



ORIGINAL ARTICLE

BUNDLE FOR THE PREVENTION OF PRESSURE INJURIES ASSOCIATED WITH MEDICAL DEVICES IN OBESE PATIENTS *

HIGHLIGHTS

1. The development of the Bundle reflects scientific and safe care.
2. The Bundle supports targeted care for people with obesity.
3. The preventive care Bundle systematizes nursing actions.
4. Bundle-supported care demonstrates the development of best practice.

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ABSTRACT

Objective: to build and validate a Bundle for the prevention of pressure injuries associated with medical devices in obese people in intensive care. **Method:** methodological study, with a scoping review and validation of the Bundle. Data collection took place between April and May 2022 at a university in southern Brazil. **Results:** nine nurses, experts in enterostomal therapy, validated the Bundle, whose items were: assessment of the skin of the obese person; hygiene care for the obese person using a medical device; nursing care for the obese person using a medical device; health education on healthy habits; continuing education on nursing care for the obese person. The items obtained a Content Validity Index $\geq 0.80\%$ and 89.8% agreement. **Final considerations:** The Bundle can standardize nursing care, guiding, and equipping nurses with the best care intervention practices.

DESCRIPTORS: Nursing Care; Nursing; Pressure Ulcer; Obesity; Intensive Care Unit; Patient Care Bundles.

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INTRODUCTION

The Intensive Care Unit is a highly complex, specialized hospital environment that is increasingly incorporating advanced technologies and techniques to treat people in critical health conditions. However, there are some additional risks in care, mainly due to hemodynamic instability and the compensation of organ systems, leading to an increase in hospitalization time and, thus, people are prone to developing pressure injuries (PI) and injuries related to medical devices, resulting in an increase in MDRPI¹⁻³.

These lesions are increasingly seen in obese patients, as the skin suffers consequences due to excess fat deposition, which increases the development of multiple dermatological conditions. The effects of obesity on the skin can be of a mechanical nature, resulting from the large volume of skin folds, or of an endocrine, metabolic, and inflammatory nature, resulting from the secretion by adipose tissue cells of various peptides with hormonal activity and cytokines⁴.

MDRPIs are considered a serious health problem that mainly affects patients in the Intensive Care Unit (ICU) and are defined as injuries associated with the use of devices applied for diagnostic or therapeutic purposes in which the injury has the same configuration as the device⁵. People in ICUs are exposed to risk factors such as difficulty in mobility due to various pathologies or their sequelae; age; nutritional status; use of various medical devices and long periods of hospitalization⁶⁻⁷.

MDRPI has become a challenge in nursing care. In this sense, the nursing team is looking for alternatives to improve and qualify care in the various places where they work, especially regarding the prevention and treatment of PI during hospitalization in the ICU⁷.

As the leader of the nursing team, nurses play a fundamental role in managing care by identifying risk factors, planning prevention and treatment measures and evaluating the care provided by the team. Some tools can help the nursing team to ensure quality care in the prevention of pressure injuries related to medical devices, such as a Bundle⁸.

The Bundle is defined as a small set of interventions based on proven scientific evidence which, when put into practice in an integrated way, can achieve much better results than separate actions⁹.

In 2001, the Institute for Healthcare Improvement (IHI) developed the Bundle to improve ICU care, assessing structural and procedural issues, based on teamwork and dialog between health professionals⁹. Some studies have indicated that the use of Bundles helps prevent and treat MDRPI¹⁰⁻¹¹.

The Bundle is a structured and conceptualized strategy of care aimed at prevention. It is a practical and effective tool, made up of proven and safe procedures. The measures proposed for structuring this instrument act directly on the most harmful factors of the health problem. In addition, the Bundle can be a powerful stimulus for teamwork, bringing standardization to the service and offering the best care for the person².

In view of this, the aim of this study was to build and validate a Bundle for the prevention of pressure injuries associated with medical devices in obese people in intensive care.

METHOD

This is a methodological study, building a Bundle-type instrument. Two stages were followed to build the methodological path. In the first stage, a scoping review was carried

out following the Joanna Briggs Institute (JBI) recommendations, using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist, which guided the description of scientific evidence on MDRPI in people with obesity.

According to the recommendations published in the JBI Manual for Evidence Synthesis, version 2020, the following steps were followed: definition of the objectives and research question; definition of inclusion and exclusion criteria; definition of the strategy for data selection and extraction; search, selection, and analysis of publications in information sources; and presentation and synthesis of the results¹².

