres que viven con CP. En la actualidad se dispone de varios cuestionarios validados específicos para la CV en general y la CV relacionada con la salud (CVRS) en pacientes con CP, como el FACT-P[4], el EORTC-QLQ-PR25[5], el UCLA-PCI[6], el EPIC-CP[7], el ROSQOLI[8], el QOLM-P[9] y el CAVIPRES[10]. Cabe señalar que la interpretación correcta de los resultados de estos test se ve influenciada por la distinta significación clínica de los parámetros medidos, así como por el entrenamiento limitado de los médicos en el uso de estos instrumentos; además, muchos son adaptaciones de las versiones originales en inglés, pudiendo existir diferencias en la traducción.

El Cuestionario Español de Calidad de Vida en Pacientes con Cáncer de Próstata (CAVIPRES-30), desarrollado y validado en España, constituye una herramienta manejable, sensible y específica para evaluar la CV en pacientes con CP[10]. El *Expanded Prostate Cancer Index Composite for Clinical Practice* (EPIC-CP) es un cuestionario específico para la evaluación del impacto de los tratamientos en la CV de los pacientes con CP, cuya versión en español se encuentra validada y presenta una excelente sensibilidad al cambio de idioma, resultando útil en nuestro medio[7].

El objetivo del presente estudio fue determinar los resultados funcionales y de CV tras tratamientos radicales para el CP localizado en nuestro centro, mediante la aplicación de cuestionarios específicos y la comparación de sus resultados en cada grupo de tratamiento.

Método

Se realizó un estudio prospectivo no aleatorizado, en el que se reclutaron 77 pacientes con CP localizado tratados mediante prostatectomía radical (PR) o radioterapia externa con terapia de deprivación androgénica (RDT + TDA), de enero a diciembre de 2015. De los 39 pacientes intervenidos, 18 fueron sometidos a cirugía abierta (PR retropúbica) y 21 a cirugía laparoscópica por el mismo equipo de cirujanos en ambos casos. Ningún paciente fue sometido a linfadenectomía. Los pacientes tratados con RDT (29) recibieron 46 Gy en 23 fracciones de 2.00 Gy al día sobre el volumen prostático, las vesículas seminales y los ganglios pélvicos con margen de seguridad, usando fotones de 6 MV procedentes de un acelerador lineal TrueBEAM y técnica VMAT (RapidArc) con dos arcos dinámicos conformados con colimador multiláminas, asociando Boost con braquiterapia de alta tasa con una fracción única de 15 Gy. Los pacientes radiados recibieron TDA 6 meses (riesgo intermedio) o 2 años (alto riesgo). Ningún paciente recibió braquiterapia exclusiva. Se excluyeron seis pacientes por recidiva oncológica posterior que precisó tratamiento de rescate y tres por pérdida de seguimiento.

La obtención de los datos se llevó a cabo mediante entrevista estructurada directa con los cuestionarios EPIC-CP y CAVIPRES-30. Cada paciente firmó previamente el consentimiento informado. Ambos se aplicaron a los 3 años de la finalización del tratamiento, y el CAVIPRES-30 también en el momento del diagnóstico.

El EPIC-CP está compuesto por 50 ítems que cubren cuatro dominios específicos: urinario, intestinal, sexual y hormonal. Cada dominio contiene tres preguntas con opciones de respuesta en una escala de 0 a 4 puntos (a menor puntuación, mejor percepción de la CVRS). En el presente trabajo hemos utilizado cada cuestión como variable que permita la comparación de los resultados en cada grupo[7].

El CAVIPRES-30 se constituye por 30 preguntas con cinco dominios: aspectos psicológicos, esperanza y futuro, apoyo social y pareja, vida sexual e información y comunicación (a mayor puntuación, mejor será la percepción de la CVRS)[10].

En ambos cuestionarios, el periodo recordatorio es de 4 semanas.

Los datos se analizaron utilizando el paquete R, 3.4.4 (R Development Core Team 2018). Los porcentajes se compararon usando la prueba de χ^2, las medias mediante la prueba t de Student y las medianas con el test de Wilcoxon para datos independientes. Para la variable CAVIPRES numérica se utilizó el test de Wilcoxon para datos emparejados. La significación estadística se estableció en $p < 0.05$.

Resultados

Se incluyeron 68 pacientes: 39 sometidos a PR y 29 a RDT + TDA. La mediana de edad en el grupo de PR fue de 62 años y en el de RDT+TDA fue de 69 años. En relación con el riesgo, en el grupo de PR hubo 14 pacientes de bajo riesgo, 21 de riesgo intermedio y 4 de alto riesgo, frente a 2, 16 y 11, respectivamente, en el grupo de RDT + TDA ($p < 0.01$) (Tabla 1).

Tabla 1. Descripción de la muestra

	Global (n = 68)	PR (n = 39)	RDT + TDA (n = 29)	p
Edad, años	64 (59-69)	62 (56-66)	69 (64-72)	< 0.0001
PSA				
< 10	55 (80.9%)	35 (89.7%)	20 (69.0%)	0.03
10-20	10 (14.7%)	4 (10.3%)	6 (20.7%)	
> 10	3 (4.4%)	0	3 (10.3%)	
BTRP				
Gleason < 7	23 (33.8%)	19 (48.7%)	4 (13.8%)	0.01
Gleason 7	36 (52.9%)	17 (43.6%)	19 (65.5%)	
Gleason > 7	9 (13.2%)	3 (7.7%)	6 (20.7%)	
Grupos de riesgo				
Bajo riesgo	16 (23.5%)	14 (35.9%)	2 (6.9%)	0.003
Riesgo intermedio	37 (54.4%)	21 (53.8%)	16 (55.2%)	
Alto riesgo	15 (22.1%)	4 (10.3%)	11 (37.9%)	

BTRP: biopsia transrectal de próstata; PR: prostatectomía radical; PSA: antígeno específico de próstata; RDT + TDA: radioterapia externa con terapia de deprivación androgénica.

En cuanto a los hábitos urinarios según el cuestionario EPIC-CP (Tabla 2), en el grupo de PR el 61.5% no usaba compresas, el 17.9% usaba una al día, el 2.6% dos al día y el 17.9% tres o más al día, frente al 72.4%, el 17.4%, el 3.4% y el 6.9%, respectivamente, en el grupo de RDT + TDA ($p = 0.68$).

El 84.6% de los operados no presentaban problemas con la disuria; en el grupo de RDT + TDA, el 48.2% consideraban tener un moderado (17.2%) o gran problema (31%) relacionado con ella ($p < 0.01$).

Ningún paciente prostatectomizado refirió tener problemas relacionados con hematuria, frente a más de la mitad en el grupo de RDT + TDA. El 24% de los pacientes radiados consideraron la hematuria como un problema moderado ($p < 0.01$).

El 48.7% de los pacientes sometidos a PR refirieron una capacidad muy mala o ninguna para tener una erección de calidad, frente al 69% en el grupo de RDT + TDA ($p = 0.27$).

En el grupo de PR, el 53.8% no consideraron ninguna merma en su CV respecto a sus hábitos urinarios actuales, frente al 31% en el grupo de RDT + TDA. En cuanto a la actividad sexual, el 23.1% de los pacientes sometidos a PR la consideraron un gran problema, frente al 17.2% en el grupo de los pacientes de RDT + TDA.

La CVRS determinada por el cuestionario CAVIPRES-30 antes del tratamiento radical en el grupo de PR fue considerada muy mala en el 2.56%, mala en el 12.82%, regular en el 76.92% y buena en el 7.69%; para el grupo de RDT + TDA los datos son 0%, 27.59%, 68.97% y 3.45%, respectivamente ($p = 0.36$).

Tras recibir el tratamiento, la CVRS en el grupo de PR era mala o muy mala en el 43.6%, regular en el 53.8% y buena en el 2.6%, frente al 68.9%, el 31% y el 0%, respectivamente, en el grupo de RDT + TDA ($p < 0.05$).

En la comparación de los valores de CAVIPRES-30 pre- y postratamiento dentro de cada grupo, existen diferencias estadísticamente significativas ($p < 0.01$) tanto en el grupo de PR como en el de RDT, hallando una diferencia positiva en ambos casos, lo que se traduce en que los pacientes presentaban mejor percepción de CV previa al procedimiento.

Se estudió la relación que pudiera existir entre grupo de riesgo y presencia o no de comorbilidad, como

Tabla 2. Resultados del cuestionario EPIC-CP

	PR (n = 39)					RDT + TDA (n = 29)					p
Hábitos urinarios											
¿Con qué frecuencia ha tenido pérdidas de orina?											
Más de una vez al día	11 (28.21%)					3 (10.34%)					0.29
Una vez al día	4 (10.26%)					2 (6.9%)					
Más de una vez a la semana	1 (2.56%)					0					
Una vez a la semana	7 (17.95%)					6 (20.69%)					
Nunca o casi nunca	16 (41.03%)					18 (62.6%)					
¿Cuál de las frases siguientes describe mejor cómo controla la orina?											
Ningún control	2 (5.13%)					2 (6.9%)					0.08
Pérdidas frecuentes	8 (20.51%)					2 (6.9%)					
Pérdidas de vez en cuando	17 (43.59%)					8 (27.59)					
Control total	12 (30.77%)					17 (58.62%)					
¿Cuántas compresas o pañales para adultos ha utilizado al día para controlar las pérdidas de orina?											
Ninguna	24 (61.54%)					21 (72.41%)					0.68
Una al día	7 (17.95% %)					5 (17.24%)					
Dos al día	1 (2.56%)					1 (3.45%)					
Tres o más al día	7 (17.95%)					2 (6.9%)					
¿Ha sido un problema para usted alguno de los siguientes aspectos?	**Ninguno**	**Muy pequeño**	**Pequeño**	**Moderado**	**Grande**	**Ninguno**	**Muy pequeño**	**Pequeño**	**Moderado**	**Grande**	
Pérdidas de orina	18 (46.5%)	4 (10.26%)	5 (12.82%)	6 (15.38%)	6 (15.38%)	19 (65.52%)	4 (13.79%)	1 (3.45%)	3 (10.34%)	2 (6.90%)	0.39
Dolor o escozor al orinar	33 (84.62%)	2 (5.13%)	2 (5.13%)	2 (5.13%)	0	12 (41.38%)	1 (3.45%)	2 (6.9%)	5 (17.24%)	9 (31.03%)	< 0.01
Sangre en la orina	39 (100%)	0	0	0	0	16 (55.17%)	1 (3.45%)	2 (6.9%)	7 (24.14%)	3 (10.34%)	< 0.01
Chorro débil o vaciado incompleto	28 (71.79%)	3 (7.69%)	4 (10.26%)	3 (7.69%)	1 (2.56%)	11 (37.93%)	2 (6.9%)	3 (10.34%)	5 (17.24%)	8 (27.59%)	< 0.01
Necesidad de orinar con frecuencia	26 (66.67%)	3 (7.69%)	3 (7.69%)	5 (12.82%)	2 (5.13%)	10 (34.48%)	3 (10.34%)	2 (6.9%)	6 (20.69%)	8 (27.59)	0.05
Hábitos intestinales											
¿Ha sido un problema para usted alguno de los siguientes aspectos?	**Ninguno**	**Muy pequeño**	**Pequeño**	**Moderado**	**Grande**	**Ninguno**	**Muy pequeño**	**Pequeño**	**Moderado**	**Grande**	
Ganas urgentes de ir de vientre	35 (89.74%)	2 (5.13%)	0	1 (2.56%)	1 (2.56%)	11 (37.93%)	3 (10.34%)	5 (17.24%)	9 (31.03%)	1 (3.45%)	< 0.01
Ir de vientre con mayor frecuencia	37 (94.87%)	0	0	1 (2.56%)	1 (2.56%)	15 (51.72%)	2 (6.90%)	3 (10.34%)	8 (27.59%)	1 (3.45%)	< 0.01

(Continúa)

Tabla 2. Resultados del cuestionario EPIC-CP *(continuación)*

	PR (n = 39)					RDT + TDA (n = 29)					p
Hábitos intestinales											
Pérdidas de control (no tener deposiciones)	38 (97.44%)	0	0	0	1 (2.56%)	22 (75.86%)	4 (13.79%)	0	0	3 (10.34%)	0.01
Deposiciones con sangre	37 (94.87%)	0	1 (2.56%)	0	1 (2.56%)	20 (68.97%)	6 (20.68%)	0	3 (10.34%)	0	< 0.01
Dolor abdominal, de recto, de pelvis o de bajo vientre	35 (89.74%)	2 (5.13%)	1 (2.56%)	1 (2.56%)	0	13 (44.83%)	5 (17.24%)	5 (17.24%)	5 (17.24%)	1 (3.45%)	< 0.01
Actividad sexual											
¿Cómo calificaría usted cada uno de los siguientes aspectos?	**Muy mala o ninguna**	**Mala**	**Regular**	**Buena**	**Muy buena**	**Muy mala o ninguna**	**Mala**	**Regular**	**Buena**	**Muy buena**	
Capacidad para tener una erección	19 (48.72%)	7 (17.95%)	10 (25.64%)	3 (7.69%)	0	20 (68.97%)	3 (10.34%)	3 (10.34%)	3 (10.34%)	0	0.27
Capacidad de alcanzar el orgasmo	15 (38.46%)	1 (2.56%)	9 (23.08%)	13 (33.33%)	1 (2.56%)	18 (62.07%)	3 (10.34%)	3 (10.34%)	5 (17.24%)	0	0.09
Calidad de las erecciones											
Ninguna calidad			22 (56.41%)					19 (65.52%)			0.84
Sin rigidez suficiente para tener cualquier tipo de actividad sexual			5 (12.82%)					3 (10.34%)			
Con suficiente rigidez para masturbarse			7 (17.95%)					3 (10.34%)			
Con rigidez suficiente para el coito			5 (12.82%)					4 (13.79%)			
Función hormonal											
¿Ha sido un problema para usted alguno de los siguientes aspectos?	**Ninguno**	**Muy pequeño**	**Pequeño**	**Moderado**	**Grande**	**Ninguno**	**Muy pequeño**	**Pequeño**	**Moderado**	**Grande**	
Sofocos	37 (94.87%)	0	1 (2.56%)	1 (2.56%)	0	15 (51.22%)	4 (13.79%)	4 (13.79%)	2 (6.9%)	4 (13.79%)	< 0.01
Sensibilidad o dolor/aumento de pechos	39 (100%)	0	0	0	0	19 (65.52%)	1 (3.45%)	5 (17.24%)	1 (3.45%)	3 (10.34%)	< 0.01
Sentirse deprimido	33 (84.62%)	1 (2.56%)	3 (7.69%)	2 (5.13%)	0	17 (58.62%)	4 (13.79%)	0	3 (10.34%)	5 (17.24%)	< 0.01
Falta de energía	34 (87.18%)	0	1 (2.56%)	3 (7.69%)	1 (2.56%)	18 (62.07%)	3 (10.34%)	0	3 (10.34%)	5 (17.24%)	0.013
Cambio de peso	38 (97.44%)	0	1 (2.56%)	0	0	21 (72.41%)	1 (3.45%)	2 (6.9%)	2 (6.9%)	3 (10.34%)	< 0.01

PR: prostatectomía radical; RDT + TDA: radioterapia externa con terapia de deprivación androgénica.

