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Protocol validation for people with venous ulcers: a quantitative study

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ABSTRACT

Aims: to confirm and refine the multidisciplinary care protocol structure for people with venous ulcers treated in primary care. **Method:** a methodological, quantitative study, carried out in three steps: development of the instrument from the literature review; and validation of the content, through the Delphi technique in two stages: one with 51 judges and one with 35. The analysis used the Kappa index ≥0,81 and Content Validity Index (CVI)> 0.80, and the Wilcoxon test for comparison between the two validation steps. **Results:** it was found that, from the 15 categories of the protocol, 12 had better scores in phase Delphi 2. For the assessment requirements of the protocol, it was found that the points awarded by the judges in the second phase were higher in nine of the 10 items, confirming the validity of the instrument. **Conclusion:** the elaborate and validated version by a professional consists of an approach script for patients with venous ulcer in primary care.

Descriptors: Varicose Ulcer; Protocols; Patient-Centered Care; Quality of Life; Primary Health Care.

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INTRODUCTION

Venous ulcers (UV) are the most common cause of injuries in the lower limbs, representing approximately 70% of these. Their main cause is venous insufficiency, resulting in changes in the dermal microcirculation and ulceration[1-2].

Between 1 and 2% of the adult population is affected by UV, that take months or years to heal. Moreover, 45% of these lesions suffer recurrences. To minimize them a multidisciplinary follow-up is necessary in order to encourage self-care and direct treatment in the most appropriate way, watching from the physical aspects to the psychosocial as factors that influence the healing process and recurrences[3].

Due to the complexity of treatment, frequency and duration, costs for the treatment of chronic ulcers are high. Spending on this type of injury is estimated to be R$ 1,620.65 for each patient, per year using conventional therapy. Added to this the significant impact that UV causes in the quality of life, especially evident in the physical domains and in functional capacity[4-5].

Currently, there are a lot of studies that demonstrate the effectiveness of different treatment options, which include topical therapies, compressive and surgical interventions. This makes the practice of care increasingly complicated, affirming the importance of clinical guidelines as a way of transmitting information based on scientific evidence[6].

The guidelines aim to improve the quality and effectiveness of health care and to identify gaps in the knowledge of a specific area. Also, they have several attributes - among them the validity, which can produce the policy effects for health. The others are the clinical reliability, reproducibility, applicability and flexibility[6].

Regarding venous ulcers, although there are numerous guidelines, there is no consensus on strong recommendations for dressings and compression. To improve care for the person with UV and reduce the waste of resources, the development of a clinical instrument is imperative, as a protocol, constructed from the consensus of experts and scientific evidence that support the provision of homogeneous and safe care[7].

Primary care is presented as an important articulator of care at different levels of health care. So, from that the person with UV should receive comprehensive care, which involves primary care referral, specialists and home care[8].

This study aimed to confirm and refine by the multiprofessional care protocol structure for people with UV treated in primary care.

METHODS

Methodological study and content validation were carried out through the Delphi technique in two phases, from September 2012 to January 2013.

There are several content validation methods in the literature. However, all have similar steps of structuring and are intended to generate a methodologically validated process to classify research. In summary, include the following steps: a) theoretical and scientific basis; b) development of an instrument that includes the measure attributes and criteria for compliance or consensus; c) elaboration of the measure of evaluation by experienced professionals in this field; d) selection of a panel of judges for a validation of the opinions expressed based on this previously elaborated instrument [9].

The content validation method enables a consensus of a group of experts on a particular phenomenon through a questionnaire, which is passed on continued times to obtain the convergence of answers, representing the consolidation of the intuitive judgment of the group.

It is assumed that the collective judgment, well organized, is greater than the opinion of a single individual. The anonymity of the respondents, the statistical representation of the distribution of the results and the feedback from the group to re-evaluate in subsequent rounds are the main features of this method [10].

From the literature review, the initial content of the protocol was composed of 15 categories and 111 items. The proposed categories were: sociodemographic data; anamnesis; risk factors; request/performance/test results; check pain, vital signs (ssvv), signs of infection, lesion location and edema; ulcer characteristics; care of the perilesional and lesional areas; drugs related to the treatment of injury currently in use; treatment of pain; compression therapy; clinical strategies to prevent relapse; educational strategies to prevent relapse; reference/referral of patients; counter-reference; assessment of quality of life *(Chronic Venous Insufficiency Questionnaire – CIVIQ)*[11].