The scoping review included: scientific articles and review articles, published in Portuguese, English and Spanish, which contained the descriptors in the study identification strategies and published between 2020 and 2021 in the Electronic Databases: Medical Literature Analysis and Retrieval System Online (Medline) - via National Library of Medicine; National Institute of Health (Pubmed); Institute for Scientific Information (ISI) Web of Knowledge - via Web of Science; The Cumulative Index to Nursing and Allied Health Literature; Embase; Cochrane; Latin American and Caribbean Health Sciences Literature (LILACS), Scopus and Scielo. The exclusion criteria were articles in the form of letters, reviews, theses, dissertations, experience reports and editorials, duplicate studies and studies that did not cover the topic and did not answer the search question. And the inclusion criteria were qualitative and/or quantitative research studies on the subject, essays, consensus published in journals from the databases selected for the study, and studies that contained the descriptors and keywords provided in the Bundle.

In the second stage, to validate the content of the Bundle, we used the agreement of a group of nurses who were experts in the subject of the research, according to the inclusion criteria: nurses with the title of stomatherapist certified by the Brazilian Association of Enterostomal Therapy (SOBEST) and who carried out care activities around research. Exclusion criteria: nurses with expertise in dermatology and who had no experience in wound care.

An active search was carried out in April and May 2022 through the SOBEST website¹³ to identify professional nurses in Brazil to evaluate the instrument, considering that the professionals' contacts are open access. The nurses were then sent an invitation letter by e-mail, along with the guidelines and justifications for this study and the Informed Consent Form.

Thirty nurses from various regions of Brazil were invited to take part in the study, of whom nine took part.

Data was collected using a Google Forms® form, which was made available electronically. This form, called Validation of a Bundle, contained a questionnaire to evaluate a Bundle for the prevention of MDRPI in people with obesity in the ICU with the following elements: a) introduction with clarifications about the research and the time needed to answer the survey; b) e-mail address of the respondent; c) ICF; d) instructions about the questionnaire; e) identification of the participant; f) instructions about the analysis procedure; and g) the questionnaire itself, with its different topics and suggestions.

The Bundle was evaluated using a Likert scale, with categories at four levels of importance and the selection of a single answer for the variable analyzed, respectively: (1) disagree; (2) partially disagree; (3) partially agree; (4) agree, and with a space for suggestions and comments. For each item presented, the experts also assessed the objectivity of the content: whether the items were direct and clear; the relevance of the content: whether it was appropriate and relevant; the accuracy of the wording of the content; the accuracy of the entries and definitions; and whether the choice of words was appropriate.

The data was imported from Google Forms into an Excel database for processing and analysis. The agreement between the judges was analyzed using the Content Validity

Index (CVI) and items that obtained above 80% agreement were considered valid. To calculate the CVI, the number of agreed answers divided by the total number of answers was considered. To make the adjustments suggested in the first round, the instrument was submitted to two rounds of evaluation¹³⁻¹⁴.

This study is part of the macro-project entitled "Care of the multi-professional team in the health of obese people and their families in times of the COVID-19 pandemic" in response to the objective: "building care technologies that support care for obese people with coronavirus in intensive care units". It was evaluated and approved by the Human Research Ethics Committee of the Federal University of Santa Catarina, under opinion no. 4.706.59

RESULTS

Nine experts made up the expert panel for the content validation process of the Bundle of nursing care for the prevention of MDRPI in people with obesity in the ICU. The sociodemographic profile showed a greater participation of females (seven - 77.8%) than males (two - 22.2%), aged between 32 and 58, all with specialization in enterostomal therapy. Four of the judges have a specialization in enterostomal therapy, two have a master's degree, one has a doctorate, and one is in the process of a doctorate. Regarding the institution where they work: four (44.4%) work in public institutions; two (22.2%) in private institutions; one (11.1%) in a philanthropic institution; and one (11.1%) in higher education teaching. Of the nine judges, seven are from the state of Santa Catarina, one from the state of São Paulo, and one from the state of Pernambuco.

The judges evaluated the Bundle, consisting of nursing care for the prevention of MRDPI in people with obesity, admitted to the ICU, as shown in Chart 1.

