

Protocol Proposal for the Care of the Person with Venous Ulcer

ORIGINAL

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Abstract

Objective: To propose a care protocol for the care of the person with a venous ulcer in highly complex services.

Methods and results: This is a methodological study, in three stages: literature review, validation of content and validation in the clinical context. The literature review was carried out from June to August/2011, being the basis for the construction of the Protocol for Venous Ulcers. The content validation included 53 judges (44 nurses, 8 physicians and 1 physiotherapist) selected through the Lattes platform to evaluate the items of the protocol. Validation in the clinical context occurred at the University Hospital Onofre Lopes, in Natal/RN with four judges (nurses), who worked in pairs, evaluating 32 patients with venous ulcers. The protocol was validated with 15 categories: sociodemographic data; anamnesis; examinations; ulcer characteristics; care with the lesion and perilesional area; medicines used to treat the lesion; evaluation and treatment of pain; surgical treatment of chronic venous disease; recurrence prevention (clinical and educational strategies); reference; counter-reference; and quality of life.

The validated protocol regarding content and clinical context was applicable. Its implementation is a viable measure that assists in the reorientation of the team in high complexity services, aiming at wound healing and restoration of the patient's integral health.

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Keywords

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Introduction

Venous ulcers are chronic lesions associated with venous hypertension of the lower limbs, and they are approximately 90% of lower limb injuries. They are characterized as the most serious complication of Chronic Venous Disease (CVD), they are recurrent and bring suffering to the patient and family, constituting an important public health problem [1-2].

The incidence and prevalence of chronic ulcers are still high in Brazil, reflecting high financial and social costs [3-4]. Despite the advancement of technologies and the development of multidisciplinary actions, the care for chronic wounds is still not standardized in most public health services.

The development of care protocols requires careful methodology and must incorporate the art and science of care with injuries [4]. Protocols used to systematize care facilitate registration and decision-making, pointing out ways for professionals without suppressing their responsibility regarding the need for theoretical-practical articulation and the use of critical thinking [5-6].

The assistance with interdisciplinary action, adoption of protocols, specific knowledge, technical ability, articulation between the complexity levels of assistance of the Unified Health System, as well as active participation of the patients with these injuries and their relatives are essential aspects of the approach to the person with venous ulcer (VU) [7].

Through a protocol, the multi-professional team can evaluate factors related to clinical, care aspects and related to the quality of life, which may interfere with the evolution of VU healing. Corroborating this idea, the Brazilian Society of Angiology and Vascular Surgery (SBACV) emphasizes guidelines on diagnosis, prevention and treatment of wounds, such as ulcer evaluation, measures and exams, compressive therapy, pain treatment, cleansing, debridements and dressings, surgical treatment and drug therapy of chronic venous disease and prevention of relapses [7-10].

Also, a protocol for the treatment of patients with venous ulcers should include anamnesis, ulcer

registration, an indication of treatment, evolution follow-up, appointment scheduling and record of findings. In the computerized protocols, there are more details than in the textual protocols, allowing care by different health professionals [11].

The use of clinical protocols is important for the need to standardize the care actions to favor the healing process. When care is poorly performed, the lesion may remain unhealed for years, resulting in a high social and emotional cost to the patient. In many cases, the presence of the ulcer distracts the individual from work, aggravating the socioeconomic conditions and the quality of life of the patients and their relatives, as well as burdening the health services [7].

The effectiveness of protocols for the prevention and treatment of chronic injuries is evidenced by a study by the Federal University of Minas Gerais, which obtained 100% epithelized wounds using a protocol that systematized the assistance provided [12].

It should be noted that it is essential to establish standardized procedures, preventive and resolute measures to reduce the incidence, prevalence, and chronicity of VUs, as well as to minimize the damages and complications caused by their evolution. Thus, the objective of this article was to propose a care protocol for the care of the person with a venous ulcer in high complexity services.