The stage of selection and inclusion of judges has been described previously. The search for the expert judges happened through the Lattes Platform, the National Council for Scientific and Technological Development (CNPq). In the first validation stage (Phase I Delphi), the assitencial protocol was sent to 102 judges and 51 agreed to participate by signing the Informed and Clarified Consent[11].

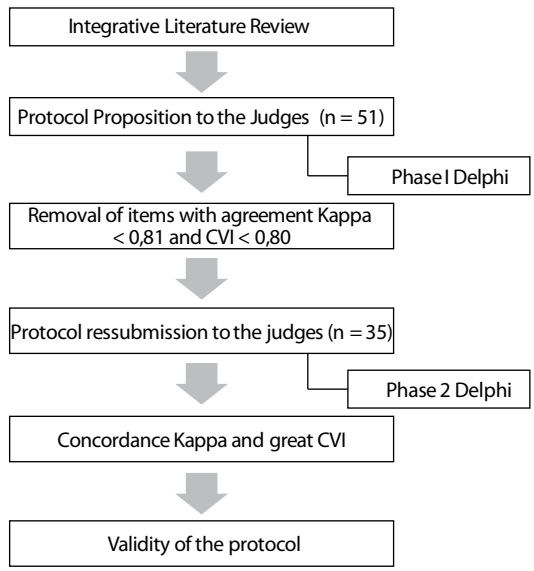
The first step allowed the initial validation of the protocol that had occurred from the classification of each item regarding the agreement or disagreement of the item in the protocol. In addition, it allowed the judges a space for suggestions so that the items could be rebuilt or improved. The items that did not obtain Kappa agreement level (K) and content validity index (CVI) excellent (K≤0,81 and CVI≤0,80) were removed [10-11].

The completion of the first stage allowed the improvement of the initial protocol from the inclusion of five items, taken from 18 items and changed three items because of suggestions of the judges[11].

In the second phase (Phase 2 Delphi), the protocol with 98 items was sent back to the 51 judges, who were asked to review the protocol after the initial settings. This time, 35 judges agreed to participate.

Figure 1 shows a summary of the steps followed in the study.

Figure 1 - Flow chart of study development. Brazil 2013.



Source: own elaboration

The categories of the protocol that did not achieve excellent Kappa scores among the research judges were: application/performance/test results (κ = 0.72; CVI = 0.74) and treatment of pain (κ = 0.79). However, the categories of sociodemographic data, medical history, risk factors and verification of pain/SSVV/pulse/signs of infection/location of the lesion/edema showed Kappa or CVI items below a certain value. After the removal of the items that obtained Kappa or CVI disagreement among the judges, it was found that the scores increased in six of the

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categories raising the Kappa indices and CVI general of the protocol. The suggestions of the judges were mostly obeyed.

Data were organized in an electronic data sheet and subsequently exported to the statistical software. After coding and tabulation, data were analyzed using descriptive and inferential statistics and indices obtained in the first and second stages were analyzed using the Wilcoxon test, adopting a significance level of less than 5%.

The development of the study met the national and international standards of ethics in research involving human subjects.

RESULTS

As characterized in Table 1, most of the judges were nurses, both in the first step or phase Delphi 1 (84.3%) and in the second step or phase Delphi 2 (85,7%).

Table 1 - Distribution of sociodemographic characteristics of professionals in phases Delphi 1 and Delphi 2. Brazil, in 2013.