Tabla 3. Relación entre la incontinencia y la disfunción eréctil con la comorbilidad y el riesgo tumoral en el grupo de prostatectomía radical

PR	Edad, mediana (años)	p	Grupos de riesgo			p	Comorbilidad			
			Bajo	Intermedio	Alto		DM2 (p = 0.71)		CI (p = 1)	
							Sí	No	Sí	No
0-1 compresa	62.50	0.50	11 (45.8%)	11 (45.8%)	2 (8.3%)	0.3	5 (20.8%)	19 (79.2%)	2 (8.3%)	22 (91.7%)
> 2 compresas	60		3 (20%)	10 (66.7%)	2 (13.3%)		4 (26.7%)	11 (73.3%)	1 (6.7%)	14 (93.3%)
							DM2 (p = 1)		CI (p = 0.25)	
							Sí	No	Sí	No
Erección mala o muy mala	61.23	0.43	7 (26.9%)	16 (61.54%)	3 (11.5%)	0.2	6 (23.1%)	20 (76.9%)	1 (3.9%)	25 (96.1%)
Erección regular o buena	59.54		7 (53.9%)	5 (38.5%)	1 (7.7%)		3 (23.1%)	10 (76.9%)	2 (15.4%)	11 (84.6%)

CI: cardiopatía isquémica; DM2: diabetes *mellitus* tipo 2; PR: prostatectomía radical.

Tabla 4. Relación entre la incontinencia y la disfunción eréctil con la comorbilidad y el riesgo tumoral en el grupo de radioterapia externa con terapia de deprivación androgénica

RDT + TDA	Edad, mediana (años)	p	Grupos de riesgo			p	Comorbilidad			
			Bajo	Intermedio	Alto		DM2 (p = 0.39)		CI (p = 1)	
							Sí	No	Sí	No
0-1 compresa	69	0.25	2 (9.52%)	9 (42.86%)	10 (47.62%)	0.12	6 (28.57%)	15 (71.43%)	1 (4.76%)	20 (95.24%)
> 2 compresas	72		0	7 (87.5%)	1 (12.5%)		4 (50%)	4 (50%)	0	8 (100%)
							DM2 (p = 0.07)		CI (p = 1)	
							Sí	No	Sí	No
Erección mala o muy mala	71	0.12	0	12 (52.17%)	11 (47.83%)	< 0.01	10 (43.5%)	13 (56.5%)	1 (4.35%)	22 (95.65%)
Erección regular o buena	65			2 (33.3%)	4 (66.7%)		0	6 (100%)	0	6 (100%)

CI: cardiopatía isquémica; DM2: diabetes *mellitus* tipo 2; RDT + TDA: radioterapia externa con terapia de deprivación androgénica.

diabetes *mellitus* tipo 2 y cardiopatía isquémica, con el uso de compresas y la capacidad de presentar una erección en cada grupo de tratamiento (Tablas 3 y 4). No se objetivaron peores resultados funcionales entre los distintos grupos de riesgo ni en aquellos pacientes con comorbilidad en cada grupo de tratamiento.

Discusión

Desde los años 1990 se ha incrementado la incidencia de CP debido a la expansión de la determinación del antígeno prostático específico (PSA), que ha permitido alcanzar cifras crecientes de diagnóstico y de tratamiento precoz.

Existen diversas opciones terapéuticas para el CP confinado al órgano, debiéndose tomar la decisión final de acuerdo con el estadio clínico, el PSA, el grado de Gleason, la edad cronológica y el estado funcional del paciente. El tratamiento debe entenderse desde un punto de vista multidisciplinario que proporcione al enfermo la mejor de las alternativas disponibles en cada caso. El paciente debe participar de manera activa en la toma de decisiones, tal como reflejan las guías clínica de la European Association of Urology[11].

La compleja elección del tratamiento final se justifica por la elevada supervivencia y la importante afectación de la CV que se puede experimentar en los años posteriores.

El concepto «calidad de vida» aparece por primera vez como término investigable en la National Library of Medicine de los Estados Unidos en 1966, en un

artículo publicado por Elkinton titulado *Medicine and the quality of life.* En la práctica clínica entendemos la CV como el mantenimiento de las funciones físicas junto con un aceptable control sintomático; sin embargo, su valoración no deja de ser una percepción subjetiva y se deben tener en cuenta no solo aquellos síntomas o funciones orgánicas derivadas de la patología, sino también la información sobre la influencia psicológica y social y el impacto que represente. Para su evaluación, la comunidad científica se ha encontrado con la dificultad de la ausencia de un método estándar para interpretar los distintos aspectos de la CV[12].

Los instrumentos de medida de la CV específica para pacientes con CP se centran en cinco dominios de salud que se repiten en los cuestionarios validados: síntomas urinarios, actividad sexual e intestinal, y aspectos sociales y de relación del paciente. En el presente estudio se ha investigado sobre el empeoramiento de la CV derivado de cada tratamiento basándonos en estos cinco ítems, además de establecer la comparación entre las distintas terapias en un intento de sustentar la toma de decisiones en datos lo más objetivos posible.

En relación con los dos efectos secundarios más relevantes atribuidos a la cirugía, la incontinencia urinaria y la disfunción eréctil, en nuestra serie, a pesar de no lograr significación estadística, a los 3 años de la PR el 61.5% están secos y el 17.9% usan tres o más compresas, frente al 72.4% y el 6.9%, respectivamente, en el grupo de RDT + TDA. Además, en el grupo de PR el 48.7% refieren una capacidad muy mala o ninguna para tener una erección y el 7.7% buena, mientras que en el grupo de RDT + TDA, habiendo pasado 1 año tras la finalización de la TDA, el 69% tienen erecciones muy malas o ausentes y el 10.3% las consideran buenas.

En comparación con la literatura disponible, considerando la continencia como no utilizar compresas, nuestros resultados coinciden con los datos publicados para PR, que oscilan entre el 60.5& y el 93% al año[13-19]. Las mejores cifras las alcanzan las series de instituciones de referencia con alto volumen de pacientes y cirujanos con una gran práctica; como bien reflejan, la experiencia y el cirujano son factores fundamentales en los resultados de la cirugía[20].

Este hecho queda aún más de manifiesto en el análisis de los datos sobre disfunción eréctil. Kundu et al.[13] describen que, al valorar los resultados de las PR realizadas entre 1983 y 2003, en los primeros 1000 enfermos la recuperación de la función eréctil fue del 68%, mientras que en los sujetos del 1000 al 3000 fue del 78% ($p < 0.01$). La subjetividad en la valoración de la potencia sexual hace muy compleja la comparación entre series.

Cabe señalar que, al preguntar específicamente sobre la afectación que implican esos ítems en su vida, el 53.8% de los pacientes con PR no consideraron ninguna merma en su CV en relación con sus hábitos urinarios actuales, frente al 31% en el grupo de RDT + TDA. Sin embargo, en cuanto a la actividad sexual, el 23.1% de los pacientes con PR consideraron que tenían un gran problema, frente al 17.2% en el grupo de RDT + TDA.

En el análisis de los ítems que con más frecuencia se asocian a la RDT + TDA, ningún paciente con PR refiere problemas relacionados con la hematuria, frente al 10.3% de los pacientes radiados, que la consideran un gran problema.

Además, en concordancia con lo publicado por Litwin et al.[20], las molestias miccionales fueron notablemente peores tras 2 años de recibir la radiación en comparación con la cirugía. En nuestra serie se objetiva que hasta el 31% consideran que la disuria significa un gran problema en su vida, mientras que ninguno de los enfermos del grupo de PR la describe de esta manera ($p < 0.01$).

Respecto a la sintomatología digestiva, la incidencia es muy baja en los pacientes con PR, que prácticamente no refieren urgencia, frecuencia defecatoria, sangre en heces, incontinencia fecal ni dolor abdominal; no sucede lo mismo en el grupo de RDT + TDA, en el que hasta un 17.2% consideran las alteraciones digestivas un problema moderado y el 3.4% un gran problema. Tal como publicaron Wei et al.[21] y Potosky et al.[22], la diarrea, el tenesmo rectal y la rectorragia son significativamente más frecuentes después de recibir radiación.

Dado que los pacientes sometidos a radioterapia externa precisan tratamiento con TDA, y a pesar de que todos los enfermos incluidos en el estudio llevaban al menos 1 año sin ella, hasta un 27.5% de los pacientes de este grupo refieren que el desánimo es un problema moderado o grande, frente al 5.1% de los del grupo de PR.

De todos estos datos podemos concluir que, en nuestra serie, la incontinencia urinaria y la disfunción eréctil son más frecuentes en los pacientes sometidos a PR, pero que en términos de CV el mayor impacto se lo llevan los efectos adversos derivados de la RDT + TDA. Los resultados concuerdan con los publicados por Resnick et al.[23], quienes compararon los

resultados funcionales tras PR o RDT a largo plazo y concluyeron que los pacientes operados tendían a presentar peores resultados en cuanto a incontinencia urinaria y disfunción eréctil a los 2 y 5 años, sin existir diferencias a los 15 años, y presentaban con menos probabilidad urgencia intestinal a los 2 y 5 años[23].

Llama la atención que, en la valoración global de la CVRS mediante el cuestionario CAVIPRES-30, los pacientes en el grupo de PR tienen una mejor percepción de su CV en comparación con el grupo de RDT + TDA, resultando las diferencias estadísticamente significativas.

En la valoración de la CVRS previa y tras haber recibido tratamiento radical, tanto en el grupo de PR como en el de RDT + TDA se evidencia que los pacientes tenían una mejor percepción antes del procedimiento ($p < 0.01$); de ahí la gran importancia de la valoración multidisciplinaria y en conjunto con el enfermo en cuanto a la decisión terapéutica definitiva.

Como limitación del presente trabajo se debe señalar que la valoración de aspectos funcionales implica una subjetividad que aumenta la variabilidad de los resultados. Sería necesario establecer una definición, un modo de evaluación y un periodo de tiempo estándar para la valoración de estos ítems; mientras tanto, el uso de cuestionarios validados permite la comparación. Además, el estudio presenta las limitaciones propias de tener un tamaño muestral reducido y de ser una serie no aleatorizada, con datos extraídos de la práctica clínica, que hacen que los pacientes dirigidos a uno u otro tratamiento no sean grupos homogéneos.

Conclusiones

Los pacientes con una peor percepción de su CVRS tras recibir tratamiento radical para CP confinado al órgano son aquellos que se someten a RDT + TDA, en comparación con PR. La hematuria, la sintomatología digestiva y las molestias miccionales fueron más habituales en el grupo que recibió radioterapia. La incontinencia urinaria y la disfunción eréctil son más frecuentes en el grupo de PR, aunque sin significación estadística.

La valoración de la CVRS antes y después de ambos tratamientos muestra en los dos casos un empeoramiento de los resultados, quedando de manifiesto el impacto de la toma de decisiones en relación con el manejo del CP.

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Conflicto de intereses

Los autores declaran no tener ningún conflicto de intereses.

Responsabilidades éticas

Protección de personas y animales. Los autores declaran que para esta investigación no se han realizado experimentos en seres humanos ni en animales.

Confidencialidad de los datos. Los autores declaran que han seguido los protocolos de su centro de trabajo sobre la publicación de datos de pacientes.

Derecho a la privacidad y consentimiento informado. Los autores han obtenido la aprobación del Comité de Ética para el análisis y publicación de datos clínicos obtenidos de forma rutinaria. El consentimiento informado de los pacientes no fue requerido por tratarse de un estudio observacional retrospectivo.

Bibliografía

1. Jemal A, Siegel R, Ward E, Hao Y, Xu J, Thun MJ. Cancer statistics, 2009. CA Cancer J Clin. 2009;59:225-49.
2. Ferlay J, Parkin DM, Steliarova-Foucher E. Estimates of cancer incidence and mortality in Europe in 2008. Eur J Cancer. 2010;46:765-81.
3. Núñez C, Angulo J, Sánchez-Chapado M, Alonso S, Portillo JA, Villavicencio H. Variabilidad de la práctica clínica urológica en cáncer de próstata en España. Actas Urol Esp. 2012;36:333-9.
4. Esper P, Mo F, Chodak G, Sinner M, Cella D, Pienta KJ. Measuring quality of life in men with prostate cancer using the functional assessment of cancer therapy-prostate instrument. Urology. 1997;50:920-8.
5. Van Andel G, Bottomley A, Fossa SD, Efficace F, Coens C, Guerif S, et al. An international field study of the EORTC QLQ-PR25: a questionnaire for assessing the health-related quality of life of patients with prostate cancer. Eur J Cancer. 2008;44:2418-24.
6. Litwin MS, Hays RD, Fink A, Ganz PA, Leake B, Brook RH. The UCLA Prostate Cancer Index: development, reliability, and validity of a health-related quality of life measure. Med Care. 1998;36:1002-12.
7. Wei JT, Dunn RL, Litwin MS, Sandler HM, Sanda MG. Development and validation of the Expanded Prostate Cancer Index Composite (EPIC) for comprehensive assessment of health-related quality of life in men with prostate cancer. Urology. 2000;56:899-905.
8. Tannock IF, Osoba D, Stockler MR, Ernst DS, Neville AJ, Moore MJ, et al. Chemotherapy with mitoxantrone plus prednisone or prednisone alone for symptomatic hormone-resistant prostate cancer: a Canadian randomized trial with palliative end points. J Clin Oncol. 1997;14:1756-64.
9. Osoba D, Tannock IF, Ernst DS, Neville AJ. Health-related quality of life in men with metastatic prostate cancer treated with prednisone alone or mitoxantrone and prednisone. J Clin Oncol. 1997;17:1654-63.
10. Gómez-Veiga F, Cozar JM, Günthner S, Puyol-Pallas M, Silmi-Moyano A, Rebollo FJ. Cuestionario Español de Calidad de Vida en Pacientes con Cáncer de Próstata como medida de la calidad de vida de los pacientes con cáncer de próstata en España: aplicación a la actividad diaria. Actas Urol Esp. 2010;34:686-93.
11. Mottet N, Van den Bergh RCN, Briers E, Bourke L, Cornford P, De Santis M, et al. EAU-ESTRO-ESUR-SIOG Guidelines on Prostate Cancer 2018. https://d56bochluxqnz.cloudfront.net/documents/EAU-Guidelines-on-Prostate-Cancer-2018.pdf
12. Cocks K, King MT, Velikova G, Fayers PM, Brown JM. Quality, interpretation and presentation of European Organization for Research and Treatment of Cancer quality of life questionnaire core 30 data in randomised controlled trials. Eur J Cancer. 2008;44:1793-8.

