


Pressure injury prevention scales in intensive care units: an integrative review

Escalas para prevenção de lesão por pressão em unidades de terapia intensiva: revisão integrativa

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 Ítalo Lennon Sales de Almeida¹
 Thiago Santos Garces¹
 Glória Yanne Martins de Oliveira¹
 Thereza Maria Magalhães Moreira¹

¹Universidade Estadual do Ceará.
Fortaleza, CE, Brazil.

Corresponding author:

Ítalo Lennon Sales de Almeida
Rua Raimundo Pinheiro Bastos, 425
CEP: 60350740. Fortaleza, CE, Brazil.
E-mail: italolennon@hotmail.com

ABSTRACT

Objective: to describe the constituent elements of nursing care present in the pressure injury risk assessment scales used in intensive care units. **Methods:** this is an integrative literature review based on LILACS, MEDLINE, SCIELO and BDNF. The descriptors used for the search were Pressure Ulcer; Decubitus Ulcer; Prevention and control; Prevention; Intensive Care Units. The final sample consisted of 13 scientific articles. **Results:** the Braden scale was the most used scale among the analyzed studies. The constituent elements highlighted were structured risk assessment, skin and tissue assessment, preventive skin care, nutrition, repositioning in bed, support surfaces, and care with medical device. **Conclusion:** the prevention of incontinence-related injuries, nutritional assessment, nutritional interventions aimed at preventing injuries and care with medical devices are constituent elements of nursing care still poorly explored or absent in the evaluated scales.

Descriptors: Pressure Ulcer; Prevention & Control; Intensive Care Units; Nursing.

RESUMO

Objetivo: descrever os elementos constitutivos do cuidado de enfermagem presentes nas escalas de avaliação do risco de lesão por pressão usadas em unidades de terapia intensiva. **Métodos:** trata-se de uma revisão integrativa da literatura a partir do LILACS, MEDLINE, SCIELO e BDNF. Os descritores utilizados para a busca foram *Pressure Ulcer; Decubitus Ulcer; Prevention and Control; Prevention; Intensive Care Units*. A amostra final foi constituída por 13 artigos científicos. **Resultados:** a escala mais utilizada entre os estudos analisados foi Braden. Os elementos constitutivos evidenciados foram avaliação estruturada do risco, avaliação da pele e tecidos, cuidados preventivos com a pele, nutrição, reposicionamento no leito, superfícies de apoio e cuidados com dispositivos médicos. **Conclusão:** a prevenção de lesões relacionadas às incontinências, avaliação nutricional, intervenções nutricionais com o objetivo de prevenir lesões e os cuidados relacionados a dispositivos médicos são elementos constitutivos do cuidado de enfermagem pouco explorados ou ausentes nas escalas avaliadas.

Descritores: Lesão por Pressão; Prevenção & Controle; Unidade de Terapia Intensiva; Enfermagem.

Introduction

Pressure injury is defined by the National Pressure Ulcer Advisory Panel (NPUAP) as damage in the underlying skin and/or soft tissues, usually over a prominent bone or related to the use of a medical device or other artifacts. It is highly incident in hospital settings, especially in critically ill patients in hospitalization units, such as intensive care units⁽¹⁻²⁾. Injury prevention is a major challenge for intensive care practitioners.

Among the main preventive measures are the use of scales to detect the risk and susceptibility of the patient to be affected by such an event. These tools support the creation of a pertinent care plan to prevent or decrease the development of injuries⁽³⁻⁴⁾. When it comes to care, nurses are the professionals who establish the closest contact with patients in intensive care units. The nursing care plan includes maintenance of skin integrity. Thus, nurses must be attentive to the risk of development injuries to act in their prevention and in situations of damaged skin integrity, treating it⁽⁵⁾.

