ORIGINAL ARTICLE

Methodological proposal for the development and validation of a scale of pain assessment in the critically burned patient

Propuesta metodológica para la elaboración y validación de una escala de evaluación del dolor en el paciente quemado en estado crítico

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Abstract

Objective: *To have a scale for pain assessment in the critical burned adult patient.* **Method:** *A literature review was carried out, and an assessment scale was built with 24 items grouped into 8 categories or dimensions: burn extension, depth, airway burn and/or inhalation injury, facial expression, mechanical ventilation, limb movement, heart rate and painful procedures, and 4 evaluation criteria were applied: sufficiency, clarity, coherence and relevance, on a scale of 1 to 4, from non-compliance with the criterion to full compliance with the criterion.* **Results:** *The Scale was revised and validated by expert judgment, reaching an overall content validity ratio of 0.96 (Lawshe) and 0.98 (Tristan-Lopez), an Aiken V of 0.96, which shows an agreement between judges over 96% and an adequate validity of the instrument. The Cronbach index was 0.74, demonstrating acceptable internal reliability and consistency.* **Conclusions:** *In the experts' opinion, it is an instrument with a high reliability rate and is recommended for application in a sample of critical burned patients for a second validation and its subsequent use and dissemination.*

Keywords: *Pain. Scale. Critical status. Burned.*

Resumen

Objetivo: *Disponer de una escala para la evaluación del dolor en el paciente adulto quemado en estado crítico.* **Método:** *Se realizó una revisión bibliográfica y se construyó una escala de valoración con 24 ítems agrupados en ocho categorías o dimensiones: extensión de la quemadura, profundidad, quemadura de vía aérea o lesión por inhalación, expresión facial, ventilación mecánica, movimiento de las extremidades, frecuencia cardíaca y procedimientos dolorosos. Se aplicaron cuatro criterios de evaluación: suficiencia, claridad, coherencia y relevancia, en una escala de 1 a 4, desde no cumplimiento del criterio hasta cumplimiento total.* **Resultados:** *La escala fue revisada y validada por juicio de expertos, alcanzando un coeficiente de razón de validez global de 0.96 (Lawshe) y 0.98 (Tristán-López), y una V de Aiken de 0.96, lo que evidencia un acuerdo entre jueces superior al 96% y una validez adecuada del instrumento. El índice de Cronbach fue de 0.74, demostrando confiabilidad y consistencia interna aceptables.* **Conclusiones:** *A juicio de los expertos, es un instrumento con un alto índice de confiabilidad y se recomienda su aplicación en una muestra amplia de pacientes quemados críticos para una segunda validación y su posterior uso y difusión.*

***Palabras clave*:** *Dolor. Escala. Estado crítico. Quemado.*

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Introduction

Burns are a public health concern all over the world. The World Health Organization reports around 180.000 deaths by burns every years. The majority of these deaths happen in countries with medium and low resources[1]. One of the international standards for healthcare is proper pain management[2].

Historically, there have been attempts to measure pain since the 19th century. Clinicians cannot assert if pain has been reduced or eliminated, unless, that pain has already been assessed and measured[3]. In order to estimate this sensation it must be evaluated both qualitatively and quantitatively, and the intensity given by each patient must be assigned[4].

Large part of the advances in the assessment and care of burn was the result of the work of war surgeons; however, one of the most historically relevant events was the fire in the Cocoanut Grove nightclub in Boston, United States, in 1942. This event generated key innovations in the treatment of burned patients[5]. Throughout time, and with available diagnostic and therapeutic tools, the study, evaluation, and treatment of pain have been evolving, and the capacity to evaluate pain intensity in patients is one of the key points.

In burned patients specifically, it has been proven that the key to a successful treatment is the continuous and precise evaluation of pain and the response to the implemented therapy[6].

The guidelines of the European Burns Association (2017) recommend that pain management for burned patients is implemented with an approach based on guidelines and in a multidisciplinary manner. Each patient must receive individualized pain management, according to their own scores[7].

According to what was published by Cáceres-Jerez et al.[8], management of acute pain in patients with serious burns must not be focused only on their somatic components, but also be extended to physical, emotional, and psychosocial components, in order to provide integral management, both drug based and non-drug based.

Adequate pain management is essential for those who suffer it in order to avoid the onset or evolution of pathological pain, which would lead to chronic pain and this would result in declining quality of life[9].

Unfortunately, inadequate pain management in burned patient is still a reality. In general, modern management of burned patients focuses on avoiding deaths, scars, and pain[10].