13. Kundu SD, Roehl KA, Eggener SE, Antenor JA, Han M, Catalona WJ. Potency, continence and complications in 3,477 consecutive radical retropubic prostatectomies. J Urol. 2004;172:2227.
14. Penson DF, McLerran D, Feng Z, Li L, Albertsen PC, Gilliland FD, et al. 5-year urinary and sexual outcomes after radical prostatectomy: results from the prostate cancer outcomes study. J Urol. 2005;173:170.
15. Stanford JL, Feng Z, Hamilton AS, Gilliland FD, Stephenson RA, Eley JW, et al. Urinary and sexual function after radical prostatectomy for clinically localized prostate cancer: the Prostate Cancer Outcomes Study. JAMA. 2000;283:354.
16. Bianco FJ Jr, Scardino PT, Eastham JA. Radical prostatectomy: long-term cancer control and recovery of sexual and urinary function ("trifecta"). Urology. 2005;66:83.
17. Harris MJ. The anatomic radical perineal prostatectomy: an outcomes-based evolution. Eur Urol. 2007;52:81-8.
18. Saranchuk JW, Kattan MW, Elkin E, Touijer AK, Scardino PT, Eastham JA. Achieving optimal outcomes after radical prostatectomy. J Clin Oncol. 2005;23:4146.
19. Bianco FJ Jr, Riedel ER, Begg CB, Kattan MW, Scardino PT. Variations among high volume surgeons in the rate of complications after radical prostatectomy: further evidence that technique matters. J Urol. 2005;173:2099.
20. Litwin MS, Pasta DJ, Yu J, Stoddard ML, Flanders SC. Urinary function and bother after radical prostatectomy or radiation for prostate cancer: a longitudinal, multivariate quality of life analysis from the Cancer of the Prostate Strategic Urologic Research Endeavor. J Urol. 2000;164:1973-7.
21. Wei JT, Dunn RL, Sandler HM, McLaughlin PW, Montie JE, Litwin MS, et al. Comprehensive comparison of health-related quality of life after contemporary therapies for localized prostate cancer. J Clin Oncol. 2002;20:557-66.
22. Potosky AL, Legler J, Albertsen PC, Stanford JL, Gilliland FD, Hamilton AS, et al. Health outcomes after prostatectomy or radiotherapy for prostate cancer: results from the Prostate Cancer Outcomes Study. J Natl Cancer Inst. 2000;92:1582-92.
23. Resnick MJ, Koyama T, Fan K, Albertsen PC, Goodman M, Hamilton AS, et al. Long-term functional outcomes after treatment for localized prostate cancer. N Engl J Med. 2013;368:5.

CASO CLÍNICO

Necrotizing fasciitis of the thigh secondary to perforated rectal cancer: the sciatic foramen as a route for infective spread

Fascitis necrotizante del muslo secundaria a cáncer de recto perforado: el agujero ciático como vía de diseminación infecciosa

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Abstract

Necrotizing fasciitis (NF) is a potentially life-threatening surgical emergency. It is a rapidly progressive infection of soft tissues, and mortality is related to the degree of sepsis and the general condition of the patient. It is a rare condition that requires a rapid diagnosis and surgical treatment is aggressive debridement. There are a small number of reported cases of perforation of a rectal malignancy leading to NF of the thigh. We present a case with rectal cancer in which the sciatic foramen had provided a channel for the spread of pelvic infection into the thigh.

Keywords: *Fasciitis, necrotizing. Debridement. Rectal neoplasms. Sepsis. Thigh.*

Resumen

La fascitis necrotizante es una emergencia quirúrgica potencialmente mortal. Es una infección de tejidos blandos rápidamente progresiva y la mortalidad está relacionada con el grado de sepsis y el estado general del paciente. Es una condición poco común que requiere un diagnóstico rápido, y el tratamiento quirúrgico consiste en un desbridamiento agresivo. Existe un pequeño número de casos notificados de perforación de neoplasia maligna de recto que conduce a fascitis necrotizante del muslo. Presentamos un caso de cáncer de recto en el cual el foramen ciático fue el canal para la propagación de la infección pélvica al muslo.

Palabras clave**:** *Fascitis necrotizante. Desbridamiento. Neoplasia rectal. Sepsis. Muslo.*

Introduction

Necrotizing fasciitis (NF) is an extremely virulent form of infectious fasciitis. It affects the skin, subcutaneous fat, and superficial and deep muscular fascia by rapidly progressive necrosis. Expeditious diagnosis and radical debridement are necessary to prevent the onset of sepsis, multisystem organ failure, and possible death. Perforated rectal cancer resulting in NF can spread to the perineum and genitals known as Fournier gangrene. This case describes an unusual case of NF of the right thigh secondary to rectal cancer perforation.

This case highlights the need for prompt diagnosis, urgent aggressive surgical debridement, and consideration of a rare underlying cause in the management of necrotizing fasciitis.

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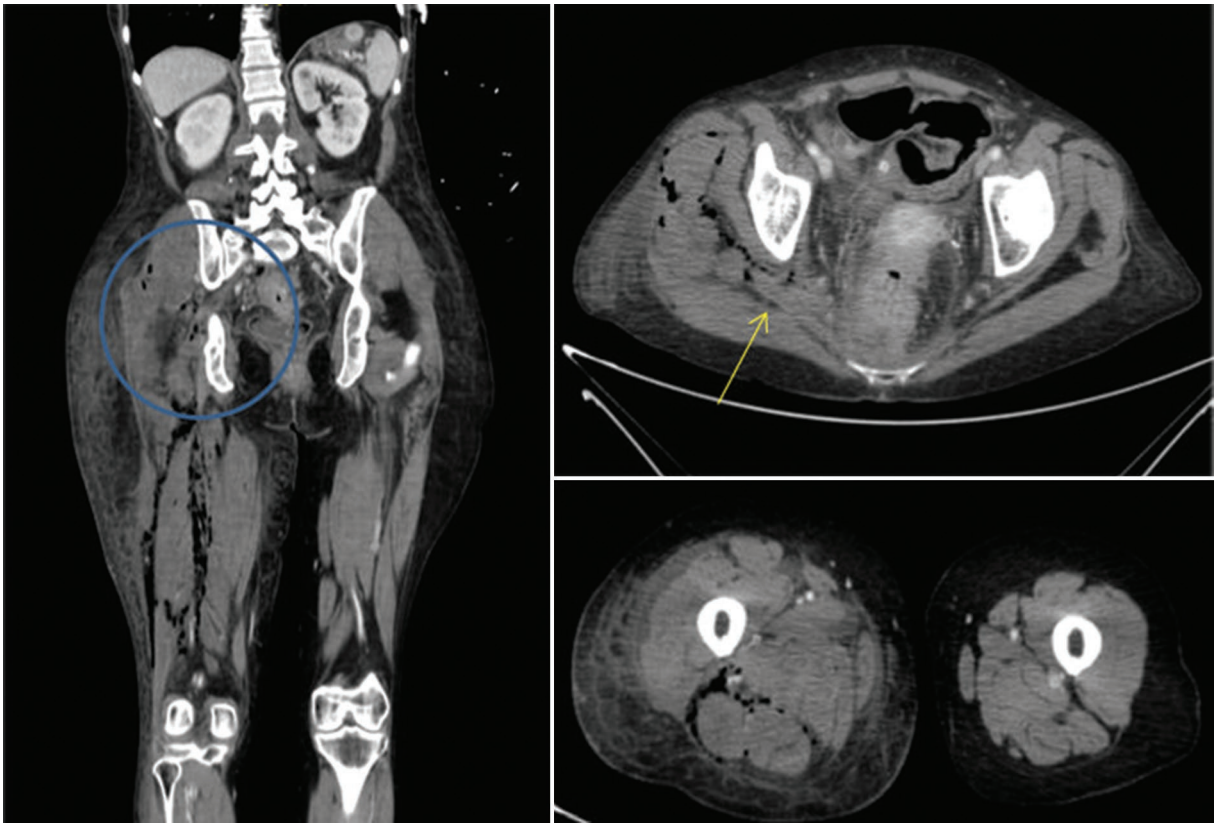

Figure 1. *Computed tomography scan of the thigh, demonstrating gas around the left femoral vessels with associated pyomyositis.*

Case report

A 61-year-old woman presented acute proctalgia and right thigh pain. She had a locally advanced rectal cancer and had recently completed neoadjuvant chemoradiotherapy.

In the emergency room, she was hemodynamically unstable and septic. On examination, she had functional impotence of the right leg and there was a large tender swelled area on the posterior thigh. Blood tests revealed elevated acute phase reactants (C-reactive protein 315 mg/L and procalcitonin 5.25 ng/mL), leukopenia, acute kidney failure, and metabolic acidosis.

The computed tomography (CT) scan showed ulcerated and perforated rectal neoplasm with a presacral abscess extending through the sciatic foramen and pyomyositis of the right leg muscles with gas around the femoral vessels and sciatic nerve (Fig. 1).

A laparoscopic diverting loop colostomy was performed, as well as debridement of the extensive pyomyositis. Intraoperatively, there was an offensive gas-forming infection of the deep fascia extending between the muscles of the posterior thigh, which was focused on the sciatic nerve (Fig. 2). All of the involved skin, fascia, and muscle were excised. Following the sciatic nerve proximally, the pus extended above the greater sciatic foramen.

Postoperatively, the patient was transferred to the Intensive Care Unit, and she underwent five further debridements in the theater. A negative pressure dressing was applied for 12 days until the skin defect was covered with skin grafts.

She was discharged after 2 months with neuropathic pain treated with morphic. Additional staging CT was performed with disease progression and the case was discussed at a multidisciplinary meeting where the decision was made to aim for palliative chemotherapy.

Discussion

Necrotizing fasciitis is a potentially life-threatening surgical emergency and can be difficult to recognize in the early stages. It is a rapidly progressive soft-tissue infection, and mortality rates are between 25 and 35%[1]. Mortality is related to the degree of sepsis and the general condition of the patient at the time of diagnosis. The infection is usually polymicrobial. Clinical findings include swelling, rapidly spreading cellulitis, severe pain, and palpable crepitus; the patient may be in septic shock.

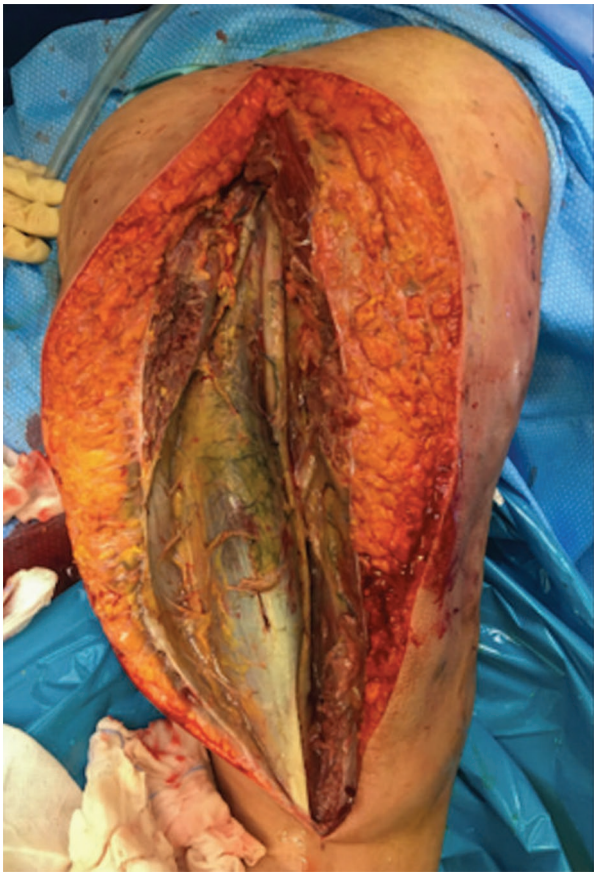

Figure 2. *Intraoperative photograph of debridement. Exploration of the left leg revealed severe soft-tissue infection involving the skin, subcutaneous fat, and fascia; the femoral vein and nerve were covered in infected fascia.*

NF can be difficult to recognize in the early stages, so a high index of suspicion is needed when confronted with rapidly spreading erythema or subcutaneous crepitus. Skin necrosis and blistering are late signs. When NF of the abdominal wall or thigh is not associated with an obvious cutaneous portal of entry, an intra-abdominal cause should be sought.

Treatment is mainly surgical, involving early aggressive debridement in conjunction with high-dose intravenous antibiotics and intensive care support[2]. The goal of the debridement is to remove all necrotic tissues, to stop the progressive infection, and to reduce systemic toxicity. Debridement should be repeated when necessary. In cases of rectal perforation, fecal diversion is recommended[3].

There are very few reported cases of perforation of a rectal malignancy leading to NF of the thigh. There are several possible routes of entry for fecal matter and infection to invade the thigh: Femoral sheath, femoral canal, psoas sheath, sciatic notch, and the obturator foramen.

However, rectal perforation should always be ruled out, especially in patients with a prior history of rectal disease[3-5]. In this patient, the femoral canal provided a channel for the intra-abdominal infection to invade the thigh.

Conclusion

NF is a rare condition that demands prompt diagnosis and surgical treatment is the aggressive debridement to healthy tissue. NF of the thigh secondary to rectal cancer perforation is unusual. Our case highlights the sciatic foramen as a channel for the spread of pelvic infection into the thigh. The loop colostomy promotes wound healing by protecting it from fecal matter.

In addition, NF is a very severe complication that can delay and hinder the definitive treatment of the cancer.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

References

1. Anaya DA, McMahon K, Nathens AB, Sullivan SR, Foy H, Bulger E. Predictors of mortality and limb loss in necrotizing soft tissue infections. Arch Surg. 2005;140:151-7.
2. Wiberg A, Carapeti E, Greig A. Necrotising fasciitis of the thigh secondary to colonic perforation: the femoral canal as a route for infective spread. J Plast Reconstr Aesthet Surg. 2012;65:1731-3.
3. Evans WD, Winters C, Amin E. Necrotising fasciitis secondary to perforated rectal adenocarcinoma presenting as a thigh swelling. BMJ Case Rep. 2015;2015:bcr2014208312.
4. Highton L, Clover J, Critchley P. Necrotising fasciitis of the thigh secondary to a perforated rectal cancer. J Plast Reconstr Aesthet Surg. 2009;62:e17-9.
5. Jenkins V, Steinke J, Rajendran N, Kumar D. Purulent myositis of the thigh as a presentation of perforated low rectal cancer. Ann R Coll Surg Engl. 2018;100:e44-5.

CASO CLÍNICO

Disasters that develop in the liver due to hydatid cyst: a case report

Desastres que se desarrollan en el hígado debido a un quiste hidatídico: caso clínico

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Abstract

Hilar cavernous transformation is the formation of venous structures rich in collateral around the portal vein. Portal vein thrombosis is a rare entity. Although there are many reasons for its etiology, few cases have been reported secondary to hydatid cysts in the liver. Here, we present a 24-year-old patient with complaints of abdominal pain and swelling. Her CT and MRI scans show cholelithiasis with portal vein thrombosis and hilar cavernous transformation due to giant hydatid cyst compression in the lateral liver sector.

Keywords: *Cavernous transformation. Hydatid cyst. Portal vein thrombosis. Gallbladder.*

Resumen

La transformación cavernosa hiliar es la formación de estructuras venosas ricas en colaterales alrededor de la vena porta. La trombosis de la vena porta es una afección poco frecuente. Aunque existen muchas razones en su etiología, se han descrito pocos casos secundarios a quiste hidatídico en el hígado. Aquí se presenta el caso de una paciente de 24 años con quejas de dolor abdominal e hinchazón. La tomografía computarizada y la resonancia magnética mostraron colelitiasis con trombosis de la vena porta y transformación cavernosa hiliar por compresión del quiste hidatídico gigante en el sector lateral del hígado.