For intensive care nursing, it is agreed that maintaining skin integrity is more feasible when performed with simple and economical techniques and technologies, such as scales that measure the risk of injury in patients. From this perspective, systematic ways of measuring risk have been sought to effectively evaluate the various clinical conditions involved in the onset of lesions and focusing on lessen the most severe associated outcomes, such as infections, unfavorable surgical outcomes, length of hospital stay, and mortality⁽⁶⁾.

In this sense, analyzing these scales is fundamental because they enable the development of a structured, individualized and systematized approach to overcome challenges and expand the facilitating aspects regarding nursing care for prevention of pressure injuries in intensive care. This is important because the quality of nursing care is intrinsically associated with a lower incidence of injuries in health

care institutions⁽⁵⁾.

Based on the above, we propose an integrative review to describe the constituent elements of nursing care present in the pressure injury risk assessment scales used in intensive care units. In this context, the review is justified by the need to analyze the available evidence about the scales that have been used in intensive care units and the constituent elements of care addressed by their evaluation. This analysis is relevant because these scales are used to support preventive care and good nursing practice in intensive care, and thus may influence the quality of care provided to patients, reducing exposure to risks of adverse events, and increasing safety to the care provided by the nursing staff.

Methods

This is an integrative review to search the main available evidence about the object of study. The review was carried out in six steps, namely: identification of the theme; search in the literature (selection of inclusion and exclusion criteria); categorization of studies; evaluation of studies; interpretation of results; synthesis of knowledge⁽⁷⁻⁸⁾.

The paired search was performed from November to December 2018. Quantitative primary studies available in full length; studies published in English, Portuguese or Spanish; and studies published between 2007 and 2018 were included in the study. The time interval was selected considering that the evidence on pressure injuries of the last twelve years are currently the most used. This period also coincides with the publication of the adapted and validated Portuguese version of the Braden Q scale in 2007. Studies developed in adult and pediatric intensive care settings were included. Exclusion criteria were studies that did not bring clear evidence on the use of scales and on the constituent elements that most impacted the prevention of pressure injuries.

The structuring of the guiding question of the integrative review involved the PICO strategy⁽⁹⁾ (P

[Population] = individuals admitted to the intensive care unit; I [intervention]: scales on pressure injury; C [comparison]: none; O [results]: constituent elements). The guiding question for the integrative review was: what constituent elements of nursing care are used to base pressure injury risk assessment scales in intensive care units?

The descriptors were selected based on the PICO strategy. The Boolean operator OR was added between synonyms and AND between different terms, forming the search key: Pressure Ulcer OR Decubitus Ulcer AND Prevention and Control OR prevention AND Intensive Care Units.

The choice of databases was based on their scope and affinity with the theme. The search in the electronic literature was performed in the following databases: Latin American and Caribbean Health Sciences Literature (LILACS), Medical Literature Analysis and Retrieval System Online (MEDLINE), through the Pubmed and BDNF (Nursing Database) interface and Scientific Electronic Library Online (SCIELO) library. In the databases, the following search filters were selected: publications available in full length; published in Portuguese, English or Spanish; years of publication; type of publication. The search and selection of the articles to be included in the review were carried out independently by two reviewers.

The study selection process was conducted using the Preferred reporting items for systematic reviews and meta-analyzes (PRISMA) protocol. The flowchart (Figure 1) shows the path taken to select publications.

The eligible studies were read in full length by the two researchers, who extracted data, as previously defined, using an instrument created by the authors. The place and year of the study, methodological design, scale applied, and the constituent elements present in the scale were information extracted from the studies. Each researcher came up with a list of primary studies. The two lists were compared and consolidated into a single list. In case of disagreement on whether or not to insert an article in the final list, a third researcher experient

on the topic was consulted. Thirteen studies were selected and analyzed to compose the corpus of this review. After reading and making a critical analysis, there was the discussion and interpretation of the results obtained, and the presentation of the evidence found. A descriptive analysis was made of the collected data.