Methods

This is a methodological study with a quantitative approach, developed in three stages: literature review, validation of content and validation in the clinical context. The literature review was conducted from June to August 2011, and it was based on the construction of the Protocol for Venous Ulcers (PVU) [7].

Content validation (CV) was then performed, including 53 judges selected the Lattes platform, to evaluate the items of the protocol [7]. The judges were 44 nurses, eight physicians, and one phy-

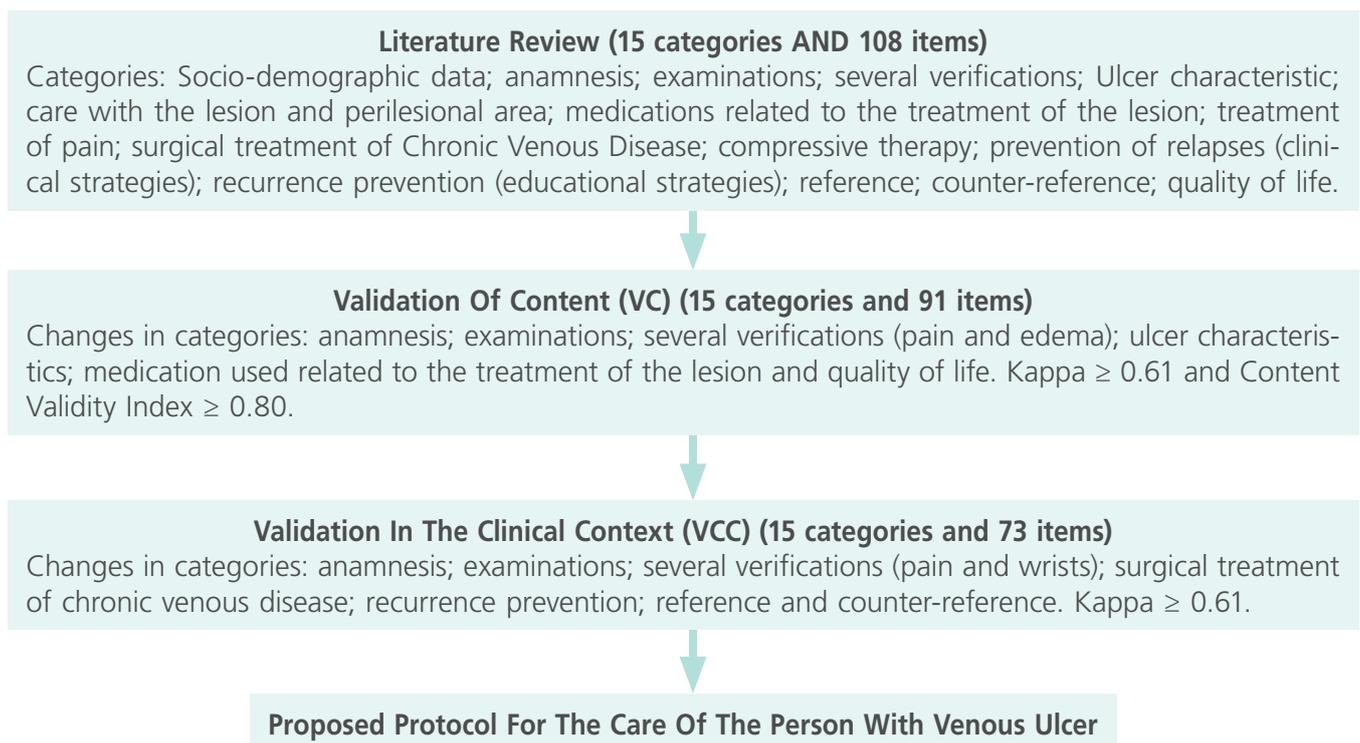
siotherapist, most of them are active in care and education; in the Northeast and Southeast Regions; between 30 and 49 years old; female; and with care for the person with VU for 1 to 10 years. The contact occurred via e-mail and the judges evaluated the protocol via Google Docs <docs.google.com>. The evaluation of categories and items of the protocol occurred from the agreement or disagreement of the specialists. Also, they could give suggestions for the items to be modified.