Palabras clave: *Transformación cavernosa. Quiste hidatídico. Trombosis de la vena porta. Vesícula biliar.*

Introduction

Hydatid cyst is a zoonotic disease caused by Echinococcus parasites. It is an endemic disease worldwide, especially in the Middle East, Asia, India, and South America[1]. While it is frequently located in the liver (75%) and lung, it is rarely seen in the spleen, pancreas, and intraperitoneal space[2]. It is generally asymptomatic unless it causes complications. Intrabiliary or intraperitoneal ruptures of the cyst are common complications and can cause serious consequences such as urticaria and anaphylaxis[3].

Here, we present a case that settled in the lateral liver sector and completely covered the lobe, eliminating the lateral sector and causing thrombosis and cavernous collateral development by compressing the portal vein.

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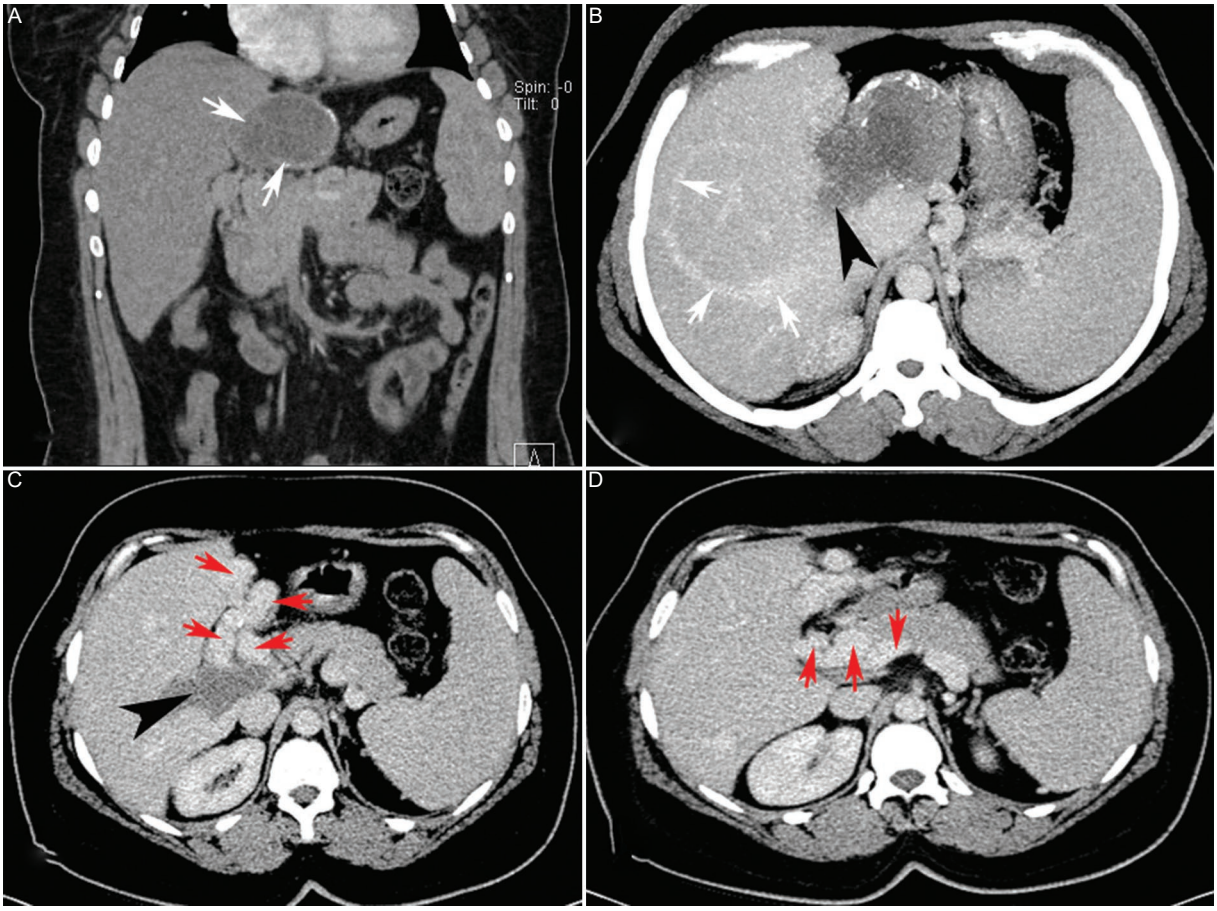

Figure 1. Top row: A: *The coronal CT shows a giant hydatid cyst (Arrows) filling the lateral sector.* **B:** *the axial section shows intrahepatic venous-venous collaterals (Arrows) extending toward the right hepatic vein can be seen as a result of portal vein thrombosis due to the cyst extending to the hilus (Black arrowhead).* **Bottom row: C:** *The axial CT shows the part of the hydatid cyst extending (Black arrowhead) to the portal hilus and pressing the portal vein, and periportal venous collaterals with phlebolite calcification (red arrows) on its wall.* **D:** *this section shows that the splenic venous flow is poured into collaterals (red arrows) at portal confluence level. Venous collaterals inside the gallbladder wall.*

Case

A 24-year-old female patient applied due to abdominal pain and swelling for the last 3 months. The patient, who did not have a history of alcohol use and medication, had not had abdominal surgery before. On physical examination, there was tenderness in the epigastric region. In laboratory examination, hydatid cyst serology was 1/320 positive, and biochemical parameters, coagulation factors, and liver enzymes were within normal limits. In abdominal ultrasonography and computed tomography, a high-density lesion, measuring 80 × 75 mm and extending to the hilus, filling the left lateral region of the liver, was consistent with the Gharbi-Stage 4 hydatid cyst (Fig. 1A and B). The cyst was compressing the portal vein. There were intrahepatic collaterals and shunts in the right lobe due to portal vein thrombosis (Fig. 1B). There were dilated cavernous structures in the subhepatic area, extending from the falciform ligament to the hilus (Fig. 1C). The patient with portal vein thrombosis did not have cirrhosis and acid but had mild splenomegaly (Fig. 1D). There were also stones in the gallbladder. The patient was started on 2 months of albendazole and prepared for the operation. The patient with aberrant and tortuous veins in the perihilar area was operated on by pre-operative blood preparation. The 80x75 mm hydatid cyst wall filling the lateral liver sector and extending to the hilus was opened, and the daughter vesicles and germinative membrane were excised (pericystectomy). The cyst cavity was washed with a hypertonic NaCl solution. Afterward, the visceral peritoneum was opened to free the gallbladder. The hilar region and Calot triangle were attempted to

be dissected. It was observed that the area between the gallbladder and its surrounding visceral peritoneum was surrounded by large vascular structures that appeared as a result of cavernous transformation. There was bleeding in all areas at the time of dissection. Cholecystectomy was performed by carefully connecting the cavernous structures. In the histopathological examination of the specimen (Fig. 2), it was observed that the cystic-looking structures around the gallbladder were thick-walled vascular cavernous collateral areas. The patient was discharged on the 6th post-operative day. The patient was followed up on the 6th month without any problems.

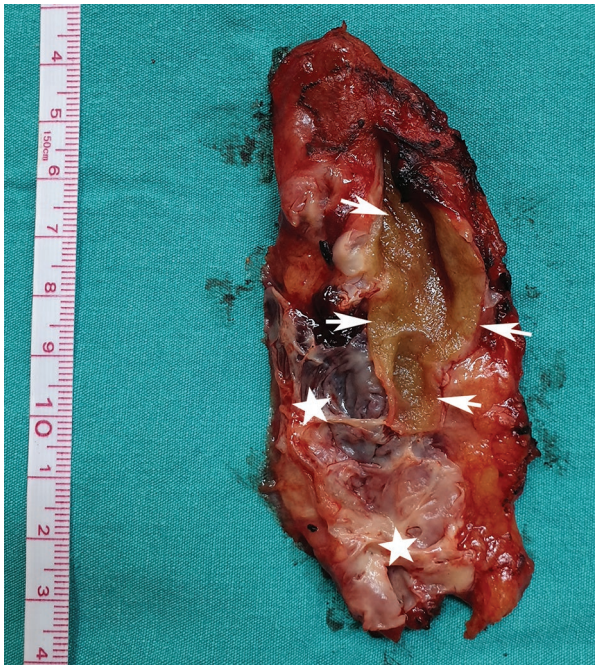

Figure 2. *Specimen shows gallblader margin (Arrows) and pericholecystic cavernous formation (Stars).*

Discussion

Hydatid cysts can apply pressure, disrupt the functions of organs, and present with very different clinical symptoms. Thrombosis and cavernomatosis are rarely seen as a result of compression of the hydatid cyst into the portal vein[4,5]. According to the literature, we found six cases that developed hydatid cyst cavernous transformation.

During chronic obstruction occurring in the portal vein, physiological mechanisms are activated for the decompression of blood reaching the liver, and new collaterals are formed around the vein. This process can be within days or months in patients with venous thrombosis. In the case of our patient, it is understood that the blood coming to the liver is attempted to decompress through the collateral veins and shunts in the intrahepatic, subcapsular, pericholecystic, pericholedocal, and falciform ligaments, starting from the left portal vein. These collaterals, which serve as secondary pathways, expanded over time and turned into the cavernous structure. In our patient, it was thought that the hydatid cyst destroyed the left lateral sector; thrombosis developed as a result of the compression of the cyst extension over the segment five or eight to the portal vein; and due to the slow progression, it did not show any clinical signs with collaterals, especially intrahepatic and subcapsular. Cirrhosis, thrombophilic disorders, pancreatitis, and cholecystitis are involved in the etiology of portal vein thrombosis. Protein S, protein C, and antithrombin III values were also within normal limits in our patient. There were also no known as liver cirrhosis and previous intra-abdominal inflammatory events. In the literature, portal vein thrombus cases secondary to the liver cyst and very few cases with cavernoma have been reported[5,6]. These occur due to compression of the cyst located in the hilus or obstruction following the invasion of parasites in the cyst directly into the portal[6]. It often occurs in the form of periportal, pericholedocal, and pericystic cavernouses. In this case, a giant hydatid cyst extending from the lateral sector to the hilus was shown as the cause of the transformation of cavernous secondary to portal vein thrombosis. The patient had stones in the gall bladder due to the compression of dilated venous structures at the hilus's level into the extrahepatic biliary tract, and the biliary stasis formed. It is a condition that requires surgical treatment due to serious and fatal complications such as hydatid cysts of the liver, spontaneous rupture, portal vein thrombosis, and anaphylaxis common in endemic regions[3]. Periportal cavernoma disrupts the Calot triangle anatomy and causes unexpected bleeding that causes mortality and morbidity during the case[7]. In our patient, the indication for surgical treatment was symptomatic gallstones and a hydatid cyst that atrophied the lateral sector. During the operation, a careful surgical technique was applied, taking into consideration both the giant cyst in the liver and its complications, as well as the perihilar and pericholecystic high-density venous collaterals.

Conclusion

It should be remembered that hydatid cysts may have different comorbidities depending on where they are

compressed, and there are many known complications. In cases where cholelithiasis and hydatid cysts coexist, the development of portal vein thrombosis and cavernous transformation should be kept in mind. Hilar dissection and surgical procedures involve difficulties in the presence of cavernous transformation.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

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References

1. Lizarralde LZ, Pérez IO, Montesinos IR, Gorrotxategi EG. Invasion of the portal vein by a hydatid cyst. Review of the literature. Gastroenterol Hepatol. 2006;29:405-8.
2. Yagmur Y, Akbulut S. Unusual location of hydatid cysts: a case report and literature review. Int Surg. 2012;97:23-6.
3. Derici H, Tansug T, Reyhan E, Bozdag AD, Nazli O. Acute intraperitoneal rupture of hydatid cysts. World J Surg. 2006;30:1879-83.
4. Kayacetin E, Hidayetoglu T. Hydatid cyst of the liver causing a cavernous transformation in the portal vein and complicated by intrabiliary and intraperitoneal rupture. J Gastroenterol Hepatol. 2004;19:1223-4.
5. Denninger MH, Chait Y, Casadevall N, Hillaire S, Guillin MC, Bazeaud A, et al. Cause of portal or hepatic venous thrombosis in adults: the role of multiple concurrent factors. Hepatology. 2000;31:587-91.
6. Ertan G, Ulus S, Kilicarslan R, Yilmaz M, Paksoy Y, Erol C. Hydatid disease of the liver with portal vein invasion mimicking portal vein thrombosis. Arab J Gastroenterol. 2019;20:50-2.
7. Tahmasebi S, Baezzat SR, Talei A, Fazelzadeh A, Lotfi M. Portal vein thrombosis: an unusual complication after laparoscopic cholecystectomy. Middle East J Dig Dis. 2009;2:106-9.

CASO CLÍNICO

Neumoperitoneo espontáneo en ausencia de perforación visceral en un paciente con esclerosis sistémica: reporte de caso

Spontaneous pneumoperitoneum in the absence of visceral perforation in a patient with systemic sclerosis: a case report

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Resumen

Presentamos el caso de una mujer de 44 años con diagnóstico de esclerosis sistémica, quien presentó dolor abdominal intenso sin datos de irritación peritoneal. Una tomografía computarizada de abdomen mostró dilatación generalizada de asas intestinales, neumatosis intestinal y neumoperitoneo extenso, por lo cual se realizó una laparoscopía diagnóstica, sin encontrar sitio de perforación. El neumoperitoneo espontáneo en pacientes con esclerodermia sin evidencia de perforación visceral es una complicación extremadamente rara. El médico deberá mantener un alto índice de sospecha para esta condición ante un paciente con esclerosis sistémica que se presente con un neumoperitoneo espontáneo sin datos de irritación peritoneal.

Palabras clave: *Neumoperitoneo. Neumoperitoneo espontáneo. Esclerosis sistémica. Esclerodermia.*

Abstract

We present the case of a 44 year old woman with systemic sclerosis who presented with intense abdominal pain without signs of peritonitis. An abdominal computed tomography showed generalized intestinal dilation, intestinal pneumatosis and an extensive pneumoperitoneum. A diagnostic laparoscopy was performed but no perforation nor gastrointestinal leakage were found. Spontaneous pneumoperitoneum in patients with systemic sclerosis without visceral perforation is an extremely rare complication. Physicians must have a low threshold of suspicion for this entity when a patient with systemic sclerosis presents with spontaneous pneumoperitoneum in the absence of peritoneal signs.