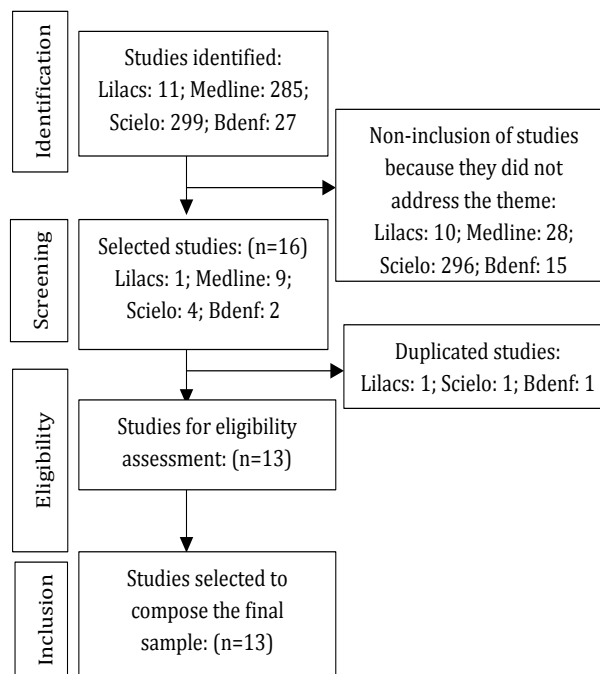


Figure 1 - Study selection flowchart (PRISMA). Fortaleza, CE, Brazil, 2019.

The nomenclatures used by the authors were adopted to define the design, when unclear, of the primary studies included in this research. The strength of the evidence was defined by the different research questions established by Fineout-Overholt and Stillwell. Thus, depending on the question of the primary study issue (meaning; Prognosis/Prediction or Etiology; intervention/treatment or diagnosis/Diagnostic test)⁽¹⁰⁾.

The studies were analyzed to describe and evaluate the follow-up of the constituent elements proposed by the Prevention and Treatment of Pressure Ulcers: Quick Reference Guide, created by the National Pressure Ulcer Advisory Panel (NPUAP). The NPUAP indicates in its publication the following measures as

key recommendations for pressure injury prevention: risk assessment, skin and tissue assessment, preventative skin care, emerging therapies for pressure injury prevention, nutrition, repositioning and mobilization in the bed, support surfaces, and care with medical devices. Each aspect will be discussed and its presence in the analyzed studies pointed out⁽⁶⁾.

Results

The data synthesized in the studies were organized in a matrix to display the information. The matrix contains information regarding the type of scale and its constituent elements (Figure 2).

Scales	Constituent elements
Risk assessment scale (Norton) ⁽¹¹⁾	Detailed documentation; Quality of the record; Periodic re-assessment of the skin; Repositioning; Application of moisturizing cream; Pressure-reducing mattress.
Risk assessment scale (Waterlow) ⁽¹²⁾	Training for quality skin assessment; Use of pressure relief devices; Care with medical devices.
Risk assessment scale (Braden Q) ⁽¹³⁾	Periodic skin assessment and registration of the information; Use of mattress for pressure redistribution; Repositioning; Nutrition (assessment of dietary protein); Care with medical devices.
Risk assessment scale (Gosnell) ⁽¹⁴⁾	Daily skin assessment; Use of cotton clothing; Washing and drying the skin (avoiding excess moisture); Manipulation of pressure with devices; Repositioning (4 hours); Use of oxygenated fatty acids; Use of visco-elastic foam mattress.
Risk assessment scale (Braden) ⁽¹⁵⁾	Repositioning schedule (3 hours); Care with skin moisture; Nutritional assessment; Use of transparent film; Use of barrier cream (Cavilon); Use of pyramidal foam mattress.
Protocol for prevention of pressure injury in the postoperative period of cardiac surgery ⁽¹⁶⁾	Use of air mattress to reduce friction and shear.
Risk assessment scale (Braden) ⁽¹⁷⁾	Creation of a specific nursing team for skin and wound assessment; Continuing education; Quality documentation; Weekly rounds; Use of positioning devices; Use of skin care products (moisturizers, essential fatty acids - EFA, barrier creams).
Risk assessment scale (Braden) ⁽¹⁸⁾	Daily skin assessment; Decubitus change (2 hours); Use of pneumatic mattress; Request nutritional support/assessment; Use of pressure relief devices; Minimization of skin exposure to moisture; Use of glycerinated soap as it does not change the pH of the skin and does not cause dryness; Avoidance of hot water; Avoid excessive friction during bath; Use of skin protector (EFA, Cavilon); Avoid massaging areas with hyperemia; Avoid massaging areas with bony prominences.
Risk assessment scale (Braden Q) ⁽¹⁹⁾	Skin assessment; Skin care; Patient care indirectly related to the skin (pain control, nutrition, hydration); Pressure-related products; Patient/family involvement.
Nutrition assessment scale ⁽²⁰⁾	Evaluating nutritional risk and implementing better forms of nutrient supplementation in patients' diets.
Risk assessment scale (Braden) ⁽²¹⁾	Fractional repositioning and observation of parameters of patients with hemodynamic instability; Care with medical devices.
Risk assessment scale (Braden) ⁽²²⁾	Pressure relief devices; Silicone dressings; Quality assessment team.
Risk assessment scale (Braden) ⁽²³⁾	Use of vasoactive drugs, skin conditions and use of invasive mechanical ventilation; Pressure injury risk assessment by the Braden scale score; Occurrence and location of pressure injuries.