Chart 1 - Validity index of the Skin Care Bundle for people with obesity, with the experts' contributions to the second round of validation. Florianópolis, SC, Brazil, 2022

Category	Validation form questions	Achieved (scores %)		Comments/ Suggestions	Modified item
		CVI	%C		
Skin assessment for obese people	1. Carry out a structured risk assessment, using the Braden Scale, and check the Body Mass Index (BMI) on admission of people with obesity.	0.80	80%	Comprehensive assessment with BMI. Body distribution for those who are bedridden or have difficulty changing position. Notify if the person has already been admitted to the unit with a pressure injury or injury of another etiology.	Repositioning body weight in patients with impaired mobility. Assessing the skin to identify pre-existing lesions (PI, traumatic) and reporting them.
	2. Carry out a complete assessment of the skin by inspecting it daily.	0.80	80%	I think it depends on the scenario we're in. You need to identify the obese person who is functional, ambulates and has bodily activity in bed and the one who has functional impairment of the body. There is a risk in both, but in addition to the body, we need to look at the underlying disease associated with the current clinical complication condition. Evaluate the person with a flexible schedule according to their perspiration and/or other eliminations, regardless of whether they use equipment for urinary and/or fecal retention.	Carry out the Braden Scale assessment whenever necessary. Perform skin assessment after bowel/vesical eliminations and during hygiene and comfort care. Perform skin assessment at medical device insertion sites and adjacent areas at each shift change. In pronated patients, assess the device insertion site and adjacent areas.

	3. Assess the skin of the obese person where the medical devices are located	0.80	80%	In general, aren't you already doing this during your daily assessment? However, in addition to these points, you should always assess the entire anatomical structure while the person is bedridden and/or in a hospital bed. - At each change of duty	This question is already part of the previous ones
	4. Assess the skin of the obese person in the prone position where the medical devices are located.	0.80	80%		
	5. Assess the fixation of the device or fixation method	0.90	90%	In general, aren't you already evaluating during the daily evaluation? Or is it continuous evaluation? And to study better devices with less local friction, as well as observing the microclimate thus, avoiding local humidity.	Assess the fixation of the medical device and adjust where necessary in the event of swelling, redness and pressure or any change in the skin. Evaluate the adjustment of the fixation of the medical device.
	6. Evaluate the tension of the medical device, adjusting, if necessary, when edema, redness and pressure are observed.	1.0	100%		
Hygiene care for obese people using medical devices	1. always keep the skin around the medical device clean and dry	0.80	80%	As well as clean and dry, you can opt for a spray that provides a barrier on the skin. Dry when referring to moisture-free skin but hydrated/maintained turgor I think are more appropriate words. Use of adjuvant for protection	Apply barrier cream and protective spray to moisturize the skin.
	2. Carry out frictionless cleaning near medical devices	0.80	80%	Cleaning should be done on the entire surface of the skin without rubbing. More sensitive skin will be more easily damaged. There are products that can be protocolized for use, which clean without trauma. - Train the staff.	
	3. Clean the skin with warm water and pH-neutral soap near the medical devices.	0.55	55%	What if the setting where the professional works doesn't have soap with a neutral pH? I think we need to think about the overall context to establish functional strategies for proper management I don't agree with the word friction because it leads to the connotation of trauma. If she wishes, gentle cleansing with light, soft fabric is more appropriate. Train the staff and guide the family members.	
	4. Carefully assess the obese person in the prone position for skin humidity and keep the area around the medical device clean and dry.	0.67	67%	Dry place refers to being free of moisture, but hydrated/maintained turgor, I think, are more appropriate words.	
Nursing care with the medical device for people with obesity	Nursing care with the medical device for people with obesity	1.0	100%		
	2- Evaluate with the multi-professional team the replacement or early removal of the medical device.	1.0	100%		
	3- Avoid humidity, friction, and pressure in the area where the medical device is installed.	0.90	90%	Not only at this location.	
	4-Discuss the safe early removal of medical devices with the multidisciplinary team.	1.0	100%		
	5- Choose the right size of medical device according to the characteristics of the obese person.	1.0	100%	Adapt each patient's anatomy.	

