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Content validity and internal consistency of an algorithm for cleansing wounds with granulation and necrotic tissues

Geraldo Magela Salomé

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Autor correspondente:
Nome: Geraldo Magela Salomé
E-mail: salomereiki@univas.edu.br
Formação: Enfermeiro
Filiação: Universidade do Vale do Sapucaí

Endereço: Avenida Francisco de Paula Quintaninha Ribeiro, 280,apt. 134- Bairro: Jabaquara. São Paulo

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Universidade Federal de Santa Maria 1960
CCS CENTRO DE CIÊNCIAS DA SAÚDE UFSM

Abstract:

Protocols in the form of algorithms allow the nurse team to make rapid decisions, lowering risks and improving outcome. There is a lack of readily available protocols for the use of correct techniques and products for wound cleansing.**Objective**. To assess the content validity and internal consistency of an algorithm for cleansing wounds with granulation and necrotic tissues. **Methods**. A literature search was conducted to identify relevant studies for the construction of the algorithm, using the following descriptors: “wounds and injuries”, “algorithms”, “cleansing agents”, “therapeutic irrigation”, and “debridement” in both English, Brazilian Portuguese and Spanish. The development of the algorithm involved the planning and production of content and definition of topics. The algorithm was assessed for content validity by 20 judges and for internal consistency by 31 judges.**Results**. An algorithm was developed to help health professionals in the cleansing of wounds. It describes wound cleansing techniques and provides recommendations for therapeutic interventions and primary dressings, based on the type of wound tissue. The judges assessing the content validity of the algorithm reached consensus in two rounds of consultation. The algorithm showed good internal consistency with a Cronbach’s alpha of 0.851. **Conclusions.** The validated algorithms will provide health professionals with relevant information to choose appropriate wound cleansing techniques and therapeutic procedures according to the type of wound tissue.

Keywords: Wounds and injuries, algorithms, cleansing agents, therapeutic irrigation, debridement

INTRODUCTION

Currently, several technological resources for wound cleansing are available in the market, making the nursing professional a fundamental element in the selection of appropriate products and procedures for the treatment of skin wounds. Evidence-based recommendations for the use of materials and protocols contribute to the decision-making process in clinical practice[1,2,3]. The access to the institution's protocols of wound management and use of proper wound cleansing agents and techniques are essential for an adequate wound cleansing[4,5].

Wound cleansing allows the health professional to inspect and evaluate the type of tissue and amount of exudate present in the wound site. The purpose of the wound cleansing is to prevent wound infection. Bacteria only invades viable tissues if they can adhere to them, leading to infection. The cleansing technique should remove the bacteria from the wound site without the use of antiseptics. Wound irrigation with saline solution or tap water applied with adequate pressure is sufficient to remove debris and loosen non-viable tissue[6,7].

Our experience shows that many health professionals perform wound cleansing inadequately and sometimes use cleansing agents that are toxic, especially to the granulation tissue. There is a lack of protocols for the use of correct techniques and products for wound care management. Protocols in the form of algorithms allow the nurse team to act preventively and to make rapid decisions, lowering risks and improving outcome[8].

Thus, the aim of this study is to assess the content validity and internal consistency of an algorithm for the cleansing of wounds with granulation and necrotic tissues. The purpose of the algorithm is to assist health professionals in choosing appropriate cleansing techniques and debriding agents, according to the type of tissue in the wound site.

MATERIALS AND METHODS

This quantitative, methodological study was conducted between February and April 2017. The study was approved by the Research Ethics Committee of the "Dr José Antônio Garcia Coutinho" School of Medical Sciences of the University of Vale do Sapucaí (UNIVÁS), Brazil (approval number 1.046,148) and conducted at the Samuel Libânio General Hospital of UNIVÁS.

A literature review was performed for the construction of a wound cleansing algorithm,

using the search terms “wounds and injuries”, “algorithms”, “cleansing agents”, “therapeutic irrigation”, and “debridement” on the Cochrane Library, Scientific Electronic Library Online (SciELO), Latin American and Caribbean Literature in Health Sciences (LILACS), U.S. National Library of Medicine (MEDLINE), International Nursing Index (INI), and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases.