Figure 2 - Characterization of scientific production on scales for prevention of pressure injuries in intensive care units. Fortaleza, CE, Brazil, 2019

Among the selected studies, six (46.0%) were developed in the United States^(13,16-17,19,21-22), three (23.6%) in Brazil^(15,18,23), one (7.6%) in Spain⁽¹⁴⁾, one (7.6%) in Portugal⁽¹¹⁾, one (7.6%) in Australia⁽¹²⁾ and one (7.6%) in Mexico⁽²⁰⁾.

Regarding the year of publication, one (7.6%) article was published in 2007⁽¹¹⁾, three (22.8%) in 2008⁽¹²⁻¹⁴⁾, one (7.6%) in 2010⁽¹⁵⁾, one (7.6%) in 2011⁽¹⁶⁾, one (7.6%) in 2012⁽¹⁷⁻¹⁸⁾, one (7.6%) in 2013⁽¹⁹⁾, two (15.2%) in 2015⁽²⁰⁻²¹⁾, one (7.6%) in 2016⁽²²⁾ and one (7.6%) in 2018⁽²³⁾. Regarding the design of the studies, eight (61%) were descriptive researches^(11,13,15-18,20-21), two (15.3%) were quasi-experimental studies^(12,22) and three (23.7%) were analytical cross-sectional studies^(14,19,23).

Regarding the types of units, six (46%) were of the general adult intensive care units^(11,12,15,18,20,23), three (23.7%) were cardiac intensive care units (coronary)^(14,16,21), two (15.1%) were general pediatric intensive care units^(13,19), one (7.6%) was an adult neurological intensive care unit⁽¹⁷⁾, and one (7.6%) was an adult clinical/surgical intensive care unit⁽²²⁾.

As regards the approach to the studies, all were quantitative studies. In the analysis of the level of evidence of the articles, it was observed that eight (60.8%) had level III^(12-13,16-17,19-22) and five (39.2%) had level II^(11,14-15,18,23).

All references analyzed indicated the use of some instrument for risk assessment. The instruments cited were the Braden scale in six studies^(15,17-18,21-23) and its adapted version for pediatrics (Braden Q)^(13,19), and the Norton scale⁽¹¹⁾, the Waterlow scale⁽¹²⁾ and Gosnell scale⁽¹⁴⁾ in one study each. Only two references did not use validated scales to specifically assess the risk of developing pressure injuries^(16,20).

The two studies in pediatric intensive care units used the Braden Q version for pressure injury risk assessment. This instrument is the adaptation of the one indicated for patients from one month of life to school age, being the version of choice for application in pediatric intensive care units.