	6- Take care with the devices when performing prone positioning.	1.0	100%	Train the staff.	
Health education on healthy habits	1- Encourage and help people with obesity to eat according to the nutritional prescription.	0.90	90%	Observe the acceptance of the diet and keep informed about diarrhea and intolerances.	Observe acceptance of oral and/or enteral diet and keep informed about diarrhea and intolerances.
	2- Encourage and advise on the importance of eating a proper diet/nutrition.	0.90	90%		
	3- Stimulate and support water intake according to the needs of the obese person.	0.90	90%		
	4- Estimulate and advise on the importance of water intake according to the needs of people with obesity.	0.90	90%		
Continuing education on nursing care for people with obesity	1- Promote training courses for nursing staff on skin care for obese people.	0.90	90%	Promoting training involving skin care for all partially or totally bedridden people is synonymous with the evolution of nursing care in minimizing iatrogenic in the person under their care.	
	2- Promote on-site training on nursing care of medical devices for people with obesity.	1.0	100%	It's an excellent strategy. I've done it this way and had very good results! Constant training, quick objectives.	
	3- Promote training on nursing care for obese people in the prone position.	0.89	100%	In training the person for promotion, we discuss the issue of body structure in relation to the lean and obese person, contextualizing, in general, but showing the profile that is more likely to develop an MDRPI.	

Source: The authors (2022).

According to the items validated by the experts, Chart 2 explains nursing care for the skin of obese people in the second round with the experts.

Chart 2 - Nursing care for the skin of obese people, validated in the second round with experts. Florianópolis, SC, Brazil, 2022

CVI	Bundle of nursing care - preventive approach	Achieved (scores %)	
		%C	
Skin assessment of the obese person			
1	Assess the skin to identify pre-existing lesions (PI, traumatic) and report them.	1.0	100%
2	Carry out the Braden Scale assessment whenever necessary.	0.80	80%
3	Perform skin assessment after bowel/vesical eliminations and during hygiene and comfort care.	0.89	89%
4	Perform skin assessment at medical device insertion sites and adjacent areas at each shift change.	1.0	100%
5	In pronated patients, assess the device insertion site and adjacent areas.	1.0	100%

6	Evaluate the fixation of the medical device and adjust whenever necessary in the event of edema, redness and pressure or any change in the skin.	1.0	100%
7	Check that the medical device is securely fastened.	1.0	100%
8	Clean the skin and areas adjacent to the medical device gently with soft tissue.	0.67	67%
Hygiene care for obese people using medical devices			
9	Apply barrier cream or protective spray to moisturize the skin.	0.80	80%
10	Clean the skin and areas adjacent to the medical device gently with a soft cloth.	0.67	67%
Health education on healthy habits			
11	Observe the acceptance of the oral and/or enteral diet and keep informed about diarrhea and intolerances.	1.0	100%

Source: The authors (2022).

Chart 3 shows the nursing care that was constructed from the results of the judges' rounds, thus making up the Bundle of nursing care for the prevention of MDRPI for people with obesity.

Chart 3 - Bundle of nursing care for the prevention of MDRPI in people with obesity. Florianópolis, SC, Brazil, 2022

Preventive care for medical device-related pressure injuries in people with obesity
Skin evaluation
Carry out a structured risk evaluation using the Braden Scale and checking the Body Mass Index (BMI) on admission of people with obesity ¹⁵⁻¹⁶ .
Carry out a skin evaluation to identify pre-existing lesions (PI, traumatic) and report them ¹⁵⁻¹⁶ .
Evaluate the skin after bowel/vesical elimination and during hygiene and comfort care ^{15,17-18} .
Evaluate the skin at medical device insertion sites and adjacent areas at each shift change ¹⁶ .
In pronated patients, evaluate the insertion site of the device and adjacent areas. ¹⁶ Evaluate the fixation of the medical device and adjust whenever necessary in the event of edema, redness and pressure or any change in the skin ¹⁵⁻¹⁶ .
Hygiene care for people with obesity and using medical devices
Keep the skin around the medical device clean and dry at all times ^{15,17-18} .
Clean the area around medical devices without rubbing ^{15,18} .
Apply barrier cream or protective spray and moisturize the skin ^{16-17,19} .
Nursing care with medical devices for people with obesity
Assess the need to maintain the medical device in the obese person ¹⁶⁻¹⁷ .
Assess with the multi-professional team the replacement or early removal of the medical device ^{15,18,20} .