Only primary studies directly related to the topic written in Portuguese, English, or Spanish, and available as full text were included in the study. There were no restrictions placed on publication date. Books, book chapters, theses, dissertations, monographs, technical reports, duplicate publications, and articles that, after reading the abstract, did not meet inclusion criteria were not included.

After the abstracts were read, articles describing cleansing techniques, jet irrigation, wound irrigation, debridement techniques, wound assessment, types of cleansing agents, and dressings used in wound debridement were obtained and read in full.

An algorithm for the cleansing of wounds with granulation tissue and necrotic tissue was developed based on the review of the selected studies.

Internal consistency and content-validity

The algorithm was evaluated by health care professionals and revised according to their suggestions. It was assessed for internal consistency by 20 judges and, for content validity, by 31 judges who did not participate in the internal consistency assessment.

Eligibility criteria to participate in the study as a judge included professionals who had at least a bachelor of science in nursing (BSN) degree and at least one year of experience in caring for individuals with wounds. Those who failed to complete the study questionnaire within 15 days in the first or second rounds of consultation were excluded from the study.

The professionals received an invitation letter containing information about the topic of the study with an objective definition of the technique used in the cleansing of wounds with granulation and necrotic tissues, a copy of the approval letter from the institutional Research Ethics Committee, and explanations about the importance of the evaluator in the study. Written informed consent was obtained from all professionals prior to their inclusion in the study with the knowledge that they were free to leave the study at any time. Participant anonymity was assured.

Those who agreed to participate received a questionnaire via email to be used in the evaluation of the algorithm and were asked to complete and return it within 15 days. The questionnaire assessed the personal characteristics of the judge (4 items), the elements of the algorithm (18 items), and the judge's opinion about the algorithm (3 items).

The items related to the elements of the algorithm were rated on a Likert-type scale with 5 alternative responses (1 = inadequate; 2 = partially adequate; 3 = adequate; 4 = very adequate; and N/A = not applicable). The questionnaire for the assessment of content validity had also opinion questions with a dichotomous choice ("yes" or "no"). If the answer was "no", the judge was requested to provide suggestions to improve the algorithm in the provided space.

The algorithm was evaluated for thematic content, graphic presentation, flow of information, clarity and ease of comprehension, relevance of the content, and adequacy of the cleansing techniques, therapeutic interventions, debridement procedures, and type of dressings recommended for the healing of wounds containing granulation and necrotic tissues with or without exudate.

The Delphi Technique was used to assess content-validity of the algorithm. According to this technique, the content of an instrument is evaluated and judged by a panel of experts through a questionnaire in the search for a consensus among the evaluators. Usually, there are two to three rounds or cycles of consultation, but more rounds may be needed[9].

The content validity index (CVI) was used to measure the per cent of judges who agreed on certain aspects of the instrument[10]. The CVI was calculated based on the number of responses "adequate" or "very adequate" for each item of the questionnaire divided by the total number of responses. For the validation of an instrument, the CVI for each item should be ≥ 0.78 when the panel is composed of six or more judges[11].

There is no consensus in the literature on the best formula to calculate the overall CVI of an instrument. In this study, overall CVI was calculated as the sum of CVI values of all items divided by the total number of items. The minimum overall CVI of 0.80 was required for content validation of the instrument[9].

Statistical analysis

Data were entered into an Excel spreadsheet (Microsoft Corporation, Redwood, WA, USA) and analysed using the Statistical Package for the Social Sciences (SPSS) 2.0 for Windows (SPSS Inc., Chicago, IL, USA).

Cronbach's alpha was used to evaluate the internal consistency of the instrument based on the correlation among the questionnaire items obtained through the analysis of the profile of the obtained answers. Cronbach's alpha ranges from 0 to 1 and increases when the correlations between the items increase.

RESULTS

Algorithm development

An algorithm for wound cleansing was created based on the literature review. The algorithm was divided into two protocols, as follows: cleansing of wounds with granulation tissue (Figure 1) and cleansing of wounds with necrotic tissue (Figure 2).

Each protocol has three main steps for the cleansing of wounds: (1) wound assessment, (2) wound cleansing, and (3) recommended interventions.

Wound assessment includes wound measurements, classification of the type of tissue found in the edges and bed of the wound, type and amount of wound exudate, if present, and check for signs of inflammation or infection.