Discussion

The limitation of the present study is that only evidence generated from research conducted in intensive care units was evaluated. This aspect prevents a broader assessment of the constituent elements that make up the scales used for injury prevention in the hospital environment in general.

The analysis of the use of scales and their constituent elements in nursing care contributes to the explanation of what has been used as care technology for injury prevention. This type of investigation corroborates with the paradigm of risk reduction to which patients are exposed during their stay in the hospital environment. Nursing is a fundamental component in the system for prevention of adverse events, such as pressure injury, and it is directly related to the care offered^(4,6).

When initiating care aimed at maintaining skin integrity, structured risk assessment for the development of pressure injury should be performed early upon admission to the intensive care unit and re-evaluation is necessary when there is a significant change in the patient's clinical condition⁽⁶⁾.

For the risk assessment to be carried out with quality on any scale, nurses must be able to recognize the risk factors related to the development of pressure injury, with the priority being mobility in bed, perfusion and oxygenation, poor nutritional status, exposure to moisture, and friction and shear^(15-18,21-23). Therefore, the instrument to be used must be able to point out each of these factors in its evaluation.

Risk assessment scales generate scores that classify the patient's risk of developing pressure injuries, and the form of classification varies between scales. The actions and measures to be taken after the classification should be clear and evident so that the team knows how to deal with low and high risk situations, in which the preventive approach needs to start early and be of quality⁽⁶⁾.

Skin assessment should diagnose hyperemic areas, risk or appearance of lesions caused by medi-

cal devices, existing lesions, quality of wound healing, and worsening/improvement of skin quality after initiation of preventive interventions. The periodicity of the assessment was widely discussed among some of the scales and varied widely among the references; the suggestions included daily or weekly periodicity, but sometimes no clear explanation on this aspect was given in the articles^(11,13,17-18). It was observed that periodicity is usually chosen according to the risk of the patient. Therefore, patients at high risk should be reevaluated with the greater frequency possible^(15,17-18,21-23).

The importance of detailed documentation of skin assessment was cited in some scales. They discussed the importance of quality records for constant care and perception of improvement/worsening in the assessments^(11,15,17,21).

In a neurological unit in the US, nursing managers and their staff created a specialized team for wound assessment to monitor and prevent hospital-acquired skin lesions. The professionals underwent a training process with a reference guide addressing the main actions and techniques aimed at diagnosing, preventing and treating injuries⁽¹⁷⁾. Other studies pointed to the importance of training and continuing education of nurses who perform skin assessment and preventive measures^(12,14,21-22).

Skin assessment is influenced by the quality of the physical examination by the nurse. In fact, this action is fundamental for intensive care professionals. The propaedeutic technique of inspection is directly linked to the search of signs and symptoms in the skin and recognition of situations that may pose risks to the maintenance of skin integrity.

The evaluated studies recommended the following main preventive care measures against emergence of injuries: avoiding positioning on flushed areas of the body, considered of higher risk; continuous maintenance of clean and dry skin using pH-balanced skin products; avoiding massages in already reddened/hyperemic areas; developing specific care plans for patients with incontinence problems by perfor-

ming immediate cleaning after each episode; protecting the skin from exposure to moisture by using barrier products, thereby reducing the risk of damage; and, finally, considering the use of emollients for hydration of dry skin portions and to avoid the risk of damage^(15,17-18,21-23).

It is noteworthy that, although indications for actively acting in the prevention of incontinence-related pressure injuries were present in the studies, few scales bring this variable. Knowing how to act in cases of incontinence is important because exposure to moisture causes changes in physiologically acidic skin pH, turning it basic, causing fragility in the skin and making it more susceptible to the effects of friction and shear stress^(14,18-19).

With regard to massages, studies show that when done in hyperemic regions, they can cause the rupture of vessels in the underlying tissues. Rubbing the skin may not only be painful, but also cause tissue damage or inflammatory reactions, especially in elderly patients who have fragile tissues^(8,18-19).