Avoid moisture, friction, and pressure where the medical device is installed ^{15,17-18} .
Choose the right size of medical device according to the characteristics of the obese person ¹⁸ .
Pay attention to device care when performing prone positioning ¹⁵ .
Health education on healthy habits
Encourage and help people with obesity to eat according to the nutritional prescription ^{15,18-19} .
Encourage and advise on the importance of eating an adequate diet/nutrition ^{15,17-18} .
Encouraging and advising on the importance of drinking as much water as the obese person needs ^{15,17-18} .
Continuing education on nursing care for obese people
Promote training courses for nursing staff on skin care for obese people ^{18,20} .
Promote on-site training on nursing care with medical devices for obese people ^{17,20} .
Promote training on nursing care for obese people in the prone position ¹⁵ .
Observe acceptance of oral and/or enteral diet and keep informed about diarrhea and intolerances ^{15,17,19} .

Source: The authors (2022).

DISCUSSION

The nursing staff plays an essential role in the prevention of PI in ICU patients through the daily evaluation of procedures to reduce continuous pressure on the skin and other factors that predispose to the appearance of lesions, or even aggravate existing ones.

In this sense, the assessment of the person's skin is part of the consensual practice of nurses, and it is essential to carry it out at the first contact to know the regions of the body with pre-existing lesions, as well as other risk areas². Corroborating other studies, visual inspection of the skin under and around the insertion site of the medical device and the nurse's clinical judgment are essential for implementing preventive care, since the main risk factor for developing an MDRPI is the use of the device²¹.

Some strategies for preventing MDRPI should be developed for people in the ICU, which include inspecting the skin on admission to check its integrity and the existence of pre-existing PI. The use of the Braden scale on admission as a routine for measuring and assessing individual risk factors should be considered¹⁷. To this end, it is essential to use risk assessment scales as strategies for the prevention of PI and for the construction of care plans, using interventions such as early mobilization in bed and the use of effective support surfaces for people in critical situations²¹.

Regarding the fixation of medical devices, the guidelines of the National Pressure Ulcer Advisory Panel NPUAP⁵ point out that devices with inadequate adjustments or strongly fixed to the skin increase the risk of MDRPI due to friction and additional pressure, minimizing skin tolerance²²⁻²⁵. When associated with edema at the device insertion site, it should be evaluated with caution, since it causes increased pressure and tension under the device, increasing the risk of skin rupture²⁵.

In the context of skin care, people with obesity deserve special attention, mainly due to the difficulty in healing wounds or injuries. There is also an increased risk of skin infections and lymphedema in these people, which contributes to greater morbidity in this population. In hospitalized patients, obesity leads to an increased risk of PI, as well as

delayed healing, which should be managed mainly with preventive measures. Therefore, hygiene measures aim to keep the skin dry by removing moisture caused by sweating, urinary or intestinal elimination^{15,17,26}.

On the other hand, keeping the skin clean and dry, both under and around medical devices, prevents moisture from modifying the microclimate, as it leaves the skin more vulnerable to changes in integrity due to frictional forces and increased edema, including irritant dermatitis and ulceration^{23,27}.

It is important to use technologies to prevent MDRPI, avoiding damage caused by the device, including barrier products such as spray or cream under the device, as they reduce moisture, friction, and shear on the skin^{15,21,26,28}.

In addition to the technologies applied to skin care, the therapeutic benefits of nutrition should be encouraged by multi-professional teams, as nutritional intervention should be considered an integral part of the treatment of PI. It is recommended that patients' nutritional status be assessed, and that adequate energy and protein intake be guaranteed, as recommended by current guidelines. Several studies point to the presence of certain nutrients that can positively affect the healing process of PI. The use of nutritional supplements enriched with arginine, zinc and antioxidants has been shown to be effective in healing PI^{15,21,28}. Nutritional assessment is essential not only for weight control, but also for improving the quality of the healing process.

The contribution of the Bundle built in this study is to present a practical tool that can guide nurses' care towards best practices, as it was developed using scientific evidence and the judges' vision. However, the study's limitations were the judges' low response rates in the evaluation rounds.

FINAL CONSIDERATIONS

The validation stage with stomatherapy experts made it possible to refine the care listed in the literature, as well as to define best practices. It should be noted that some of the items were not validated due to disagreement between the judges. However, the validated items are extremely relevant for the prevention of MDRPI in people with obesity and were considered valid with a CVI ≥ 0.80 and an 89.9% agreement rate between the experts.

Finally, it is hoped that this Bundle can contribute to minimizing MDRPI in people with obesity, guiding professionals on the importance of care, qualifying care, and seeking to improve patient safety.

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