Keywords: *Pneumoperitoneum. Spontaneous pneumoperitoneum. Systemic sclerosis. Scleroderma.*

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Introducción

El neumoperitoneo se define como la presencia de aire libre extraluminal en la cavidad peritoneal[1], siendo el resultado en el 90% de los casos de una perforación de víscera hueca que generalmente se asocia a datos de irritación peritoneal y requiere una intervención quirúrgica pronta[2]. Sin embargo, en el 10% de los casos restantes puede existir neumoperitoneo sin perforación de una víscera hueca[3]. Algunas causas de neumoperitoneo en ausencia de perforación o peritonitis son abscesos hepáticos rotos, colecistitis enfisematosa, peritonitis bacteriana espontánea, neumotórax con fuga hacia la cavidad abdominal y diálisis peritoneal[4]. En el contexto de la esclerosis sistémica, el neumoperitoneo espontáneo (en ausencia de perforación) se ha descrito excepcionalmente y se postula que se debe a los cambios del tejido conectivo del tracto gastrointestinal que ocurren en dicha enfermedad. Reconocer el neumoperitoneo espontáneo en un paciente con esclerosis sistémica, ante la ausencia de otros datos (dolor persistente, falta de resolución, signos de irritación peritoneal, síndrome compartimental abdominal, etc.), evitará intervenciones quirúrgicas innecesarias. Presentamos el caso de una mujer de 44 años con neumatosis intestinal y neumoperitoneo espontáneo en ausencia de perforación visceral, secundario a esclerosis sistémica.

Caso clínico

Mujer de 44 años con diagnóstico de lupus eritematoso sistémico diagnosticado 10 años previo a su ingreso, en tratamiento con sulfasalazina, deflazacort y metotrexato; además de diagnóstico de esclerodermia con síndrome CREST (calcinosis, fenómeno de Raynaud, dismotilidad esofágica, esclerodactilia, teleangiectasias) en tratamiento con baricitinib. Inició su padecimiento actual 6 meses previos a su ingreso con dolor abdominal tipo cólico, intermitente, generalizado y de intensidad 6/10. En la exploración física se encontró abdomen blando, depresible, doloroso a la palpación media y profunda en el mesogastrio, sin datos de irritación peritoneal. Tras abordarse mediante una radiografía de abdomen con datos sugestivos de perforación intestinal, la paciente fue referida al servicio de urgencias, donde se realizó una tomografía computarizada (TC) de abdomen con contraste oral e intravenoso (Fig. 1), la cual mostró un estómago parcialmente distendido, dilatación generalizada de las asas intestinales, además de neumatosis intestinal, principalmente en el yeyuno y el íleon, y abundante aire libre intraabdominal compatible con neumoperitoneo extenso, sin que se lograra identificar un sitio de fuga franco para el medio de contraste oral. Los laboratorios se encontraban dentro de parámetros normales, por lo que se decidió su ingreso para vigilancia, durante la cual presentó aumento de la distensión abdominal y progresión del dolor, motivo por el cual se decidió realizar una laparoscopía diagnóstica de urgencia, que como hallazgos reportó hipertensión intraabdominal (presión intraabdominal de apertura de 12 mmHg), neumoperitoneo, neumatosis intestinal, diafragmática y mesentérica, serositis generalizada y líquido libre intraabdominal (Fig. 2). Se realizó una panendoscopia transoperatoria, la cual no evidenció sitio de perforación ni anormalidades anatómicas, reportando únicamente la presencia de gastritis erosiva sin otros hallazgos significativos, por lo que se procedió a realizar conteo intestinal total, con lavado y drenaje de la cavidad. Al no encontrar un sitio de perforación o fuga gastrointestinal, se decidió continuar con vigilancia y manejo médico en hospitalización con procinéticos, antibióticos parenterales y reposo intestinal, presentando mejoría franca del dolor tras el abordaje quirúrgico. Se realizó una TC simple de abdomen a las 24 horas del posquirúrgico, encontrando una disminución significativa del neumoperitoneo y la neumatosis intestinal (Fig. 3), por lo que se decidió su alta hospitalaria para continuar el manejo por consulta externa.

Discusión

La esclerosis sistémica o esclerodermia es una enfermedad reumatológica del tejido conectivo caracterizada por fibrosis de ciertos órganos y sistemas[5]. La clasificación de esta enfermedad se basa en el involucro dérmico: la esclerosis sistémica limitada (antes llamada síndrome CREST) se caracteriza por engrosamiento de la piel distal a los codos y las rodillas sin involucro del tronco, mientras que la esclerosis sistémica difusa involucra los segmentos proximales de las extremidades, la cara y el tronco; ambas formas se asocian con manifestaciones sistémicas. En el 70% de los casos habrá positividad para anticuerpos anticentrómero, anti-Scl 70 o anti-RNA polimerasa 3. Los órganos más comúnmente afectados en la esclerosis sistémica son la piel, el tracto gastrointestinal, los pulmones, el pericardio, los riñones y el sistema musculoesquelético[6].

Los cambios gastrointestinales clásicos de la esclerosis sistémica incluyen atrofia de la capa muscular propia y su reemplazo por tejido conectivo a base de

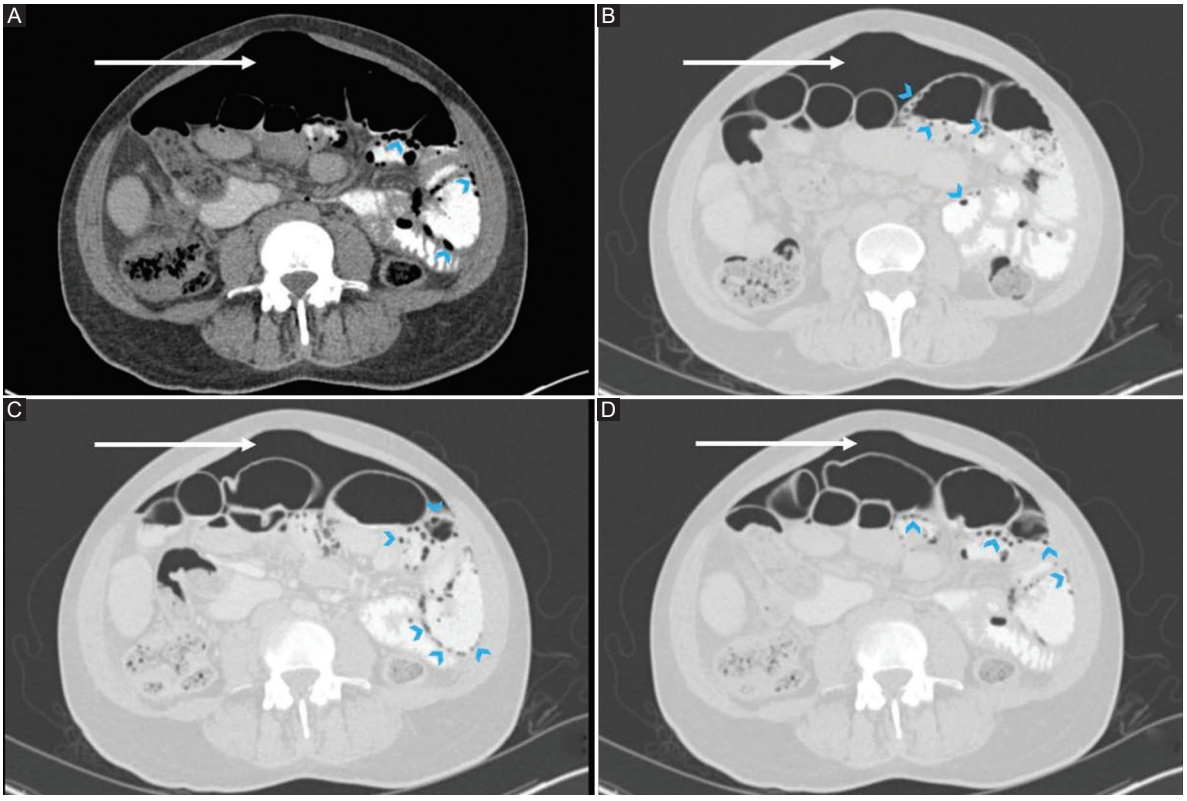

Figura 1. *Tomografía computarizada con doble contraste de abdomen.* **A:** *ventana para abdomen. Neumoperitoneo (flecha blanca) y neumatosis intestinal (puntas de flecha azules).* **B, C** *y* **D:** *ventana de pulmón para mejor visualización. Neumoperitoneo (flechas blancas). Neumatosis en la pared de las asas intestinales (puntas de flecha azules) y dilatación generalizada de las asas intestinales. Sin sitio de fuga del medio de contraste.*

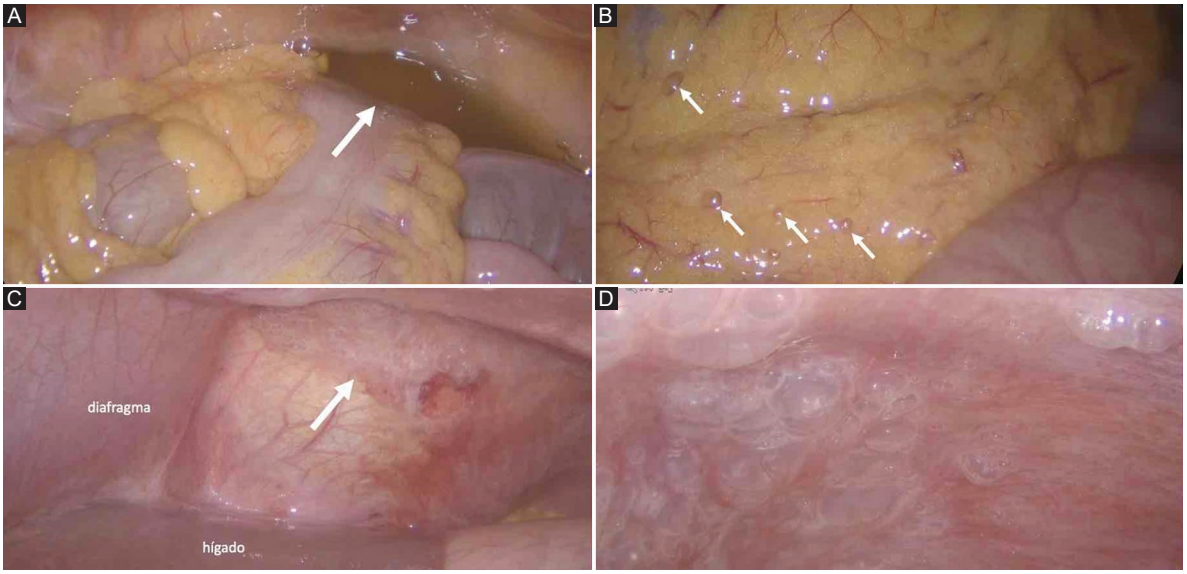

Figura 2. *Exploración laparoscópica de la cavidad abdominal.* **A:** *líquido libre en la cavidad abdominal e intestino dilatado, pero de apariencia normal.* **B:** *neumatosis mesentérica (flechas blancas).* **C:** *neumatosis diafragmática (flecha blanca).* **D:** *neumatosis diafragmática a mayor aumento.*

colágeno, lo que ocasiona disminución de la actividad peristáltica y estasis[7]. Además, puede existir dismotilidad esofágica, retraso en el vaciamiento gástrico, diverticulosis yeyunal, malabsorción y neumatosis intestinal[8]. La neumatosis intestinal, que se presenta solo en el 8% de los casos, es una patología intestinal rara caracterizada por la presencia de gas dentro de la pared intestinal, en general en la mucosa y la

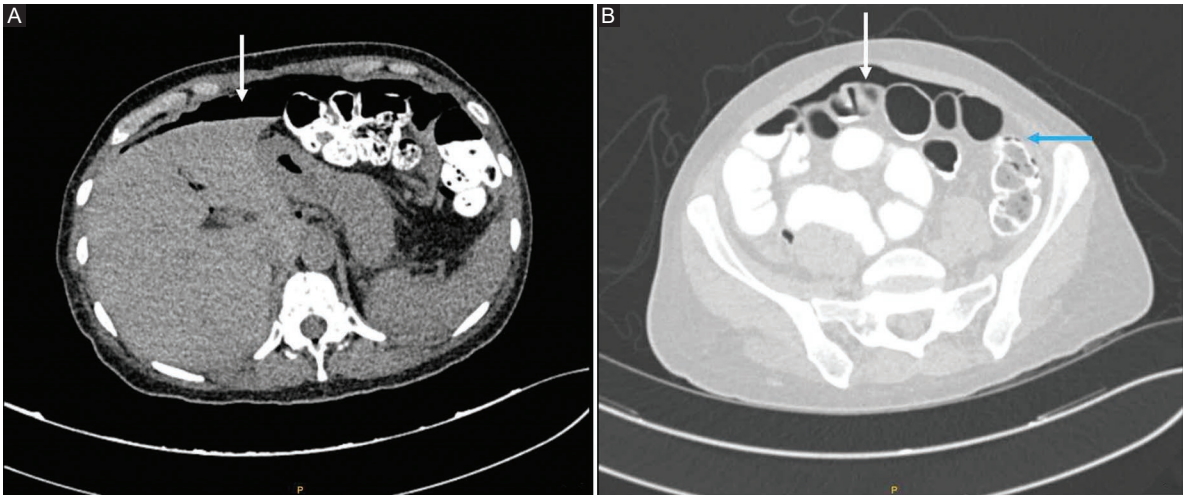

Figura 3. *Tomografía computarizada simple de abdomen, un día después de la intervención quirúrgica. Resolución parcial del neumoperitoneo (flecha blanca) y de la neumatosis intestinal (flecha azul).* **A:** *ventana de abdomen.* **B:** *ventana de pulmón, para mejor visualización.*

submucosa, siendo las localizaciones extraintestinales excepcionalmente raras[9]. El paso del gas intraluminal a la submucosa requiere un daño en la capa muscular de la mucosa, que se puede dar por incremento de la presión intraluminal, procesos inflamatorios o autoinmunitarios (como la esclerosis sistémica), infección por *Clostridioides difficile,* enfermedad pulmonar obstructiva crónica, fibrosis quística o agentes inmunosupresores[9,10]. Los corticosteroides y otros agentes inmunosupresores han sido implicados como factores causantes debido a que inducen atrofia de la mucosa intestinal, depleción de tejido linfoide intestinal y pérdida de la integridad de la barrera mucosa que permite la disección del aire intraluminal a través de la submucosa y la subserosa[11]. En el contexto de la esclerosis sistémica, la neumatosis intestinal parece ser una complicación tardía y representa un peor pronóstico a 6 meses en comparación con los pacientes sin esta afección[12]. En nuestra paciente, diversos factores, como la propia esclerosis sistémica y el uso de corticosteroides y agentes inmunosupresores, pudieron predisponer a la extensa neumatosis intestinal por las razones descritas. Otra afección que se ha relacionado con la esclerosis sistémica y el lupus eritematoso sistémico es la neumatosis quística intestinal, que es la presencia de quistes dentro de la pared intestinal y que en ocasiones se puede asociar a neumoperitoneo cuando estos quistes se rompen[13,14]; sin embargo, en la neumatosis quística intestinal los quistes son visibles macroscópicamente o por estudios de imagen[15,16].