The use of barrier creams was mentioned in the studies to be used in bony prominences and in perianal and perineal skin, which are affected in incontinence episodes. It is noteworthy that such creams must not be applied with massage techniques, in view of the abovementioned risk of adamage^(15,18-19).

In the analysis of the scales, essential fatty acids were indicated as an emollient product for protection and hydration of the epidermis^(14,17). There are several types of fatty acids, but linoleic and linolenic acids are the most commonly used on wounds^(15,18-19). These acids form a protective barrier that prevents maceration. They are important agents in the processes of cellular inflammation, relief after the first application, and local cellular nutrition, besides presenting the capacity to promote tissue regeneration^(15,18-19).

Nutrition was evidenced as an important aspect for preventive care related to pressure injury. Nutritional screening is the process used to identify patients who need complete assessment of their nutritional status due to characteristics that put them at

potential nutritional risk. Qualified nurses may perform such screening at the time of admission to the health institution or during the first outpatient consultation. Individuals identified as being at risk for malnutrition or nutritional *deficit* status should be referred to receive care from nutritionists or multidisciplinary nutrition teams^(13,15,18,20).

One of the studies analyzed brought the possibility of implementing a specific pressure injury prevention scale for nutritional care⁽²⁰⁾. The evidences pointed out as important aspects the maintenance of daily caloric intake according to the body needs of each individual patient. The assessment of protein intake, enrichment of diet with vitamins and minerals, and the choice of the ideal form of diet administration (oral, enteral) are also aspects considered important^(13,15,18,20). The nutritional status should be assessed as soon as the patient is admitted to the intensive care unit and this can be performed with the aid of assessment instruments.

It is essential to prepare repositioning plans that indicate the frequency and duration of position switching. Among the scales analyzed, the alternation period ranged from 2 to 4 hours. Periodicity should consider the following aspects of the individual: tissue tolerance, activity and mobility level, general clinical picture, treatment objectives, skin condition, and comfort^(14,15,18,23).

In the scale implemented in a cardiac unit that receives patients in the postoperative phase of cardiac surgery, repositioning practices had to be reviewed due to the patients' hemodynamic instability, because frequent and abrupt repositioning caused edema due to poor perfusion, refractory hemorrhage, and malignant arrhythmias. The technique used by nurses in the unit suggested 10-degree rotation every 10 minutes and careful visual inspection of patient parameters, with the possibility of adding 10 degrees, if tolerated⁽²¹⁾.

Repositioning is one of the aspects that most changes with the development of new studies. Repositioning time has been decreased. It has proved to be

an important factor to prevent injuries, and should be the focus of campaigns among the nursing staff because it is a low-cost technique that requires little *expertise* and is effective to relieve pressure on skin surfaces, an aspect directly related to the genesis of lesions.

Support surfaces are devices that redistribute pressure, designed to manage tissue loads, microclimate and therapeutic functions (i.e. mattresses, integrated bed systems, replacement of mattresses, overlay mattresses, seat cushions, or seat cushion overlays)⁽¹⁴⁻¹⁵⁾.

The choice should focus on each individual, taking into account the patient's needs for pressure redistribution and other therapeutic functions. The manufacturer's recommendations must be observed. Standards also meet manufacturers' needs as guides for product development and enhanced quality assurance⁽¹⁴⁻¹⁵⁾.

Among the scales, the one adopted in the study conducted in a cardiac unit in the US stood out. To reduce the incidence of pressure injuries, the intensive care unit staff decided, in addition to providing preventive nursing care, to use an air-fluidized bed for pre-selected cardiac surgery patients in the postoperative phase. The bed was chosen because it reached low interface pressures between the surface and the patient, providing maximum immersion and involvement. The patient floats on a cover that encloses fluidized silicon beads, minimizing shear and friction. Moisture flows through the bed, and this further help minimizing skin maceration⁽¹⁶⁾.