The integrity of the human body and mental balance ensure higher quality of life and productivity, as well as country development. The opposite not only creates great financial burden, but it also affects the family unit, puts more pressure on healthcare professional providing care, especially when patients need care due to their burns, whose effects are immediate and long-term, leaving physical scars and psychological sequelae.

Burns are the greatest physical aggression a human being can suffer, as it is the most severe and painful form of trauma. Burns create pain from the time of the injury, and their physiopathology has many factors and is complex.

In burned patients, when the dermal receptors are injured, a nociceptive amplification leads to an altered function of the perception, transmission, and modulation of the painful stimulus[11].

The main function of pain is to alert an individual of any harmful agents, whether real or potential; however, this unpleasant sensation frequently persists beyond the trigger, and may evolve independently[12].

One of the elements that separates burned patients from other patients in critical condition is the evolution of pain. Due to the involvement of factors that affect the conscious perfection of the patient, such as mood, genetic predisposition, substance abuse, cultural context, expectations and past experiences, characteristics and presentation will be different in the course of time.

Scales have been developed in order to evaluate pain in critically ill patients, but they have not been validated for use in burned patients in critical condition.

Due to the complexity of pain, it cannot be measured or observed directly. In order to measure it, a strategy is used to group its characteristics in wider categories that are always present, and this is known as the development of a domain or factor structure[13].

The next step is measuring each of the domains or factors by asking questions or using specific examination aspects (items), whose responses or results can be given in a categorical o continuous score. The resulting collection of items that measure factors is what is known as a scale[13].

With the introduction of a new tool, based on the lack of an instrument to evaluate pain in burned patients in critical conditions, and its validation, a new resource is proposed to evaluate pain in a more dynamic and objective manner, as these patients

exhibit greater difficulty to express their symptoms, and consequently to receive adequate and timely treatment.

Method

The methodology included reviewing the literature, building the scale, reviewing it, and validating it using the judgment of experts, as well as the statistical analysis of the results obtained and a subsequent discussion of such results.

A comprehensive review of all literature regarding pain origin, physiopathology, and assessment scales was conducted as a foundation to create the contents of the scale proposal. The review shows a sustained effort by researchers to have at their disposal instruments that allow to reflect the intensity of pain in patients more accurately, and consequently, to provide treatment according to the pathology. The literature review focused on validated scales and questionnaires at the disposal of researchers in order to assess pain, comparing them and reviewing the consideration of pain as an object of evaluation and rating in different countries according to their scales.

The proposed instrument has eight groups of parameters or areas to assess, with a total of 24 items, for a maximum score of 20 (Table 1). It was designed to be applied in patients of ≥ 18 years of age, intubated and unable to communicate verbally, with severe burns: burned body surface ≥ 15%, inhalation injury or airway burn, high-voltage electric burns, chemical burns, or severe concomitant trauma, such as moderate to severe head trauma, or closed thoracoabdominal trauma.

A list of experts was created taking into account the criterion of direct care with the burned patient in critical condition, their reputation, their availability to respond to the instrument, and impartiality. The instrument was sent to each expert electronically and responses were received through the same means.

Experts responded directly to the researcher without knowing the other experts or their answers, thus ensuring greater objectivity of each expert based on their own experience and training as healthcare providers caring for critical burned patients.

According to the publications of McGartland et al.[14], the literature differs regarding the number of judges required for validation. The recommendation is between 6 and 20 experts. A larger number of experts can generate more information regarding the measurements. Hyrkäs et al.[15] state that 10 expertswould provide a reliable estimation of the validity of the contents of an instrument. If 80% of experts agree on the validity of an item, it can be added to the instrument.

In the particular case of this research, 41 experts were invited to participate in the treatment of critical burned patients in Mexico, the United States of America, and Panama. Each one received a personalized invitation, a form to collect their general information, instructions to fill out the validation instrument template and the template itself.

The list of experts invited to participate as judged was comprised of 11 intensive care doctors, 1 physical medicine and rehabilitation specialist, 12 surgical