After the analysis of the indices obtained in the CV stage, the protocol was adjusted and submitted to validation in the clinical context (VCC), at the University Hospital Onofre Lopes (HUOL), in Natal/RN. The validation in the clinical context involved four expert judges, who worked in pairs, evaluating 32 patients with venous ulcers in the clinical context of high complexity. The experts evaluated the items and categories for their relevance and applicability of the protocol and proposed suggestions for improvement.

The Kappa index (K) and Content Validity Index (CVI) were used to analyze the answers of the specialists. The Kappa index evaluates the concordance ratio, which ranges from “minus 1” to “plus 1”. The closer to 1, the better the level of agreement among observers. As acceptance criterion, a concordance ≥ 0.61 was established among the judges, being considered a good level¹³. The CVI was calculated by dividing the number of judges who agreed to the item by the total number of judges (CVI for each item). As a consensus, CVI ≥ 0.8014 was considered. Both in the evidence of validation of content and in the evidence of validation in the clinical context, the items of the protocol that did not reach established Kappa and CVI indexes were excluded and some items were modified or included after the judges' suggestions. The stages of the study are shown in **Figure 1**.

The study followed the ethical principles contained in Resolution 466/12, approved by the Research Ethics Committee of the Federal Uni-

Figure 1: Figure 1: Stages of the study. Natal, Rio Grande do Norte, Brazil.



Source: The author.

versity of Rio Grande do Norte (UFRN) (CAAE: 07556312.0.0000.5537).

Results

The procedures for validation of content and validation in the clinical context allowed the improvement

of the proposed protocol for care of the person with a venous ulcer, which initially contained 15 categories and 108 items (**Table 1**).

In the content validation process, items that obtained unsatisfactory Kappa and CVI ($K < 0.61$ and $CVI < 0.80$) were excluded and/or modified according to the experts' suggestions. The excluded

Table 1. The initial composition of the Protocol for Venous Ulcers (categories and items), built from the literature review. Natal, Rio Grande do Norte, Brazil.

Categories	Items
Socio-demographic data	Name, the number of the Unified Health System record, chart number, referenced, age, gender, address, marital status, education level, profession/occupation, family income, other (describe).
Anamnesis	Who performs the dressing on the week, the place where the dressing is done in the week, the place where the dressing is done at the weekend, who performs the dressing on the weekend, chronic diseases, allergies, medications, alcohol, activities during the day, rest, sleep, beginning of the 1st venous ulcer, time of current ulcer, relapse and risk factors.
Examinations (Request/performance/results)	Complete blood exam, fasting blood glucose, serum albumin, urine type I, brachial-ankle index, echocardiography, phlebography, plastography, a biopsy (suspected infection), others (describe).
Several verifications	Pain, pedal, tibial and popliteal pulses, edema, signs of infection, body mass index, blood pressure, temperature, pulse, respiratory rate, lesion location, others (describe).
Ulcer characteristics	Level, exudate (type, quantity), odor, border, perilesional area, lesion layer, exchange rate, ulcer measurement during treatment, others (describe).
Care with the lesion and perilesional area	Cleaning of the perilesional area, products used in the perilesional area, cleaning of the lesion, an indication of coverage, products used in the lesion area, others (describe).
Medications related to the treatment of the lesion	Antibiotic, phlebotropic, others (describe).
Pain treatment	Absent, present, physiotherapeutic measures, what physiotherapeutic measures, analgesics, what analgesics, others (describe).
Surgical treatment of the chronic venous disease (CVD)	An indication of surgical treatment, type of surgical treatment, compressive therapy after surgery, others (describe).
Compressive therapy	Absent, present, what compression therapy, application of adequate compression, oriented use of compression stockings, oriented rest with high legs (2-4 hours/day) and raise bed feet of 10-15 centimeters, targeted use of contraction exercises and calf flexion and walking, lower limb elevation 30 minutes before compression, others (describe).
Relapse prevention (clinical strategies)	Venous and surgical investigation, compression therapy during life, the regular follow-up to monitor skin conditions for recurrence, others (describe).
Relapse prevention (educational strategies)	The importance of adherence to the use of compression stockings, skin care, prevention of accidents/trauma to the lower limbs, orientation to seek assistance for signs of possible skin continuity, encouragement of mobility/exercises, elevation of affected limb, others (describe).
Reference	Absent/present, origin unit, professional, other.
Counter-reference	Destination, clinical summary, test results, diagnosis, behavior, others (describe).
Quality of life	Chronic Venous Insufficiency Questionnaire (CIVIQ) [15].