The use of foam mattress was highlighted in two studies⁽¹⁴⁻¹⁵⁾. Other studies cited the use of mattresses for pressure redistribution, but did not specify which type was used. It is important that surfaces used for pressure reduction, such as foam mattresses, undergo periodic review of quality. For example, when pressure is ceased, the mattress must return to its original shape. High specificity reactive foam mattresses are recommended instead of mattresses of low specificity^(11,13,19).

Other care measures suggest that gel mattresses

ses must be evaluated as to whether they have sufficient amounts of gel in their whole extension, and to ensure that gel has not been removed from any area. Alternating air mattresses inflate and deflate properly. It is noteworthy that air mattresses or alternating pressure overlays and alternating pressure mattresses with cells smaller than 10 cm in diameter should not be used because they cannot be sufficiently inflated to ensure pressure relief on deflated cells^(11,13,19).

Few scales mentioned care with medical devices^(12-13,21). One of the scales used in a cardiac unit described the standardized care for each type of device used in the unit (central catheters, invasive blood pressure catheter, mechanical circulatory assistance device, endotracheal tube, tracheostomy tube, feeding tube)⁽²¹⁻²³⁾.

All patients using medical devices should be considered at risk for the development of device-associated injuries. Examining the skin under and around medical devices at least twice a day for signs of injury to adjacent tissue is a care measure that must be promptly implemented⁽²¹⁻²³⁾.

The use of transparent films to protect the neck, ear and groin area is indicated in the case of catheters inserted into the femoral or internal jugular vein. In order to prevent the development of injuries related to left ventricular assist devices, the transmission should be stabilized on the patient's skin with a tubing and catheter anchor. The skin under the anchor must be inspected every five days, with replacement of the anchor as needed⁽²¹⁾.

In the case of tracheostomy, sutures are no longer routinely used to ensure fixation in percutaneous tracheostomy, they are rather replaced by velcro. Reducing the use of sutures in routine percutaneous tracheostomy patients have allowed nurses to achieve pressure relief in the insertion area⁽²¹⁾.

Mucosal injuries caused by endotracheal tube included most device-related lesions, leading the intensive care team to add surveillance for tube repositioning in their rounds. Best recommendations for

tube management include rotation every 24 hours when tape is used as a safety method. A similar approach was adopted with feeding tubes, changing nasogastric tubes every 24 hours to prevent mucosal damage. Repositioning requires inspection, removal and application of the date and time on the safety tape securing the tube⁽²¹⁾.

The overall analysis of the findings and the discussion showed that pressure injury prevention and nursing care are closely related. To dominate this field, it is important that nursing researchers have interest in searching for ever better evidence as a way to base their practice on evidence and increase the quality of the care provided.

Finally, it is noteworthy that the Braden scale and its adapted versions were the most used for the prevention of pressure injuries in intensive care units, reinforcing the hegemony of this scale in every hospital setting. However, further reviews are required, including systematic reviews with meta-analysis, so that evidence may be generated to support the effect of using this scale on the occurrence of severe outcomes.

Conclusion

Among the constituent elements evaluated by the scales, the ones that stood out were risk assessment for the development of pressure injury using a validated instrument; skin evaluation following pre-established periodicity and quality records to ensure continuous care; skin care, and especially prevention against excess moisture; and use of products to ensure skin hydration and protection. The constituent elements evidenced in the evaluated scales contribute to the prevention of pressure injuries in intensive care units.

However, the review showed that prevention of incontinence-related injuries, nutritional assessment, nutritional interventions aimed at preventing injuries, and medical device-related care are constituent elements of nursing care that are little explored or

even absent in the scales evaluated. These four points should be urgently investigated, considering their importance in the prevention of injuries, as evidenced in the literature.

Collaborations

Almeida ILS, Garces TS and Oliveira GYM contributed to the conception and design of the study, analysis and interpretation of data, writing of the article and relevant critical review of the intellectual content. Moreira TMM contributed to the writing of the article, relevant critical review of the intellectual content, and final approval of the version to be published.

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