Wound cleansing procedures consider the type of tissue present in the wound site and distribution of the viable and non-viable tissues (i.e., necrosis or slough). The recommended cleansing procedures involve wound irrigation using a 20-ml syringe coupled to an 18-G needle (or 40x12 needle). In the presence of granulation tissue, wound irrigation is performed with warm 0.9% saline solution or tap water, and in the presence of necrotic tissue, it is done with chlorhexidine detergent solution combined with smearing.

Therapeutic interventions are recommended for the cleansing of the wound to prevent infection, remove debris, bacteria, and necrotic tissue from the wound site, and promote wound healing. The recommended interventions are based on the type of tissue and exudate found in the wound and involve the use of debridement techniques and wound dressings available in the market.

Figure 1. Diagram of the protocol for cleansing wounds with granulation tissue

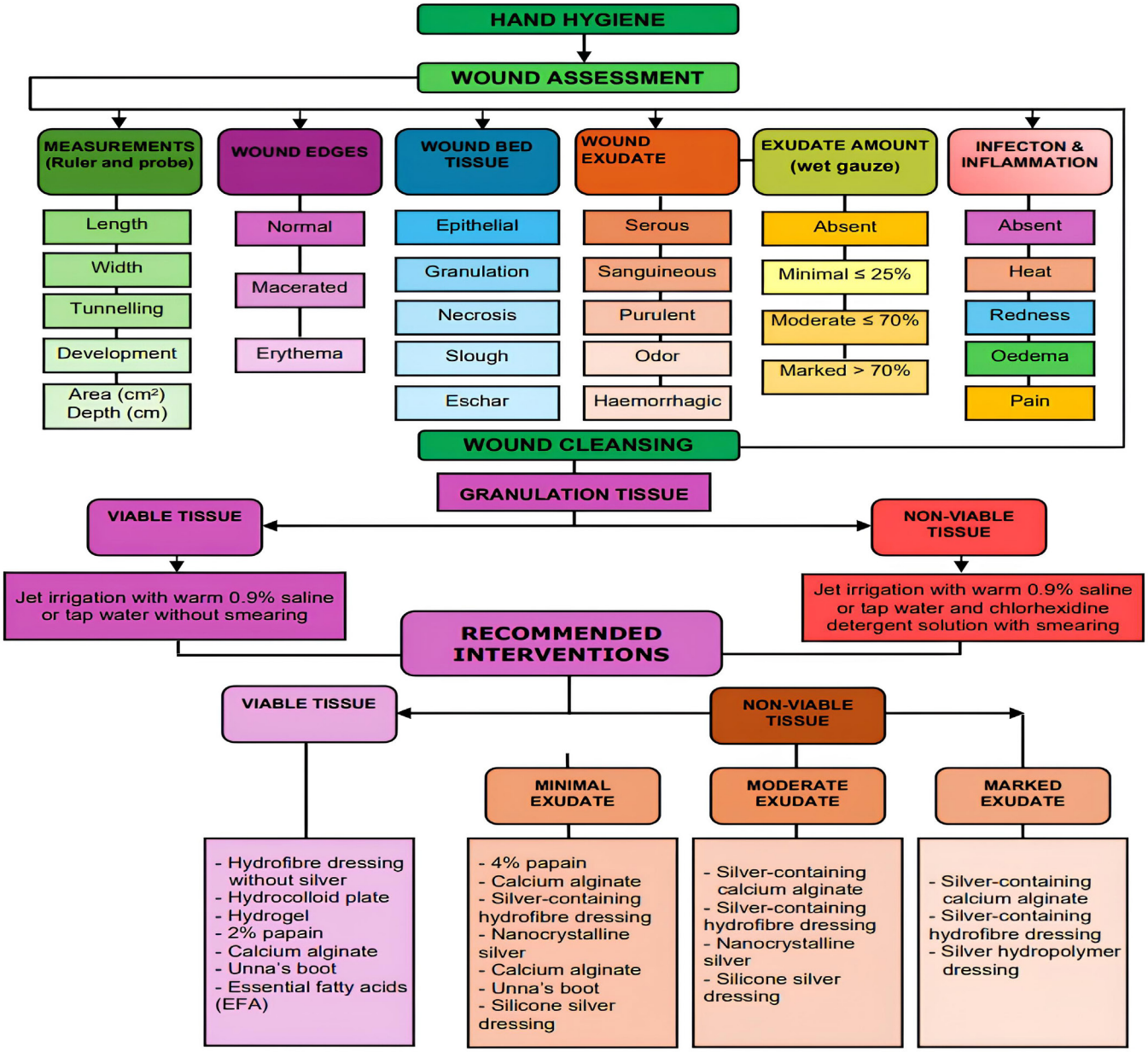
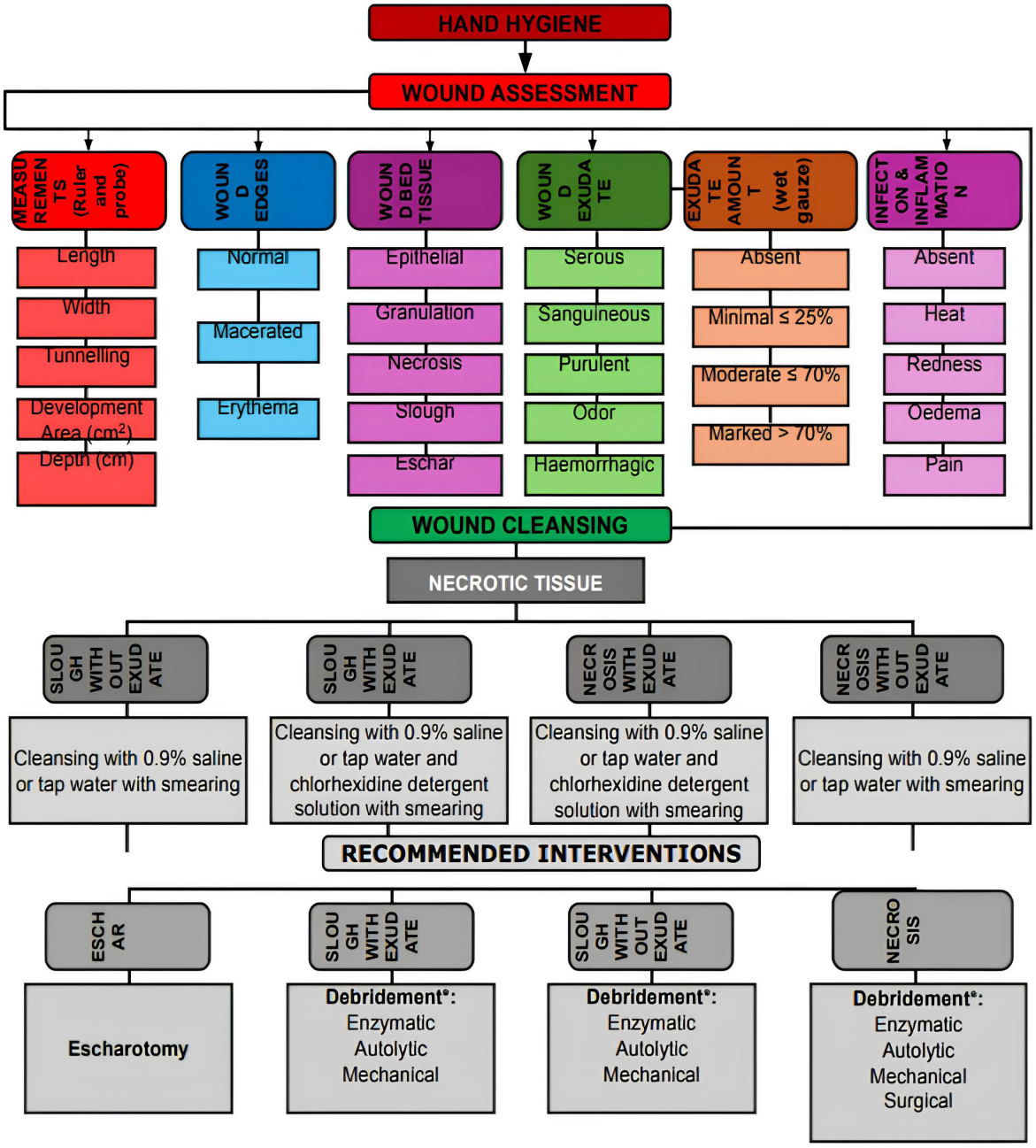


Figure 2. Diagram of the protocol for cleansing wounds with necrotic tissue



* Types of debridement	Recommended materials/products
Enzymatic	10% papain
Autolytic	Hydrocolloid plate, hydrogel, polyurethane films
Mechanical (smearing, irrigation)	Wet and dry gauze, 20-ml syringe and 18-G needle for jet irrigation, tissue forceps with teeth
Surgical	Cutting instruments, scissors, tissue forceps with teeth, scalpel, silver nitrate sticks, and anaesthetics.