Source: The author.

items belonged to the categories: anamnesis; examinations; several verifications (pain and edema); ulcer characteristics; medications used related to the treatment of the lesion; and quality of life. In the stage of validation in the clinical context, the items that obtained insufficient Kappa ($K < 0.61$)

and were excluded and/or altered by the judges were in the categories: anamnesis; examinations; several verifications (pain and wrists); surgical treatment of chronic venous disease; recurrence prevention; reference; and counter-reference, as seen in **Table 2**.

Table 2. Suggestions of the judges in the Content Validation (CV) and Validation in the Clinical Context (VCC) stages. Natal, Rio Grande do Norte, Brazil.

Categories/Items	Average	Median
Suggestions	STAGE	
Religion	Included	Content Validation
Referenced	Transferred to the category "Reference."	Validation in the Clinical Context
Anamnesis		
Chronic Diseases (neurologic disease)	Retired	Content Validation
Chronic diseases (leprosy)	Retired	Content Validation
Chronic diseases (chest pain episode)	Retired	Content Validation
Chronic diseases	Retired "quantity of years."	Validation in the Clinical Context
Medications currently used	Retired "time of use."	Validation in the Clinical Context
Activities/day	Retired "number of hours."	Validation in the Clinical Context
Risk factors	Retired "duration, recurrence and time."	Validation in the Clinical Context
Examinations		
Urine type I	Retired	Content Validation
Plethysmography	Retired	Content Validation
Phlebography	Retired	Content Validation
Albumin	Retired	Validation in the Clinical Context
Miscellaneous verifications		
Pain	Transferred to category "Evaluation and treatment of pain."	Content Validation
Edema	Include expression "measure 10 cm above medial malleolus."	Content Validation
Pulses	Include in the evaluation "not applicable due to the injury."	Validation in the Clinical Context
Characteristics of the ulcer		
Edge	Modified by "margin."	Content Validation
Medications used related to the treatment of the lesion		
Anti-inflammatory	Included	Content Validation
Evaluation and treatment of pain		
Physiotherapeutic measures	Modified to "Non-pharmacological measures."	Content Validation
Pain	Transferred from the category "several verifications."	Content Validation
	Modified analog scale rating (0 to 10) for "absent" or "mild" or "moderate" or "intense."	Validation in the Clinical Context

Categories/Items	Average	Median
Surgical Treatment of Chronic Venous Disease		
Cause of the disease (valve insufficiency)	Retired	Validation in the Clinical Context
Cause of the disease (venous obstruction)	Retired	Validation in the Clinical Context
Type of surgery (insufficient perforation ligature method)	Retired	Validation in the Clinical Context
Compressive Therapy		
Orientation for rest with legs elevated (2-4 h/day) and raise feet of bed at 10-15 cm.	Retired	Validation in the Clinical Context
Reference	Evaluated only in this item, retired from the category "Sociodemographic data."	Validation in the Clinical Context
Counter-reference		
Exam results	Changed to "clinical summary."	Validation in the Clinical Context
Diagnosis		
Behavior		
Quality of life (Chronic Venous Insufficiency Questionnaire (CIVIQ) [15].		
Monthly evaluation	Modified for quarterly evaluation	Content Validation
Source: The author		

After validation and validation in the clinical context, the Protocol for Venous Ulcers (PVU) was validated with 15 categories and 76 items.