Characterization of professionals	Dephi 1 n (%)	Dephi 2 n (%)
Professional qualification		
Nurses	43 (84,3)	30 (85,7)
Doctors	8 (15,7)	5 (14,3)
Gender		
Female	37 (72,5)	26 (74,3)
Male	14 (27,5)	9 (25,7)
Age group		
21 to 30 years	13 (25,5)	15 (42,9)
31 to 40 years	19 (37,3)	8 (22,9)
41 to 50 years	12 (3,5)	8 (22,9)
> 50 years	7 (13,7)	4 (11,4)
Institution where work		
Care	27 (52,9)	15 (42,9)
Educational institution	24 (47,1)	20 (57,1)
Care time to the person with UV		
1 to 5 years	20 (39,2)	14 (40)
> 10 years	18 (35,3)	11 (31,4)
6 to 10 years	13 (25,5)	10 (28,6)
Region working		
Northeast	26 (51)	15 (42,9)
Southeast	20 (39,2)	15 (42,9)
Southl	2 (3,9)	2 (5,7)
North	2 (3,9)	2 (5,7)
Midwest	1 (2)	1 (2,9)
Total	51 (100,0)	35 (100,0)

Source: Own elaboration.

As for the care time with UV, one to five years was the period that predominated, both in Delphi 1 (39.2%) and in Delphi 2 (40.0%). With regard to the region of professional activities, the Northeast prevailed with 51% in Delphi 1 and 42.9% in Delphi 2, followed by the Southeast Region, with 39.2% in Delphi 1 and 42.9% in Delphi 2.

In Chart 1, it was found that, from the 15 categories of the protocol, 12 showed higher scores on phase 2 Delphi; and the other three categories (treatment of pain, prevention of relapses - clinical strategies and reference/referral) maintained the same Kappa and CVI indices of the previous stage.

The comparison of the indices obtained in the protocol items showed significant differences between the scores obtained in the two phases of the study to the history categories (ρ=0.003), checking the circulation/infection/body mass index (BMI)/location of the lesion (ρ=0.048) and general care/compression therapy (ρ=0.046). In the other categories there was an increase of indices, without, however, statistical significance (Chart 1).

Regarding the average of the evaluation protocol requirements, there has been a change from 8.8 to 9.2 in stage 1 Delphi, averaging 9.1. In the Delphi 2 phase were obtained in all categories average above 9.1, ranging from 9.1 to 9.5, and an overall average of 9.4. All items obtained better averages in the second evaluation, with statistical significance (ρ = 0.038) in the simplicity requirement, indicating that the suggestions of the judges about the protocol were simple, as in Chart 2.

Chart 1 - Judges trial on categories of protocol composition in phase Delphi 1 and Delphi 2 and the Wilcoxon test

Protocol composition categories	Evaluation Delphi 1 (n=50)		Delphi 2 Evaluation (n=35)		Wilcoxon Test	
	KAPPA	IVC	KAPPA	IVC	KAPPA	IVC
Sociodemographic data	0,93	0,96	0,97	0,98	0,171	0,171
Anamnesis	0,94	0,97	0,99	0,99	0,003	0,003
Risk factors	0,93	0,96	0,95	0,97	0,237	0,207
Request for examination/realization/ results	0,87	0,93	0,98	0,99	0,069	0,069
Verification of circulation/infectio/BMI/ location of lesion	0,91	0,95	0,95	0,97	0,068	0,048
Ulcer features	0,91	0,95	0,97	0,98	0,065	0,057
Caring for perilesional and lesional areas	0,96	0,98	0,99	0,99	0,593	0,593
Drug treatment-related injury	0,89	0,94	1	1	0,317	0,317
Pain treatment	0,92	0,96	0,92	0,96	1	1
General care and compression therapy	0,87	0,93	0,94	0,97	0,046	0,046
Relapse prevention (Clincal Strategies)	0,91	0,95	0,91	0,95	0,593	0,785
Relapse prevention (Educational Strategies)	0,92	0,96	0,99	0,99	0,074	0,074
Reference/referral of patients	0,89	0,94	0,89	0,94	0,655	1
Counter-reference	0,89	0,94	0,97	0,98	0,058	0,068
Aspects related with quality of life	0,96	0,98	1	1	0,114	0,125