CONTENT VALIDATION

The algorithm was assessed for content validity by 31 judges. the responses of the judges to the items of the questionnaire in the first round of consultation are shown in table 1. most judges considered that the content and elements of the algorithm were adequate or very adequate.

Table 1. evaluation of content and elements of the algorithm for wound cleansing by the judges in the first round of consultation.

Evaluated elements	Inadequate		Partially adequate		Adequate		Very adequate		P-value
	N	%	N	%	N	%	N	%	
Graphic presentation	0	0	0	0	7	22.60	24	77.40	0.001*
Clarity and ease of comprehension	1	3.20	0	0	3	9.70	27	87.10	0.021*
Flow of information	1	3.20	0	0	8	25.80	22	71.00	0.001*
Vocabulary	1	3.20	0	0	6	19.40	24	77.40	0.019*
Relevance of the content	1	3.20	0	0	3	9.70	27	87.10	0.021*
Wound measurements	0	0	0	0	6	19.40	25	80.60	0.001*
Type of wound tissue	0	0	0	0	8	25.80	23	74.20	0.019*
Type of exudate	0	0	0	0	8	25.80	23	74.20	0.019*
Classification of the amount of exudate	0	0	0	0	14	45.20	17	54.80	0.079
Cleansing of wounds containing:									
Slough and exudate	0	0	0	0	12	38.70	19	61.30	0.021*
Slough without exudate	0	0	0	0	12	38.70	19	61.30	0.021*
Necrosis and exudate	0	0	0	0	9	29.00	22	71.00	0.017*
Necrosis without exudate	0	0	0	0	9	29.00	22	71.00	0.017*
Viable granulation tissue	2	6.50	0	0	9	29.00	20	64.50	0.020*
Non-viable granulation tissue	2	6.50	0	0	9	29.00	20	64.50	0.020*
Escharotomy technique	1	2.90	3	8.60	15	42.90	16	45.70	0.082
Debridement technique	0	0	0	0	11	35.50	20	64.50	0.020*
Dressings used in wound debridement	2	6.50	0	0	9	29.00	20	64.50	0.020*

* STATISTICAL SIGNIFICANCE ($P < 0.05$)

In the first round of consultation, the minimum CVI value of 0.78 required for validation of the algorithm was not reached in the following items: "relevance of the content", "type of wound tissue", "classification of the amount of exudate", "debridement technique", "cleansing of wounds presenting viable granulation tissue", and "escharotomy technique". The algorithm was revised according to the judges' suggestions and the consensus was reached in the second round of consultation. The overall CVI value was 0.99 and therefore greater than the minimum overall CVI of 0.80 required for content validation of the manual. The CVI values for the two rounds of consultation are listed in Table 2.

Table 2. Content validity index (CVI) values for the two rounds of consultation

Evaluated elements	CVI values	
	1° assessment	2° assessment
Graphic presentation	0.87	0.98
Clarity and ease of comprehension	0.97	1.0
Flow of information	1.0	1.0
Vocabulary	0.89	1.0
Relevance of the content	0.75	0.99
Wound measurements	1.0	1.0
Type of wound tissue	0.79	0.97
Type of exudate	0.85	0.93
Classification of the amount of exudate	0.75	1.0
Cleansing of wounds containing:		
Slough and exudate	0.91	1.0
Slough without exudate	1.0	1.0
Necrosis and exudate	1.0	1.0
Necrosis without exudate	0.99	1.0
Viable granulation tissue	0.75	0.97
Non-viable granulation tissue	0.97	1.0
Debridement technique	0.77	0.97
Escharotomy technique	0.63	1.0
Dressings used in wound debridement	0.71	0.99

The internal consistency of the instrument was evaluated using the Cronbach's alpha coefficient. The overall Cronbach's alpha was 0.851, showing that the algorithm has good internal consistency (Table 3).