Discussion

The clinical diagnosis of the chronic venous disease and the venous ulcer is performed through anamnesis and physical examination. Therefore, a complete clinical history should be known, with emphasis on lesion evaluation and exams. The important examination to be performed are complete blood exam, fasting blood glucose, brachial-ankle index (ABI), biopsy on suspicion of infection and color echocardiography [1, 8].

The physical examination should be directed to the evaluation of the patient, the vascular state and the characteristics of the lesions. In the evaluation of the patient, it is important to highlight the vital signs, peripheral pulses, chronic diseases, medications used, life habits, nutritional and hygiene conditions, and risk factors for CVD [1, 16].

In the vascular state of the patient, the history of the current ulcer (onset of the first ulcer, time of injury, relapses), medications in use to treat the lesion, surgical treatments, and compressive therapies are highlighted beside the diseases and risk factors for CVD [1, 7-9].

Regarding medication for the treatment of the lesion, it is important to emphasize that antibiotics should be used only in cases of infections and with the certification of results of cultures of biopsied tissue, considering a large number of patients who develop resistance to these medications [12]. Phlebotropes act in the macrocirculation, improving venous tone, and in the microcirculation, reducing capillary hyperpermeability, and may be an alternative for patients who present with pain and edema. Nevertheless the anti-inflammatory action of these drugs is emphasized, that can interfere with the natural process of tissue repair [17].

Regarding the characteristics of the lesions, studies [1, 7-10] emphasize the observation of the

place, depth, margins, layer, exudate, injured area and pain.

The evaluation and recording of pain are fundamental steps for the effective control of this symptom. Pain relief is a patient's right and it shows a humanized care, as well as improving the quality of life of people with venous ulcers and improving the healing of ulcers [18].

Despite the relevance of this symptom, few types of research have explored pain in patients with VU [19]. However, an international study [18] found that patients who used compressive therapy, who received guidance on its use and lower limb elevation, presented lower pain intensity and less impact on daily activities.

Adequate care for people with venous ulcers involves the performance of a multi-professional team, highlighted for providing care in the evaluation of injuries, performing necessary dressings and referrals, and preventive actions (educational and clinical) for a favorable evolution of the healing process and prevention of the occurrence of relapses [20].

The reference and counter-reference system should be a structured flow between health services since it improves the efficiency and effectiveness of care, minimizing gaps and deficits in treatment and reducing the chances of relapse [16].

It is also important to highlight that the quality of life of people with VU is compromised as a result of pain, physical limitation, removal from leisure and work activities, and these factors can still be aggravated by the difficulty of adherence to treatment, contributing to the chronicity of the lesions, and further deteriorating the QOL [21]. Thus, it is recommended to check the quality of life of these people every three months [22].

The use of a care protocol is important to improve the quality of care for people with venous ulcers, since it facilitates the flow of care, standardizes behaviors of the professionals and brings trust to the patient, and it becomes indispensable for

directing actions [23]. Another important factor is the use of the proposed protocol in the clinical context, which may point out difficulties and suggest improvements [24].

Conclusions

The Protocol for Venous Ulcers (PVU) validated in its content and the clinical context has proved to be applicable to the highly complex service. The implementation of a protocol for the care of the person with a venous ulcer is a viable measure that assists in the orientation of the health team, in the services of high complexity, aiming not only at the healing of the injury but also at the restoration of the patient's integral health.

It should be emphasized that further studies are necessary to evaluate the clinical impact of the application of this protocol in other health units. It is believed that its use will bring benefits to patients, families, and staff as it will provide standardization in care. Also, its applicability will enable to adapt to the reality of each health service.

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