Table 1. Proposal of pain assessment scale in critical burned patients

Items	Score
Burn extension	
> 15% SCQ	1
16-30% SCQ	2
31-39% SCQ	3
> 40% de SCQ	4
Burn depth	
> 50% of burns are third degree	1
> 50% of burns are mixed second degree	2
> 50% of burns are superficial second degree	3
Airway burn or inhalation injury	
Suspected or confirmed	1
Facial expression	
Relaxed face, expressionless	0
Painful expression, frown, eyelid shut tight	1
Very tense, clenched jaw	2
Mechanic ventilation	
Attached to ventilator, no cough	0
Coughing, but tolerates MV most of the time	1
Bites endotracheal tube, MV dissociation, asynchrony	2
Moves limbs	
No movement, or occasional movement, relaxed, resting	0
Flexed limbs, fists clenched	1
Rigorous movement of limbs or rigid or contracted	2
Cardiac frequency (last 6 h)	
No changes in baseline CF	0
> 10% of baseline CF	1
> 20% of baseline CF	2
Painful procedures	
Invasive procedures (arterial lines or central venous access)	1
Change of bed linens	2
Change of dressings	3
Patient in immediate post-surgical period	4
Total	/20

CF: cardiac frequency; BBS: burned bodily surface; MV: mechanical ventilation.

emergency specialists, 12 nurses (specialized in caring for adults in critical condition, pediatric nurses, and cardiovascular nurses), 2 anesthesiologists, 1 specialist in pediatric burns, and 2 physical therapists, all with experience in caring for critical burned patients.

After collecting all the information using the questions provided in the templates sent to the experts, statistical analysis and calculations were performed.

Results

The content validity ratio (CVR) was developed by Lawshe in 1975 and is based on the evaluation of a group of experts of each of the items in the test, from unnecessary to essential. The degree of agreement is expected to be over 50% of the total of participating judges to consider an item eligible to be part of the instrument in question and contribute to search for the content validation evidence, necessary for success in the development of a measurement instrument[16]. The result was 0.96 (Table 2). The CVR was modified by Tristán-López in 2008 (CVR')[17] and its minimum acceptable value is 0.5823, regardless of the number of evaluating judges. The results in this research was 0.98 (Table 3).

Once the CVR of all items has been calculated and all those with values higher than the minimum proposed by Lawshe, the mean CVR is calculated and the content validity rate of the entire test is calculated[17], which in this case was 0.96%.

Aiken's V is a ratio that quantifies the relevance of the items within an area using the evaluations of N judges. This method offers a magnitude that informs regarding the proportion of judges that provide a positive assessment of the item evaluated, that can be adopted as a criterion to make decisions regarding the need to review or remove items[18]. In this case it was 0.96 (Table 4).

The consistency of a test refers to the degree of cohesion of different items or aspects of the instrument and it can be checked with different statistical methods[19]. The internal consistency of a test or instrument must be achieved by applying Cronbach's alpha for all items[20]. The ratio varies between 0 and 1. The closer to 1, the more consistent are the items. In this case it was 0.74.

Table 2. Content validity ratio (CVR), Lawshe method

Item	Sufficiency	Clarity	Consistency	Relevance
	CVR	CVR	CVR	CVR
1	0.94	1.00	1.00	0.94
2	1.00	1.00	0.94	1.00
3	0.94	0.94	0.88	0.69
4	0.94	0.94	0.94	0.94
5	0.94	1.00	1.00	1.00
6	0.94	1.00	1.00	1.00
7	1.00	1.00	1.00	1.00
8	1.00	1.00	0.94	1.00
Average	0.96	0.98	0.96	0.95
Global CVR = 0.96				

Source: data obtained from the scale validation instrument template.

Table 3. Content validity ratio (CVR), Tristán-López method

Item	Sufficiency	Clarity	Consistency	Relevance
	CVR'	CVR'	CVR'	CVR'
1	0.97	1.00	1.00	0.97
2	1.00	1.00	0.97	1.00
3	0.97	0.97	0.94	0.84
4	0.97	0.97	0.97	0.97
5	0.97	1.00	1.00	1.00
6	0.97	1.00	1.00	1.00
7	1.00	1.00	1.00	1.00
8	1.00	1.00	0.97	1.00
Average	0.98	0.99	0.98	0.97
Global CVR' = 0.98				

Source: data obtained from the scale validation instrument template.

Discussion

This is a first approach to a scale designed to be applied specifically to burned patients in critical condition, and therefore, in addition to including areas used in other pain assessment scales for critical patients who are unable to communicate, it includes specific and unique characteristics of burned patients.