El neumoperitoneo espontáneo en pacientes con esclerodermia sin evidencia de perforación visceral ni neumatosis quística intestinal es una complicación sumamente rara de la esclerosis sistémica, la cual, a conocimiento de los autores, solo ha sido reportada en seis ocasiones en la literatura mundial, sin haber sido ninguno de los casos publicado en México[7,17-19]. En este escenario se ha postulado que, ante la ausencia de datos de perforación visceral franca, como líquido libre, extravasación del contraste enteral o peritonitis, el neumoperitoneo se origina de las colecciones de gas intramural, pasando por defectos microscópicos en una mucosa debilitada y que con el incremento de la presión intraluminal por cualquier causa (estasis, disminución en la motilidad, etc.) logra pasar a la cavidad peritoneal, formando así el neumoperitoneo[20]. La presentación clínica en estos casos es variable y el espectro puede abarcar desde ser asintomático hasta mostrar dolor abdominal intenso, distensión prominente, hematoquezia u otros[14,21]. El método de referencia para el diagnóstico es la TC de abdomen con doble contraste, mostrando habitualmente hallazgos como edema interasas, engrosamiento de la pared intestinal que refuerza con el contraste y gas intramural[14,22]. Algo característico y único del caso clínico presentado es que los hallazgos no solo incluían neumatosis intestinal y neumoperitoneo franco, sino que durante la laparoscopía diagnóstica se evidenció neumatosis mesentérica y neumatosis del epiplón y del peritoneo parietal a nivel del diafragma (Fig. 2). Una explicación probable que ofrecemos para los hallazgos de aire en el peritoneo parietal y el mesenterio podría ser la serositis autoinmunitaria que se desarrolla en el contexto del lupus eritematoso sistémico[9,23]. A pesar de que no hay un consenso establecido, la mayor parte de los autores recomiendan que ante un paciente con

neumoperitoneo y esclerosis sistémica, en ausencia de signos de alarma y de irritación peritoneal, se deberá establecer un manejo expectante con vigilancia y tratamiento médico basado en reposo intestinal, alimentación parenteral, oxigenoterapia y antibióticos[17]. La alimentación parenteral reduce la disponibilidad de nutrientes en el intestino, reduciendo así la producción de gas por la flora colónica, mientras que los antibióticos y la oxigenoterapia tienen el beneficio teórico de reducir el número de bacterias anaerobias productoras de gas[24]. Ante cualquier deterioro en la condición clínica o sospecha de perforación, se recomienda realizar una pronta exploración quirúrgica, mientras que en situaciones de duda diagnóstica se prefiere realizar una exploración laparoscópica por el riesgo de obviar patologías quirúrgicas que pongan en riesgo la vida[3,7].

Conclusión

El conocimiento de distintas patologías y sus presentaciones, a pesar de infrecuentes, permitirá al cirujano mantener un alto índice de sospecha ante un paciente con diagnóstico de neumoperitoneo espontáneo sin perforación intestinal en el escenario de esclerosis sistémica o de otras enfermedades reumatológicas e inmunitarias, logrando normar una conducta terapéutica apropiada aun cuando el caso aparente ser quirúrgico por los estudios de imagen. Conocer esta afección y su manejo evitará procedimientos innecesarios, como resecciones intestinales, que pudieran llegar a comprometer la función de absorción intestinal y la vida del paciente.

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Conflicto de intereses

Los autores declaran no tener conflicto de intereses.

Responsabilidades éticas

Protección de personas y animales. Los autores declaran que para esta investigación no se han realizado experimentos en seres humanos ni en animales.

Confidencialidad de los datos. Los autores declaran que han seguido los protocolos de su centro de trabajo sobre la publicación de datos de pacientes.

Derecho a la privacidad y consentimiento informado. Los autores han obtenido la aprobación del Comité de Ética para el análisis y publicación de datos clínicos obtenidos de forma rutinaria. El consentimiento informado de los pacientes no fue requerido por tratarse de un estudio observacional retrospectivo.

Uso de inteligencia artificial para generar textos. Los autores declaran que no han utilizado ningún tipo de inteligencia artificial generativa en la redacción de este manuscrito ni para la creación de figuras, gráficos, tablas o sus correspondientes pies o leyendas.

Bibliografía

1. García-Santos E, Puerto-Puerto A, Sánchez-García S, Ruescas-García FJ, Alberca-Páramo A, Martín-Fernández J. Síndrome compartimental abdominal por neumoperitoneo a tensión secundario a barotrauma. Presentación de un caso. Cir Cir. 2015;83:429-32.
2. Hoover EL, Cole GD, Mitchell LS, Adams CZ Jr, Hassett J. Avoiding laparotomy in nonsurgical pneumoperitoneum. Am J Surg. 1992;164:99-103.
3. Omori H, Asahi H, Inoue Y, Irinoda T, Saito K. Pneumoperitoneum without perforation of the gastrointestinal tract. Dig Surg. 2003;20:334-8.
4. O'Neill SB, McLaughlin PD, Kelly D, Quigley E, Maher MM. Chronic pneumoperitoneum in systemic sclerosis. Can Assoc Radiol J. 2013;64:154-5.
5. Denton CP, Khanna D. Systemic sclerosis. Lancet. 2017;390:1685-99.
6. Adigun R, Goyal A, Hariz A. Systemic sclerosis. En: StatPearls. Treasure Island (FL): StatPearls Publishing; 2022.
7. London NJ, Bailey RG, Hall AW. Spontaneous benign pneumoperitoneum complicating scleroderma in the absence of pneumatosis cystoides intestinalis. Postgrad Med J. 1990;66:61-2.
8. Weston S, Thumshirn M, Wiste J, Camilleri M. Clinical and upper gastrointestinal motility features in systemic sclerosis and related disorders. Am J Gastroenterol. 1998;93:1085-9.
9. Braumann C, Menenakos C, Jacobi CA. Pneumatosis intestinalis — a pitfall for surgeons? Scand J Surg. 2005;94:47-50.
10. Knechtle SJ, Davidoff AM, Rice RP. Pneumatosis intestinalis. Surgical management and clinical outcome. Ann Surg. 1990;212:160-5.
11. Han BG, Lee JM, Yang JW, Kim MS, Choi SO. Pneumatosis intestinalis associated with immune-suppressive agents in a case of minimal change disease. Yonsei Med J. 2002;43:686-9.
12. Pun YL, Russell DM, Taggart GJ, Barraclough DR. Pneumatosis intestinalis and pneumoperitoneum complicating mixed connective tissue disease. Br J Rheumatol. 1991;30:146-9.
13. Miercort RD, Merrill FG. Pneumatosis and pseudo-obstruction in scleroderma. Radiology. 1969;92:359-62.
14. Balciscueta Coltell I, Álvarez Martínez D, Blanco González FJ. Intestinal pneumatosis. An uncommon cause of acute abdomen. Gastroenterol Hepatol. 2019;42:557-8.
15. Pata F, Di Saverio S. Pneumatosis cystoides intestinalis with pneumoperitoneum. N Engl J Med. 2019;380:e17.
16. Ebert EC, Hagspiel KD. Gastrointestinal and hepatic manifestations of systemic lupus erythematosus. J Clin Gastroenterol. 2011;45:436-41.
17. Vischio J, Matlyuk-Urman Z, Lakshminarayanan S. Benign spontaneous pneumoperitoneum in systemic sclerosis. J Clin Rheumatol. 2010;16:379-81.
18. Wang CL, Wang F, Wong KC, Jeyamalar R. Benign persistent pneumoperitoneum in systemic sclerosis. Singapore Med J. 1993;34:563-4.
19. Lang B, Meske S, Billmann P, Vaith P, Peter HH. Spontanes pneumoperitoneum bei progressiver systemsklerose (generalisierter sklerodermie). Z Rheumatol. 1986;45:64-7.
20. Naiditch JA, Duerst R, Pillai S, Chin A. Nonoperative management of pneumatosis intestinalis and pneumoperitoneum in a patient with acute lymphoblastic leukemia: case report and review of the literature. Eur J Pediatr Surg. 2010;20:426-9.
21. Galm O, Fabry U, Adam G, Osieka R. Pneumatosis intestinalis following cytotoxic or immunosuppressive treatment. Digestion. 2001;64:128-32.
22. Marinello DK, Rafael D, Paiva Edos S, Dominoni RL. Systemic lupus erythematosus complicated by intestinal vasculitis and pneumatosis intestinalis. Rev Bras Reumatol. 2010;50:596-602.
23. Capobianco A, Cottone L, Monno A, Manfredi AA, Rovere-Querini P. The peritoneum: healing, immunity, and diseases. J Pathol. 2017;243:137-47.
24. Koysombat K, Capanna MV, Stafford N, Orchard T. Combination therapy for systemic sclerosis-associated pneumatosis intestinalis. BMJ Case Rep. 2018;2018:bcr2018225068.

ARTÍCULO DE REVISIÓN

Endoscopic treatment of gastroesophageal reflux disease

Tratamiento endoscópico de la enfermedad por reflujo gastroesofágico

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Abstract

The endoscopic treatment of gastroesophageal reflux disease (GERD) has evolved significantly in the past 20 years. Current practices include devices specifically designed for GERD. Newer techniques aim to use less extra equipment, to be less costly, and to use accessories readily available in endoscopy units, as well as using standard endoscopes to apply such techniques. It is of utmost importance to properly select the patients for endoscopic therapy, and it should be done in a multidisciplinary approach.

Keywords: *Endoscopic therapy. GERD. Gastroesophageal reflux disease.*

Resumen

El tratamiento endoscópico de la enfermedad por reflujo gastroesofágico (ERGE) ha evolucionado significativamente en los últimos 20 años. Las prácticas actuales incluyen dispositivos diseñados específicamente para la ERGE. Las técnicas más nuevas tienen como objetivo utilizar menos equipos adicionales, ser menos costosos y utilizar accesorios fácilmente disponibles en las unidades de endoscopia, así como utilizar endoscopios estándar para aplicar dichas técnicas. Es de suma importancia seleccionar adecuadamente a los pacientes para la terapia endoscópica, y debe hacerse en un enfoque multidisciplinario.

Palabras clave: *terapia endoscópica. ERGE. Enfermedad por reflujo gastroesofágico.*

Introduction

Gastroesophageal reflux disease (GERD) is a common clinical condition that can evolve into a debilitating chronic illness and be associated with complications, including the development of esophageal cancer. It is a heterogeneous condition and has been globally classified as an erosive or non-erosive disease[1]. It is increasing in prevalence and incidence worldwide (clinically defined as the presence of symptoms and complications, related to the reflux of gastric contents into the esophagus[1-3]. GERD is a common disorder that affects the quality of life and is responsible for a high resource expenditure for both patients and payors. In the US, the annual expenditure on diagnosing and treating the disease exceeds 9 billion dollars[4,5]. The increasing prevalence and incidence of GERD appear to be closely related to aging, obesity, tobacco use, certain medications such as calcium channel blockers, and tricyclic antidepressants[1-5].

GERD can occur in normal individuals without representing disease. Pathologic GERD occurs primarily due to an inappropriate transient relaxation of the lower esophageal sphincter, and this can be further

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enhanced by the presence of a hiatal hernia which can be associated with LES incompetence, displacement of the acid pocket closer to the esophageal mucosa as well as shortening of the esophagus[6-8]. Other contributing factors include a balance of protective factors: adequate saliva production, esophageal elimination of luminal contents, integrity of the natural antireflux barrier, acid clearance from the esophageal lumen, esophageal mucosa resistance to acid, and non-esophageal components such as degree of gastric acidity, volume of regurgitant and, in specific instances, duodenal contents[6-8].

The mainstay of treatment of GERD is symptom relief and resolution and prevention of complications. A multimodal approach is needed in all patients. The management is always started with medical therapy, including pharmacologic and non-pharmacologic interventions. Endoscopic and surgical treatments aim to improve or normalize the mechanical component of GERD. Independent of what intervention is carried out; patients require lifestyle changes including dietary habits, avoiding eating late at night or lying recumbent soon after eating, prandial postural modifications, weight loss, and tobacco abstinence. The use of proton pump inhibitors and potassium channel modifiers is the first line. Acid suppression with Proton pump inhibitor (PPI) is quite effective and easy to follow, with very good response and efficacy and limited adverse events[9]. There are patients that appear to develop a less effective response overtime and may respond to either a different PPI or changing to a potassium channel modifier. Best responders include patients with typical symptoms of GERD, whereas those with more visceral or functional components and those with extraesophageal symptoms do not fare so well. There is increased awareness in the public for potential PPI-related long-term side effects that prefer an alternative therapy. There is a subgroup of patients (approximately 40%) that may not have an appropriate response to adequate dosing and duration of therapy with PPI and are classified as refractory GERD[10,11].

In surgical anti-reflux procedures, main objectives include increasing the LES basal pressure, repair of the hiatal hernia, fixation the LES to the hiatus, augmentation the intra-abdominal segment of the esophagus, decrease the amount of gastric reflux into the esophagus, and improve esophageal clearance[12-14]. Usual indications for surgical intervention include patients not responding to appropriate trials of medications, the development of side effects, the concern of long-term use of medications and the unwillingness to do so, contraindications to PPIs, large volume refluxate, or the presence of non-responsive complications such as strictures and Barrett's esophagus. The most frequent surgical procedures performed include laparoscopic 360° fundoplication (Nissen) and partial fundoplication (Toupet), with an expected efficiency in the 90% range as well as a reduction in the use of medications, in the high 80% range[12-14]. Short-term outcomes show that approximately 10% of patients do not respond, and that increases to approximately 30% long-term, and a significant number of patients may remain on medications. Because of that, being more invasive, and the possible side effects including inability to belch, vomit, dysphagia, gas bloat, diarrhea, increased flatus, incisional hernia, and need for revision surgeries, an increasing number of patients opt for endoscopic therapies.

Endoscopic correction of GERD is not new, now spanning over 3 decades of various attempts with mixed results. Some of those therapies were designed as a definitive treatment whereas others were conceptualized as a bridge therapy between medications and definitive surgery. The appropriate selection of patients is of paramount importance for endoscopic approaches. An important determinant is the gastroesophageal flap valve (GEFV). Grading of the GEFV is according to Hill's classification[15]: Grade I: fold of tissue tightly surrounds the endoscope; Grade II: fold is prominent but there is intermittently opening and closing around the scope; Grade III: fold is not obvious and the diaphragmatic hiatus is freely open, with no or minimal sliding hiatal hernia visible; Grade IV: fold disappeared, and the diaphragmatic hiatus increased significantly, showing a well-defined sliding hiatal hernia.

Over the years, there have been endoscopic therapies that have now disappeared include the silicon prosthesis[16], endo-plication[17], and injection of bulking agents[18]. While success was reported, the long-term results were not favorable, and some were associated with increased morbidity and mortality. Endoscopic therapies now have evolved to include different forms of plication, ablation, tissue removal, and ligation. Ablative therapies include radiofrequency (Stretta), and other thermal therapies (ARMS, ARMA). Ligation therapy includes Peroral endoscopic cardial constriction with band (PECC-B). Plication therapies include MUSE, TIF-1, TIF-2, and GERD-X. Tissue removal includes mucosectomy.

The development of endoscopic techniques has gone from requiring relatively inexpensive devices,

easy to use, to requiring expensive add-on devices and technically difficult, to back to less expensive, easy-to-apply techniques that include those used for other purposes in the gastrointestinal tract. While some of these techniques are relatively new, their technical feasibility and familiarity with endoscopists make them very attractive for immediate use. There is also an impetus in combining techniques (ablative and plication) (plication and laparoscopic hiatal hernia repair) considering the various mechanisms of GERD[19] or TIF with laparoscopic HH repair[20]. The current endoscopic methods also offer benefits as a complementary intervention in reducing PPI intake and improving quality of life, especially since the causes of GERD are so variable. This makes anti-reflux endoscopy not only an alternative to PPIs but also a complementary tool that can reduce their consumption help improve quality of life, and improve the GERD-HRQL score[21,22].