Table 3. Internal consistency of the elements of the algorithm for wound cleansing

Evaluated elements Overall Cronbach's alpha = 0.851	**Scale mean if item deleted**	**Scale variance if item deleted**	**Corrected item-total correlation**	**Cronbach's alpha if item deleted**
Graphic presentation	24.11	11.751	0.6870	0.848
Clarity and ease of comprehension	24.51	11.316	0.638	0.846
Flow of information	23.77	12.182	0.805	0.839
Vocabulary	24.06	12.585	0.684	0.850
Relevance of the content	23.83	12.617	0.657	0.846
Wound measurements	23.86	12.950	0.618	0.851
Type of wound tissue	24.09	11.904	0.647	0.843
Type of exudate	24.17	11.911	0.620	0.846
Classification of exudate amount	24.77	13.189	0.809	0.849
Cleansing of wounds containing:				
Slough and exudate	25.06	13.585	0.689	0.850
Slough without exudate	24.83	12.619	0.659	0.8464
Necrosis and exudate	25.86	11.950	0.618	0.8459
Necrosis without exudate	25.09	10.904	0.647	0.849
Viable granulation tissue	24.17	11.911	0.720	0.846
Non-viable granulation tissue	23.86	13.950	0.618	0.875
Escharotomy technique	25.09	12.904	0.749	0.853
Debridement technique	24.77	13.189	0.809	0.849
Dressings used in debridement	24.17	11.911	0.620	0.846

DISCUSSION

Internal consistency assessment and content validation are important steps in building evidentiary support for the use of an algorithm.12 Clinical algorithms may be used for guiding the step-by-step care of specific problems, therapeutic interventions or diagnostic procedures. The use of algorithms facilitates the training of a multidisciplinary team, information standardization, and patient understanding of treatment instructions in a simple language. The algorithm was developed based on a literature review and validated for

content by a panel of specialists in wound care, as previously described[12]. Well-developed instruments, such as guidelines, protocols, and algorithms, may modify the health status of specific populations, and therefore their content has to be adequately selected[3,13].

The use of algorithms favours behavioural changes, making health professionals, caregivers, and patients confident to perform certain therapeutic procedures, such as assessing the wound and choosing the cleansing technique, cleansing agents, debridement procedures, and dressings for the different types of wound tissue. Algorithms may also be used in education and training of preventive and therapeutic interventions[2,13,14].

In this study, we used wound cleaning with PHMB and hypochlorous acid as a standard to clean viable or non-viable granulation tissue with or without exudate. These products have antimicrobial action and low toxicity. If the institution does not have this material, drinking water or chlorhexidine can be used regularly to clean non-viable granulation tissue devitalized with exudate. and the use of drinking water. When cleaning with chlorhexidine, the professional must exercise caution due to its toxicity.

In this study, the judges considered that the algorithm has an excellent potential to helped health professionals in the cleansing of wounds. The results showed that the validated version of the algorithm has a good consistency (Cronbach's alpha = 0.851), providing reliable and adequate information for wound cleansing, according to the type of wound tissue.

Wound assessment is one of the key steps in treatment planning for the different wound types. International consensuses for wound management recommend frequent (at least weekly) wound assessments, using standardized instruments that allow reliable monitoring of the healing process[3,15].

The assessment of a wound by different health professionals may result in divergent or conflicting interpretations. It is necessary to ensure interobserver reliability, that is, a high degree of agreement among health professionals reporting on the same events. This is possible through the use of validated standardized instruments and the training and skilling of health professionals in wound care management[3]. Wound assessment include the determination of its anatomical location, size, colour, type of tissue found in the bed and edges of the wound, the presence of foreign bodies, fistulas, tunnelling, and cysts, and wound exudate characteristics, among other factors[3,15].

Standardized instruments for wound assessment allow the detection of possible complications, which can interfere in the healing process, and selection of appropriate interventions to address these factors, thus improving healing conditions[3].