IVC - Content Validity Index

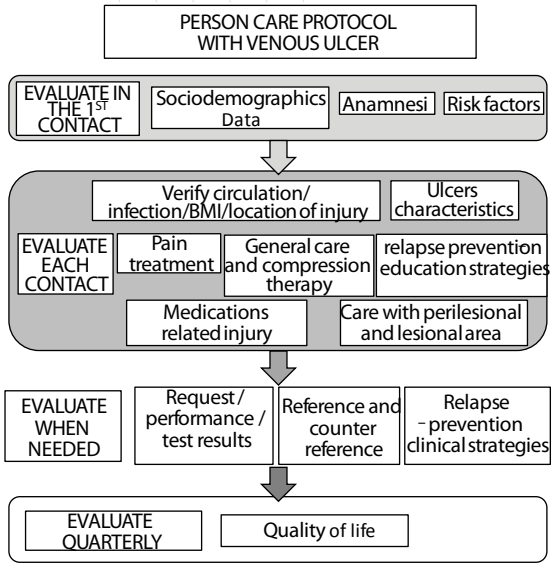
Chart 2 - Average, standard deviation and Wilcoxon test of the marks awarded by the judges to the protocol in phase Delphi 1 and Delphi 2. Brazil, in 2013.

Assessment requirements	Delphi 1		Delphi 2		Wilcoxon Test
	AVERAGE 1 (n=50)	Standard deviation	AVERAGE 2 (n=35)	Standard deviation	
Utility/relevance	9,2	1	9,5	0,8	0,284
Consistency	9,2	1,3	9,3	1,1	0,523
Clarity	9,2	1,3	9,2	1,1	0,107
Objectivity	9,1	1,2	9,4	0,9	0,094
Simplicity	9,1	1,3	9,5	0,9	0,038
Practicable	9,1	1,4	9,2	1,5	0,6
Update	9	1,2	9,6	0,8	0,173
Precision	8,9	1,5	9,1	1	0,318
Instructional sequence of topics	8,8	1,3	9,5	0,9	0,185
General evaluation of the protocol	9,1	1	9,4	0,9	0,088

Source: Own elaboration.

From the results of this study, we elaborated the care protocol to people with UV (Figure 2).

Figure 2 - Explaning network of the use of the care protocol to the person with venous ulcers.



Source: own elaboration.

The explanatory proposed network subdivides the categories by the need to evaluate the person with UV, facilitating the applicability of the health professionals' protocol.

DISCUSSION

In the first step of the study, the following categories received recommendations from the judges, some of which were included in the protocol. In socio-demographic data, religion and beliefs were included. In the anamnesis, nutritional assessment, mobility, bowel habits and diuresis were included. In the category of checking pain/SSVV/pulse/ signs of infection/location of the lesion/ edema, the judges recommended specifying the extent of the edema, which was accepted and added to the protocol. The characteristic of the ulcer, the suggestion change the term "edge" to "margin" was also accepted. On the care of the perilesional and lesional areas were added the questions: how to protect the wound in the bath? The use of dressing ointments? As to medication related to the treatment of the lesion currently in use, it was agreed to include anti-inflammatories [11].

As for the characterization of the judges sample, it is known the difficulty to define the criteria for inclusion in the validation studies, considering the dissent in the literature on specific criteria. However, the sample of judges in this study included physicians and nurses from all regions of the country, qualified and committed to academic and research activities and/or proven experience in assisting people with UV[10].

About categories of protocol composition, the inclusion of sociodemographic characteristics is presented as a fundamental stage in its execution, because, from them, it is possible to identify various determinants and health conditions involving UV. An example of this is in the relationship of gender with sedentary, extended stay in certain postures during work activities, education levels, economic classes, clinical conditions and the quality of life of people with UV [8].

These conditions are also covered in the protocol anamnesis step, as emphasizes the identification of risk factors that hinder the healing process, as the presence of infection, diabetes mellitus, obesity and systemic arterial hypertension. The laboratory tests proposed by the instrument corroborate with several authors. Despite considering the diagnosis of mainly clinical UV, these authors emphasize the importance of the complete blood count, fasting blood glucose, serum albumin, exudate culture, among others, that help monitor the healing process, allowing the identification of elements that will possibly extend the lesion treatment time[8,12].

Clinical evaluation is constituted as a primary step in assisting people with UV, as features like the location, depth, the appearance of edges and adjacent tissues are criteria for identifying the type of injury and direction of subsequent conduct. Based on this phase it is possible to recognize the physical and physiological conditions of healing from various indicators such as exudation, type of tissue in the wound bed and edges[12-14].