Offering endoscopic therapy should be carried out equally to offering surgical intervention. At the present time, when appropriately selected, endoscopic therapies have not shown inferiority to surgery, and offer advantages including fewer complications acutely and fewer symptom side effects in the long-term, shorter procedural time, less cost, and, importantly, do not preclude future surgery if needed.

Endoscopic therapies

Ablative methods

Radiofrequency

Stretta procedure (Restech, Houston, TX, USA) uses radiofrequency energy in the muscles of the LES and in the gastric cardia to decrease gastroesophageal junction (GEJ) compliance, resulting in an improvement of reflux symptoms[22]. The Stretta catheter is advanced perorally over a guidewire and positioned 0.5 cm proximal to the GEJ, at the GEJ, and 0.5 cm below the GEJ. At each level, the balloon basket assembly is inflated, and then four nitinol needle electrodes (22-gauge, 5.5-mm) extend into the muscular layer to deliver a radiofrequency current and induce a thermal reaction. This is followed by a 45° rotation clockwise and ablation is again performed. There have been numerous studies of Stretta compared to PPI and sham controls.

The Stretta® procedure has been evaluated in numerous studies including randomized trials *vs* PPI's, sham control, and other endoscopic modalities[22-26]. Results have been equivocal, some showing short-term improvement but lacking significant improvement long-term. Results of various studies have revealed post-procedural improvement in symptoms and quality of life but no improvement in basal LES pressure and pH studies. While the procedure is safe and well-tolerated, with most of the adverse events being esophageal mucosa erosions and lacerations, mediastinitis, pneumonia, and pleural effusion. Stretta has been around for > 2 decades; yet, its long-term effects are not well established.

ARMS and ARMA

ARMS involves mucosectomy of the cardias which then develops a deep scar that strengthens the gastroesophageal junction: this can be performed using endoscopic submucosal dissection and endoscopic mucosal resection techniques. ARMA utilizes a triangular-tipped knife J connected to an electrocautery generator in a spray coagulation mode (Figs. 1A-C). Mucosal ablation is performed around the cardia after the creation of a submucosal cushion with saline and Indigo Carmine in a butterfly shape, leaving two areas of normal mucosa (approximately the width of the endoscope) to avoid stenosis[27-36]. ARMA can also be used with Argon Plasma Coagulation (Figs. 2A-C) forced mode 100W or spray coagulation 50 W, effect 2. ARMS can be performed in a 180° and 270° fashion, both showing a significant improvement in the GERD-Q and decreased use of medications at 6 and 12 months. The overall safety profile is excellent for both ARMS and ARMA, with side effects perhaps being more common with 270° ARMS, and mostly related to dysphagia from stricture formation. While the initial observation of reduction in GERD symptoms after mucosectomy for Barrett's esophagus was noted, the mechanism of action is not well known but may relate to suppression of backflow of gastric content, enhancement of the GEJ flap valve, increasing the integrated relaxation pressure and LES resting pressure and reduction of GEJ distensibility.

Both ARMS and ARMA, especially the latter, offer technical simplicity, do not require costly add-on devices, and can be performed in a standard endoscopy room. While the procedure is not standardized, most authors do not involve the esophageal mucosa, only the gastric cardia and spare 1 cm of normal mucosa along the greater and lesser curvature.

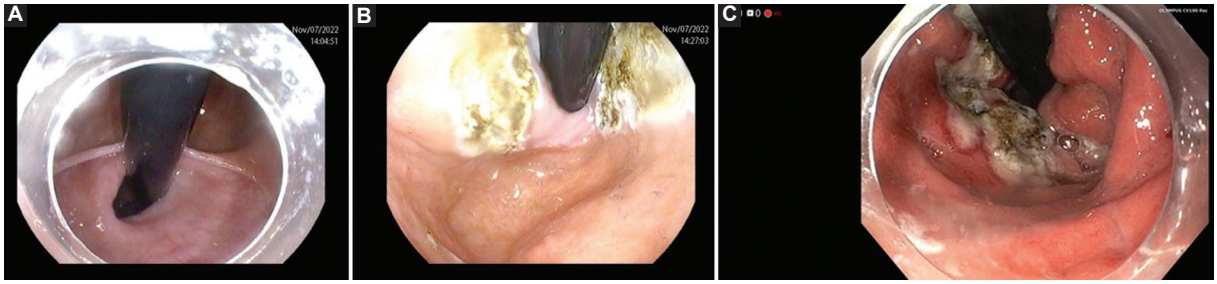

Figure 1. A: *endoscopic retrograde appearance of the cardias showing a hiatal hernia and a cap on the endoscope.* **B:** *the endoscopic image of the area ablated to the side of the cardias.* **C:** *endoscopic view of the ablated area by the cardias.*

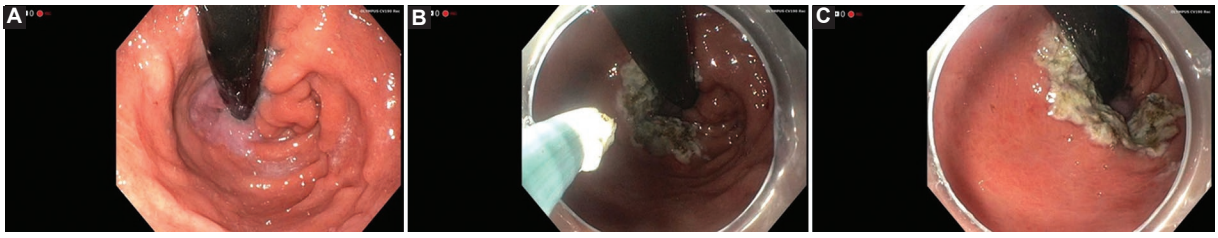

Figure 2. A: *endoscopic retrograde appearance of the cardias showing a hiatal hernia.* **B:** *the endoscopic image of the area ablated to the side of the cardias with Argon plasma coagulator.* **C:** *endoscopic view of the ablated area by the cardias.*

There have been multiple non-randomized studies with varying follow-up from 2 months to 3 years[28-34]. The clinical success varies from 60 to 100% in the short term (< 6 months) and around 75% at 3 years. The overall safety of the procedure has been high. The most common adverse event has been dysphagia (5-10%). Perforation has been the most severe adverse event (ARMS only) occurring in <2% of patients. Chest pain, odynophagia, and epigastric pain have also been reported. All studies have reported statistically significant improvement in the GERD-HRQL scores, median Hill flap grade, and pH median De-Meester score.

This procedure, especially ARMA, is very attractive considering its simplicity, familiarity with the technology, time and cost of procedure, safety, and efficacy. While randomized studies are lacking, it is a very promising technique.

Aplication

Medigus ultrasonic surgical endostapler (MUSE), Medigus, Omer, Israel is a transoral fundoplication using a video-guided surgical stapler[37-39]. It combines visual, ultrasonic, and surgical stapling capabilities into one device, which enables a single endoscopist to perform a transoral anterior fundoplication. This flexible surgical endostapler resembles an endoscope with a rigid section holding a cartridge with five standard 4.8-mm titanium surgical staples. The distal tip contains an anvil for bending the staples, two small 21-gauge screws, and an ultrasonic transducer to measure the distance to the cartridge. MUSE is a three-step procedure that includes: (1) Advancing the device into the stomach through an overtube and retroflex; (2) Retraction of the device to 3 cm proximal to the GEJ for clamping when the tissue thickness measurement reaches 1.4-1.6 mm and actuating the stapler; and (3) The procedure is repeated 5 times to create an anti-reflux barrier. The results of various prospective studies have been compared favorably with Stretta and TIF-2 (see below). Overall patients report symptomatic improvement and reduction of PPI use. Long-term follow-up includes data to 5 years. Significant improvement in GERD-HRQL score and reduction in the number of patients taking PPIs daily, 69-92% and 64%, respectively, have been reported. Limited functional analysis of the impact on pH monitoring has been positive for reduction in acid exposure. The safety profile of the device is robust, with reported complications including gastrointestinal bleeding, perforation, pneumothorax, and empyema, all < 3%. Most studies have included patients with GERD with a hiatal hernia < 3 cm.

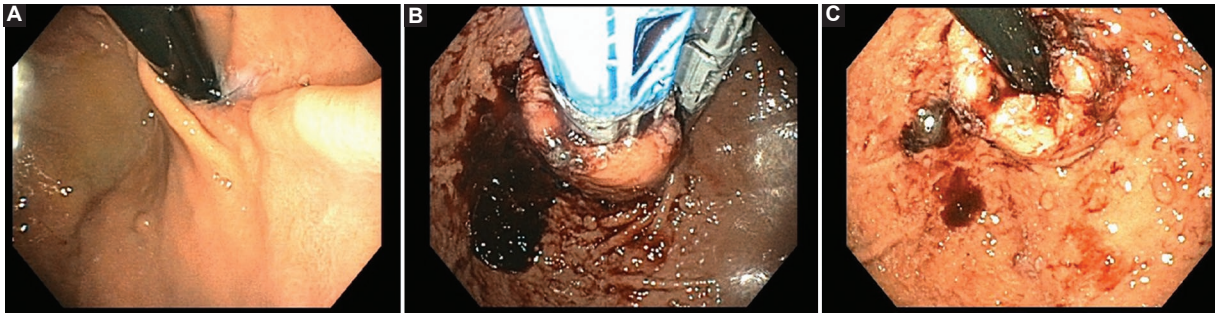

Figure 3. A: *endoscopic retrograde appearance of the cardias showing a hiatal hernia and a cap on the endoscope.* **B:** *endoscopic view showing TIF-2 device plicating.* **C:** *endoscopic view of a completed TIF-2 plication.*

TIF involves the use of EsophyX EndoGastric Solutions, Inc., Redmond, WA, United States. The EsophyX is a device inserted through the mouth and positioned in the esophagus and stomach and creates folds of tissue held together by plications, creating a mechanical antireflux barrier. The device has evolved, along with the technique, in creating circumferential plications rather than longitudinal. The circumferential plication encompasses 200° to 300° in circumference and ~3-cm length wrap over the distal esophagus below the diaphragm to create full-thickness plications. The current version of EsophyX is easier to use and more automated with a result that mimics a Toupet surgical fundoplication (Figs. 3A-C)[40-42].

Best candidates for TIF are patients with a Hill Grade II LES incompetence without a concomitant HH. Patients with a hiatal hernia > 2 cm and a Hill grade 3-4 can be treated with concomitant hernia repair and TIF. Most studies, randomized and non-randomized, have included patients with small to no hiatal hernia, absent severe erosive disease, or Barrett's epithelium. Rates of success range from 50% at 1 year to 92% at 10 years. Overall, improvement in GERD-HRQL score, reduction in heartburn and regurgitation is observed in ~70% of patients, and a reduction in PPI use of approximately 63% at 1 year. Studies randomized to TIF versus sham have included responses up to a year, with a primary endpoint being an equal or > 50% reduction in GERD-HRQL. Data at 5 years have shown improvement in 80-86% of patients. Performing a combined endoscopic plication with TIF and laparoscopic fundoplication may provide a greater insight into the most desired intervention and actional mechanisms[43].

Acid measurement and lowering of acid reflux episodes have been documented at 3 months but not at a year follow-up point. Adverse events are uncommon, occurring in < 3%. TIF has been favorably compared to antireflux surgery in reducing symptoms and decreasing PPI use with a better safety profile and fewer adverse events long-term.

GERDx (G-SURG GmbH, Seeon–Seebruck, Germany) involves performing a full-thickness plication with the GERDx system, which creates a plication with a pretied transmural suture. It uses hydraulic elements for control and requires a slim gastroscope that works as a light source. Symptomatic improvement is achieved in 93.3% of patients and 63% were able to discontinue PPI[44]. However, almost 20% required surgical anti-reflux procedures at 3 months. Improvement in DeMeester score was reduced with ~60.0%) achieving normal levels. Reduction in PPI use was reported with most being on demand or off medication, ~80%. The complication rate is around 10%, including a suture passing through the left hepatic lobe, GE junction hematoma, a Mallory–Weiss tear, and empyema.

Ligation

PECC-B ligation involves ligating GEJ mucosa with a band[45,46]. After a routine esophagogastroduodenoscopy is performed, the endoscope is then loaded with a standard ligating device advanced to the gastric fundus, and retroflexed. The mucosa around the cardia opening of the gastric fundus is suctioned and a ligation is performed. This is repeated up to 4 times, depending on the degree of cardial incompetence. The first band is placed ~ 1 cm above the cardia along the lesser curvature and the second band is ~ 1 cm above the greater curvature. A clip may be placed at the base of the bands to minimize the risk of band slippage. This procedure can be performed in patients with all Hill grades. Statistically significant reduction in the GERD-Q scores at 1, 3, 6, and 12 months was

statistically significantly decreased, with apparent better results in patients with Hill Type III. Randomized controlled trials of patients with refractory GERD have shown significant improvement in GERD-HRQL score and the number of reflux episodes at 1 year. The overall safety profile of the technique is good, with only minor side effects reported, including transient dysphagia and epigastric pain, in 25% and 40%, respectively. Overall, data are limited and lack proper follow-up and randomization. Advantages include simplicity of technique, use of familiar equipment and devices, safe profile, and reported efficacy.

Conclusion

GERD is a complex and chronic condition. Symptoms can be caused by multiple factors and not necessarily only from reflux of gastric contents. The management should be multimodal, always starting with the least invasive and effective treatment, medical. For patients with an inappropriate response or those not wanting to take long-term medications, endoscopic and surgical interventions are warranted. The selection of patients is important to determine the most appropriate therapeutic route. Endoscopic therapies have evolved to include easier techniques, simpler, widely available, effective, and safe, that do not require cumbersome add-on devices. Independent of technique, the clinical success, and reduction of medication intake are similar across all techniques. The appropriate selection will be made after a thorough discussion with the patient.

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Conflicts of interest

Advisory board and Speaker Bureau for Boston Scientific, Microtech, Pentax, Olympus, ConMed, Endosound, and Medtronic. Co-owner of EndoRx.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that no patient data appear in this article. Furthermore, they have acknowledged and followed the recommendations as per the SAGER guidelines depending on the type and nature of the study.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

Use of artificial intelligence for generating text. The authors declare that they have not used any type of generative artificial intelligence for the writing of this manuscript nor for the creation of images, graphics, tables, or their corresponding captions.