The instrument was evaluated by 32 experts, which make up 78% of the judges who were invited to participate. The highest response percentage (83%) was obtained from nurses who care for burned patients in critical condition and emergency physician (83%), followed by intensive care physicians (64%). We obtained

Table 4. Aiken's V validity ratio

Area	Aiken's V	Aiken's V by area	Area	Aiken's V	Aiken's V by area
Sufficiency			Consistency		
1	0.94	0.95	1	0.97	0.96
2	0.97		2	0.91	
3	0.91		3	0.95	
4	0.95		4	0.96	
5	0.97		5	1.00	
6	0.94		6	0.95	
7	0.98		7	0.98	
8	0.96		8	0.95	
Clarity			Relevance		
1	0.97	0.96	1	0.95	0.96
2	0.96		2	0.99	
3	0.93		3	0.85	
4	0.96		4	0.98	
5	1.00		5	0.99	
6	0.96		6	0.97	
7	0.99		7	1.00	
8	0.95		8	0.99	
Aiken's V total = 0.96					

Source: data obtained from the scale validation instrument template.

evaluations from one pediatric burns specialist and two physical therapist, in addition to two anesthesiologists with pain management experience.

The CVR (Lawshe) value of 0.96 is interpreted as a degree of agreement among the judges of 96%, which is higher than the 50% that determines that each item is eligible to become part of the instrument. The higher degree of agreement among the judges was seen in area 7, corresponding to the baseline cardiac frequency, which was considered sufficient, clear, coherent, and relevant, even taking into account that, being a physiological parameter, it is easily modifiable by different pain elements. The total CVR' (Tristán-López) of 0.98 is interpreted as a degree of agreement between the judges of 98%, which is higher than the acceptable minimum established by the author. The content validity rate of the entire test was 0.96%, which establishes that 96% of the items of the instrument are acceptable. Aiken's V of 0.96, since it is > 0.8, represents an adequate validity. Sufficiency, clarity, coherence, and relevance for the eight areas of the instrument, both individually and globally, showed an Aiken's V of ≥ 0.95 (Table 4).

A Cronbach's alpha of 0.74 classifies the instrument as having acceptable internal reliability and consistency.

The most significant result of this research is that this is a new instrument that allows pain assessment of a critical burned patient, and it facilitates the implementation of timely interventions, thus reducing morbidity and mortality in these patients, and providing timely and adequate treatment within the framework of their right to healthcare. Experts made recommendations and they propose the modified *pain assessment scale for critical burned patients* (EvaDoPaQ) (Table 5). The instrument showed great validity and reliability according to the experts.

Conclusions

Measuring pain properly ensures adequate analgesic treatment and psychological support, taking into account that it is a subjective and multidimensional experience that involves from sensory aspects to personality factors of the individual, in many cases linked to early resilience experiences.

The research proposed a specific instrument to assess pain in critical burned patients, and this goal was achieved by reviewing the literature and analyzing existing scales, which allowed for the design of the EvaDoPaQ. After validating the proposed instrument and obtaining statistically encouraging results, expert recommendations were added. In the experts' opinion, it is an instrument with a high reliability rate and is recommended for application in a sample of critical burned patients for a second validation and its subsequent use and dissemination.

Table 5. Modified pain assessment scale in critical burned patients (EvaDoPaQ)

ITEMS	Score
Burn extension	
10-20% TBS*	1
21-30% TBS*	2
≥ 31% TBS*	3
Burn depth	
Over 50% of burns are third degree	1
Over > 50% of burns are mixed second degree (superficial and deep)	2
Over 50% of burns are superficial second degree	3
Airway burn or inhalation injury	
No airway burn and/or inhalation injury*	0
Suspicion of airway burn and/or inhalation injury*	1
Confirmed airway burn and/or inhalation injury*	2
Facial expression	
Relaxed face. Expressionless	0
Painful expression. Frown. Eyelids shut tight.	1
Very tense. Clenched jaw. Facial muscles contracted*	2
Mechanical ventilation (MV)	
Attached to ventilator. No cough.	0
Coughing, but tolerates MV most of the time	1
Bites endotracheal tube. MV dissociation. Asynchrony.	2
Moves limbs	
No movement or occasional movement. Relaxed. Resting.	0
Limbs flexed. Fists clenched.	1
Rigorous movement of limbs or rigid or contracted.	2
Cardiac frequency (CF) (last 6 hours)	
No changes in baseline CF	0
> 10% of baseline CF	1
> 20% of baseline CF	2
Painful procedures	
Invasive procedures (placement of arterial lines or central venous access), *negative pressure therapy*	1
Change of bed linens	2
Change of dressing or special bandages with or without application of silver sulfadiazine	3
Patient in immediate post-surgical period	4
Total	/20

*Modifications according to expert recommendations are identified in bold and with an asterisk.

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Conflicts of interest

The authors declare that there are no conflicts of interest to report.

Ethical disclosures

Protection of people and animals. The authors declare that no experiments have been made on human beings or animals for this research.

Data confidentiality. The authors declare that no patient data appears in this article.

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

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