Therefore, in the case of the perilesional area, it is possible to identify various types of surrounding tissue changes to injury, such as maceration, dermatitis, erythema, desquamation and epithelialization. The recognition and execution of the proper care required in this area are essential for healing, because margins epithelialization favours the contraction of the wound and, on the other hand, maceration harms this process. The choice of a topical therapy for the treatment is associated to favour epithelialization or not, furthermore the choice of the cover is likely to change over time depending on the state of the ulcer [12-14].

For the treatment of UV various products are used; highlighting alginates, films, foams, hydrogels, hydrocolloids, hidrofibras and antibiotics. Furthermore, studies have shown the effectiveness of new topical therapies, such as vegetal biomembrane, neutrophil and Dermagraft. Added to the range of interventions are the application of microcurrent, electromagnetic therapy and compression therapy, which contribute to the acceleration of the healing process and reduce venous hypertension, the major etiological causes of UV [14-18].

Pain is a symptom frequently reported by people with UV, one of the main aspects that affects the quality of life. In addition to the elevation of the lower limbs and the use of compression therapy, there are specific therapies for UV that help in reducing pain, such as the application of microcurrent, ibuprofen foam, skin grafts and complementary and alternative medicine[16-18].

On the general care and compression therapy, options for treatment are intermittent pneumatic compression, the stocking system, multi layer bandage, two layers of short stretch bandages and an unna boot. The first three are the most efficient, while the unna boot is presented as an alternative that improves the quality of life for people with UV [18].

The quality of life of people with UV is compromised due to pain, physical limitation, removal of leisure and work activities. These can be further aggravated by the difficulty of treatment adherence, contributing to the chronicity of the lesions, further worsening QV. It is essential to check the quality of life of people every three months, as, in a systematic literature review, QV assessment studies have been found to show significant results in the period between reviews of three months and six months [17,19].

It's noted that the process of construction and validation of a protocol includes several steps, some complex, but which are fundamental and should be followed with methodological precision. The development of care protocols should reflect the best available evidence, combined with the clinical experience of experts in the field. Moreover, it is important that the protocol is applicable to the population, the context and the objectives which it is intended standardizing behaviors and contributing to improving the care and the patients' quality of life. After the first validation steps the protocol must be submitted to clinical validation that allow finer adjustments and refinements.

The assessment of the person with UV

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through a protocol can stimulate health professionals to qualify the assistance, in addition to functioning as a tool to assess the quality of care provided. The use of a protocol allows the standardization of procedures and the direction of the necessary changes to the team work process that provides the assistance. It is emphasized that this is one of the steps of the validation process, still being necessary to its application to the target population to prove their clinical validation.

CONCLUSION

The multiprofessional protocol support for people with UV treated in primary care had its structure confirmed after the second validation step. It was found that, out of the 15 initial categories of the protocol, 12 had better scores in the Delphi 2 phase and the other three categories remained the same Kappa and CVI indices of the previous phase.

As an average of the protocol evaluation requirements, it was found that the scores assigned by the judges in the second stage were higher in nine of the 10 items remaining the same average in only one of the items indicating protocol enhancement and evidence of validity instrument content in the consensus of the judges.

Finally, the main difficulty of this study included the non-return of instruments, after repeated contacts, which extended the time interval of data collection..

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All authors participated in the phases of this publication in one or more of the following steps, in According to the recommendations of the International Committee of Medical Journal Editors (ICMJE, 2013): (a) substantial involvement in the planning or preparation of the manuscript or in the collection, analysis or interpretation of data; (b) preparation of the manuscript or conducting critical revision of intellectual content; (c) approval of the versión submitted of this manuscript. All authors declare for the appropriate purposes that the responsibilities related to all aspects of the manuscript submitted to OBJN are yours. They ensure that issues related to the accuracy or integrity of any part of the article were properly investigated and resolved. Therefore, they exempt the OBJN of any participation whatsoever in any imbroglios concerning the content under consideration. All authors declare that they have no conflict of interest of financial or personal nature concerning this manuscript which may influence the writing and/or interpretation of the findings. This statement has been digitally signed by all authors as recommended by the ICMJE, whose model is available in http://www.objnursing.uff.br/normas/DUDE_eng_13-06-2013.pdf

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