References

1. Aziz Q, Fass R, Gyawali P, Miwa H, Pandolfino JE, Zerbib F. Functional esophageal disorders. Gastroenterology. 2016;150(6):1368-79.
2. Eusebi LH, Ratnakumaran R, Yuan Y, Solaymani-DOdaran M, Bazzolli F, Ford AC. Global prevalence of, and risk factors for, gastroesophageal reflux symptoms: a meta-analysis. Gut. 2018;67:430-40.
3. Delshad SD, Almario CV, Chey WD, Spiegel BM. Prevalence of gastroesophageal reflux disease and proton pump inhibitor-refractory symptoms. Gastroenterology. 2020;158:1250-61.
4. Tack J, Becher A, Mulligan C, Johnson DA. Systematic review: the burden of disruptive gastro-esophageal reflux disease on health-related quality of life. Aliment Pharmacol Ther. 2012;35:1257-66.
5. De la Coba OC, Arguelles Arias F, de Argila M, de Prados C. Proton-pump inhibitors adverse effects: a review of the evidence and position statement by the Sociedad Espanola de Patologia Digestiva. Rev Esp Enferm Dig. 2016;108:207-24.
6. Chen J, Brady P. Gastroesophageal reflux disease: pathophysiology, diagnosis, and treatment. Gastroenterol Nurs. 2019;42:20-8.
7. Tack J, Pandolfino JE. Pathophysiology of gastroesophageal reflux disease. Gastroenterology. 2018;154:277-88.
8. Clarrett DM, Hachem C. Gastroesophageal reflux disease (GERD). Mo Med. 2018;115:214-8.
9. Sandhu DS, Fass R. Current trends in the management of Gastroesophageal reflux disease. Gut Liver. 2018;12:7-16.
10. Rettura F, Bronzini F, Campigotto M, Lambiase C, Pancetti A, Berti G, et al. Refractory gastroesophageal reflux disease: a management update. Front Med (Lausanne). 2021;8:765061.
11. Katz PO, Dunbar KB, Schnoll-Sussman FH, Greer KB, Yadlapati R, Spechler SJ. ACG clinical guideline for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. 2022;117:27-56.
12. Frazzoni M, Piccoli M, Conigliaro R, Frazzoni L, Melotti G. Laparoscopic fundoplication for gastroesophageal reflux disease. World J Gastroenterol. 2014;20:14272-9.
13. Watson DI. Laparoscopic treatment of gastro-esophageal reflux disease. Best Pract Res Clin Gastroenterol. 2004;18:19-35.
14. Oelschlager BK, Quiroga E, Parra JD, Cahill M, Polissar N, Pellegrini CA. Long-term outcomes after laparoscopic antireflux surgery. Am J Gastroenterol. 2008;103:280-7; quiz 288.
15. Hill LD, Kozarek RA, Kraemer SJ, Aye RW, Mercer CD, Low DE, et al. The Gastroesophageal flap valve: in vitro and in vivo observations. Gastrointest Endosc. 1996;44:541-7.
16. Kozarek RA, Phelps JE, Sanowski RA, Grobe JL, Fredell CH. An anti-0reflux prosthesis in the treatment of gastroesophageal reflux. Ann Intern Med. 1983;98:310-5.
17. Chen YK, Raijman I, Ben-Menachem T, Starpoli AA, Liu JJ, Pazwash H, et al. Long-term outcomes of endoluminal gastroplication: a U.S. multicenter trial. Gastrointest Endosc. 2005;61:659-67.
18. Cohen LB, Johnson DA, Ganz RA, Aisenberg J, Deviere J, Foley TR, et al. Enteryx implantation for GERD: expanded multicenter trial results and interim post approval follow-up to 24 months. Gastrointest Endosc. 2005;61:650-8.
19. Benias PC, D'Souza L, Lan G, Gluckman C, Inamdar S, Trindade AJ, et al. Initial experience with a novel resection and plication (RAP) method for acid reflux: a pilot study. Endosc Int Open. 2018;6:E443-9.
20. Janu P, Shughoury AB, Venkat K, Hurwich D, Galouzis T, Siatras J, et al. Laparoscopic hiatal hernia repair followed by transoral incisionless fundoplication with EsophyX device (HH + TIF). Efficacy and safety in two community hospitals. Surg Innov. 2019;26:675-86.
21. Richter JE, Kumar A, Lipka S, Miladinovic B, Velanovich V. Efficacy of laparoscopic Nissen fundoplication vs transoral incisionless fundoplication or proton pump inhibitors in patients with gastroesophageal reflux disease: A systematic review and network meta-analysis. Gastroenterology. 2018;154:1298-308.

22. Rodriguez de Santiago E, Albeniz E, Estremera-Arevalo F, Teruel Sanchez-Vegazo C, Lorenzo-Zuniga V. Endoscopic anti-reflux therapy for gastroesophageal reflux disease. World J Gastroenterol. 2021;27:6601-14.
23. Kalapala R, Shah H, Nabi Z, Darisetty S, Talukdar R, Nageshwar Reddy D. Treatment of gastroesophageal reflux disease using radiofrequency ablation (Stretta procedure): an interim analysis of a randomized trial. Indian J Gastroenterol. 2017;36:337-42.
24. Lipka S, Kumar A, Richter JE. No evidence for efficacy of radiofrequency ablation for treatment of gastroesophageal reflux disease: a systematic review and meta-analysis. Clin Gastroenterol Hepatol. 2015;13:1058-67.
25. Zerbib F, Sacher-Huvelin S, Coron E, Coffin B, Melchior C, Ponchon T, et al. Randomized clinical trial: esophageal radiofrequency energy delivery versus sham for PPI-refractory heartburn. Aliment Pharmacol Ther. 2020;52:637-45.
26. Xie P, Yan J, Ye L, Wang C, Li Y, Chen Y, et al. Efficacy of different endoscopic treatments in patients with gastroesophageal reflux disease: a systematic review and network meta-analysis. Surg Endosc. 2021;35:1500-10.
27. Sui X, Gao X, Zhang L. Clinical efficacy of endoscopic antireflux mucosectomy vs. Stretta radiofrequency in the treatment of gastroesophageal reflux disease: a retrospective, single-center cohort study. Ann Transl Med. 2022;10:660.
28. Inoue H, Tanabe M, de Santiago ER. Anti-reflux mucosal ablation (ARMA) as a new treatment for gastroesophageal reflux refractory to proton pump inhibitors: a pilot study. Endosc Int Open. 2020;8:E133-8.
29. Shimamura Y, Inoue H, Tanabe M, Ushikubo K, Yamamoto K, Kimoto Y, et al. Clinical outcomes of anti-reflux mucosal ablation for gastroesophageal reflux disease: an international bi-institutional study. Gastroenterol Hepatol. 2023;39:149-56.
30. Tanabe M, Inoue H, Abad MR. 878 clinical outcomes of endoscopic anti-reflux treatment methods; anti-reflux mucosectomy (ARMS) and anti-reflux mucosal ablation (ARMA). Gastrointest Endosc. 2020;91:AB72.
31. Kalapala R, Jagtap N, Nabi Z. Anti-reflux mucosal ablation (ARMA) for refractory gastroesophageal reflux disease-an interim analysis. Endoscopy. 2021;53:OP210.
32. Hernández Mondragón OV, Zamarripa Mottú RA, García Contreras LF. Clinical feasibility of a new antireflux ablation therapy on gastroesophageal reflux disease (with video). Gastrointest Endosc. 2020;92:1190-201.
33. Patil G, Dalal A, Maydeo A. Feasibility and outcomes of anti-reflux mucosectomy for proton pump inhibitor dependent gastroesophageal reflux disease: first Indian study (with video). Dig Endosc. 2020;32:745-52.
34. Inoue H, Ito H, Ikeda H. Anti-reflux mucosectomy for gastroesophageal reflux disease in the absence of hiatus hernia: a pilot study. Ann Gastroenterol. 2014;27:346-51.
35. Yang X, Tan J, Liu Y, Feng Y, Shi R. Comparison of 180° anti-reflux mucosectomy versus 270° anti-reflux mucosectomy for treatment of refractory gastroesophageal reflux disease: a retrospective study. Surg Endosc. 2022;36:5002-10.
36. Yoo IK, Ko WJ, Kim HS. Anti-reflux mucosectomy using a cap-assisted endoscopic mucosal resection method for refractory gastroesophageal disease: a prospective feasibility study. Surg Endosc. 2020;34:1124-31.
37. Kim HJ, Kwon CI, Kessler WR. Long-term follow-up results of endoscopic treatment of gastroesophageal reflux disease with the MUSE™ endoscopic stapling device. Surg Endosc. 2016;30:3402-8.
38. Zacheri J, Roy-Shapira A, Bonavina L, Bapaye A, Liesslich R, Schoppmann SF, et al. Endoscopic anterior fundoplication with the Medigus Ultrasonic Surgical Endoplaster MUSE endoscopic stapling device. Surg Endosc. 2016;30:3402-8.
39. Kauer WK, Roy-Shapira A, Watson D, Sonnenschein M, Sonnenschein E, Unger J, et al. Preclinical trial of a modified gastroscope that performs a true anterior fundoplication for the endoluminal treatment of gastroesophageal reflux diseasr. Surg Endosc. 2009;23:2728-31.
40. Trad KS, Barnes WE, Prevou ER. The TEMPO trial at 5 years: transoral fundoplication (TIF 2.0) is safe, durable, and cost-effective. Surg Innov. 2018;25:149-57.
41. Testoni S, Hassan C, Mazzoleni G. Long-term outcomes of transoral incisionless fundoplication for gastro-esophageal reflux disease: a systematic review and meta-analysis. Endosc Int Open. 2021;9:E239-46.
42. Chimukangara M, Jalilvand AD, Melvin WS, Perry KA. Long-term reported outcomes of transoral incisionless fundoplication: an 8-year cohort study. Surg Endosc. 2019;33:1304-9.
43. Nguyen NT, Chinn J, Chang K. Collaboration between GI surgery & Gastroenterology improves understanding of the optimal antireflux valve-the omega flap valve. Surg Endosc. 2021;35:3214-20.
44. Weitzendorfer M, Spaun GO, Antoniou SA, Witzel K, Emmanuel K, Koch OO. Clinical feasibility of a new full-thickness endoscopic plication device (GERDx™) for patients with GERD: results of a prospective trial. Surg Endosc. 2018;32:2541-9.
45. Li ZT, Ji F, Han XW. Endoscopic cardial constriction with band ligation in the treatment of refractory gastroesophageal reflux disease: a preliminary feasibility study. Surg Endosc. 2021;35:4035-41.
46. Li Z, Li Y, Wu Y, Li M, Yan Z, Nie S, et al. Endoscopic tightening of the cardia mucosa in gastroesophageal reflux disease: a case series of 120 patients up to 1-year follow-up. J Clin Transl Res. 2022;8:147-51.

LETTER TO THE EDITOR

Comments on "Sigmoid volvulus in a young adult, a manifestation of Hirschsprung disease"

Comentarios a 'Vólvulo de sigmoide en un adulto joven, manifestación de la enfermedad de Hirschsprung'

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To the Editor,

We read the paper written by Rojas-Gutierrez et al.[1] on sigmoid volvulus (SV) complicating Hirschsprung disease (HD). HD complicated by SV is a very rare clinical entity with about 34 cases reported in 26 papers to date[2,3]. Our comments relate to this comorbidity based on our 56.5-year (from June 1966 to January 2023) and 1063-case SV experience, the most comprehensive monocenter SV series over the world[4].

First, HD is seen in 0.6-3% of SV cases[2]. Hence, 2 (0.2%) of our patients had SV complicating HD; both were young adults such as the authors' case and with SV recurrence following endoscopic decompression. Most likely due to the rarity of this comorbidity, its pathophysiology is not clearly defined in the literature[2,5]. In our opinion and experience, the cause and effect relation between SV and HD may be explained by two different mechanisms. In some cases, HD initiates SV by triggering the twisting of the sigmoid colon, while HD mimics SV by inducing an obstruction-like clinical picture in the remained patients. No matter which mechanism is more effective, our experiments demonstrate that the denominator is the impairment or absence of the ganglion cells of the intestinal plexus in SV and HD.

Second, although the authors could not take the advantages of endoscopy, definitive surgery following endoscopic decompression of SV and histopathological evaluation of rectal biopsy materials is the preferred management option in patients with HD complicated by SV[2,5]. On the other hand, inadequate resection and unnoticeable HD are the most important causes of recurrent SV. For this reason, in our opinion, resection of a maximum length of the colon involving all aganglionic segments and enabling a tension-free anastomosis is essential in such cases.

We congratulate the authors and we look forward to their reply.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for

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analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

References

1. Rojas-Gutierrez CD, Haro-Cruz JS, Cabrera-Eraso DF, Torres-Garcia VM, Salas-Alvarez JC, Valencia-Jimenez JO. Case report: sigmoid volvulus in a young adult, a manifestation of Hirschsprung disease. Cir Cir. 2022;90:842-7.
2. Uylas U, Gunes O, Kayaalp C. Hirschsprung disease complicated by sigmoid volvulus: a systematic review. Balkan Med J. 2021;38: 1-6.
3. Web of Science. Sigmoid Volvulus and Hirschsprung Disease. Available from: https://www.webofscience.com/wos/woscc/summary/ccf0d56c-2722-498d-8e73-d88aea0ce5da-6d0dee44/relevance/1 [Last accessed on 2023 Jan 31].
4. Atamanalp SS, Peksoz R, Disci E. Sigmoid volvulus and ileosigmoid knotting: an update. Eurasian J Med. 2022;54:91-6.
5. Gosaye AW, Nane TS, Negussie TM. A case report of Hisrschsprung's disease presenting as sigmoid volvulus and literature review, Tikur Anbessa Specialized Hospital, Addis Ababa, Ethopia. BMC Surg. 2021;21:109.

CARTA AL EDITOR

Could reconstructive post-colonial criticism and critical epistemology contribute to forming a more critical doctor in Latin America?

¿Pueden la crítica poscolonial reconstructiva y la epistemología crítica contribuir a la formación de un médico más crítico en Latinoamérica?

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We live in a hyperfragmentation state, deinstitutionalization, and coexistence of multiple minorities that they do not coincide in several of their social aspirations. An emerging reconstructive post-colonial critique, as a critique of power relations, and not just a deconstructive post-colonial criticism, could recover the experiences of places, peripheral for the generation of knowledge[1].

On the other hand, critical epistemology is a proposal that supposes the construction of knowledge through the recovery of historical perspectives from multiple subaltern subjects in response to the neoliberal paradigms imposed by the West[2]. It make possible for multiple narratives to coexist and feed off each other.

The construction of one's thought from a more holistic epistemic perspective that responds to sociocultural demands is one of the supreme assets of current Latin American critical epistemology attached the task of epistemic decolonization.

We could take elements of these theories to develop objectives such as interpreting the life stories of patients through the analysis of their disease constructs concerning culture, developing communication skills for interaction with community leaders and with people, and identifying and interpreting the use of indigenous knowledge of communities and traditional medicine in healing practices.

The development of skills and abilities with these objectives it is important in countries with unequal access to health resources, but with a rich accumulated experience in traditional and alternative medicine that has not been taken advantage of by doctors.

The use of educational activities based on critical epistemology and reconstructive post-colonial criticism could contribute to the formation of a more committed Latin American physician capable of interacting with the complex problems of medical practice in marginalized communities in the region and understanding with a more critical sense, the unstable geocultural realities of Latin America.

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References

1. Kozlarek O. The challenges for a critical social theory. Towards a "reconstructive postcolonial critique". Sociological. 2017;92:41-68.
2. Gallegos Elias C, Rosales Carranza G. Critical epistemology. Educ Itiner. 2012;26:15-29.

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