After wound assessment, the algorithm developed in this study provides means for health professionals to choose the most appropriate wound cleansing technique according to the type of wound tissue. Irrigation with warm 0.9% saline solution or tap water is recommended in the presence of granulation tissue, whereas the use of chlorhexidine detergent solution combined with smearing is recommended for wounds with necrotic tissue.

Wound cleansing is of paramount importance in preventing infection, thus promoting wound healing. Non-toxic cleansing agents should be used to remove excess exudate, necrotic tissue, and foreign bodies from the wound site, providing an appropriate environment for wound healing.6 Wound cleansing agents should preserve the viable granulation tissue, not cause sensitivity reactions, reduce the number of microorganisms in the wound site, and be widely available and inexpensive[7]. These criteria are fulfilled by 0.9% saline, an isotonic solution, which does not interfere with the healing process or cause damage to tissues, and therefore it is the cleansing agent of choice for wound irrigation[2,13,14,16,17,18]. Although tap water can be used in wound cleansing, factors such as water quality and concentrations of fluoride and chlorine in the water should be evaluated; the use of boiled water is recommended[6,7].

Wound irrigation prevents damage to the newly-formed tissue and ensures proper cleansing of the wound bed. However, excessive pressure of the irrigation fluid may drag debris deeper into the wound bed, increasing the risk of infection, whereas insufficient pressure is not effective in removing debris or exudate19. The cleansing of wounds with granulation tissue should be performed by jet irrigation with a warm saline solution or tap water to prevent a decrease in the wound bed temperature and stimulate local vasodilatation, accelerating the healing process. Optimum irrigation pressure ranges from 4 to 15 psi[6,7,19]. An adequate irrigation pressure of 8 psi can be obtained with a 35-ml syringe coupled to a 19-G needle (or 40x11 needle[6,7,19]. In Brazil, an irrigation pressure of about 9 psi is obtained using a 20-ml syringe coupled to an 18-G needle (or 40x12 needle) because these products are more readily available[6,7,19].

In this study, the recommended cleansing procedures for wounds with non-viable tissues involved the use of saline solution or tap water, smearing, and enzymatic, autolytic, mechanical or surgical debridement.

Debridement is the removal of non-viable tissue from the wound site and is part of the autolytic and physiological processes of wound healing under normal conditions. Neutrophils and macrophages act in the inflammatory phase, digesting and removing cellular debris. The natural process of debridement, however, becomes insufficient with the accumulation of necrotic tissue in the wound site.19,20 Thus, wound debridement has to be performed by the health professional to remove necrotic tissues and any foreign body from the wound bed, reducing the bacterial load, toxins, and other factors that impair wound healing[7,19,20].

Mechanical debridement involves the use of a mechanical force to remove necrotic tissue from the wound site[21,22,23,24]. It includes procedures such as smearing and wound irrigation[25].

Surgical debridement is a medical removal of necrotic tissue using cutting instruments, such as a scalpel, scissors, or laser, among others[7,20].

Enzymatic debridement is the removal of necrotic tissue from wounds by proteolytic enzymes through the degradation of collagen. Enzymatic debriding agents are topically applied to the wounds with a moisture-retentive dressing[6,7,17,18].

Autolytic debridement is achieved with the use of synthetic dressings that induce autolysis, that is, the natural breakdown of necrotic tissue through the action of lysosomal enzymes released by macrophages in the wound bed[6,7,17,18].

The use of cleansing techniques in wounds containing purulent exudate and signs of infection may be not sufficient to reduce bacterial load, thus requiring the use of antiseptics[23,24]. Antiseptics are substances that kill, inhibit the growth or reduce the number of microorganisms, playing an important role in controlling the microbial load in infected wounds[17-19]. Antiseptics have been used in the prevention and treatment of wound infection. Although some antiseptic agents have been developed as topical solutions with varying degrees of antimicrobial activity, a number of concerns have been raised. Cleansing solutions containing antiseptic agents can affect normal human cells due to antimitotic effects, negatively interfering with normal tissue repair and impairing the healing process[17-19].

CONCLUSIONS

This study resulted in the development and validation of an algorithm for cleansing wounds with granulation and necrotic tissues. The validated algorithm showed good consistency, and therefore, provide health professionals with relevant information to choose appropriate wound cleansing techniques and therapeutic procedures according to the type of wound tissue, and may be used in clinical practice, nursing education, and scientific research.

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