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Assistance protocol to people with venous ulcers: a methodological study

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ABSTRACT

Aim: To investigate the content validity of the Assistance Protocol for people with venous ulcers in primary care. **Method**: Methodological study, conducted from September to November 2012. A set of items to consider in multidisciplinary care protocol was produced. This proposal was submitted to content validation by judges selected from the Lattes Platform. With a list of items grouped into categories, 51 judges opined in relation to whether or not to keep them in the protocol. For the analysis, we adopted the Kappa index (K) and the Content Validity Index (CVI), with the cutoff point values > 0.80. **Results**: Nurses and doctors participated as judges. After removing items with K or CVI values lower than those previously set, the scores of categories achieved optimal values. **Conclusion**: The content of the protocol was validated, representing the initial consensus-based approach for people with venous ulcers in primary care.

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

INTRODUCTION

Venous ulcers constitute an important public health problem[1]. Their treatment is costly and requires assistance to be provided by trained professionals and systematized through protocols. In daily life, however, the practices do not always follow the scientific evidence, and care protocols and care system are missing, which interferes with wound healing and quality of life of those affected[2].

The pursuit of quality care services refers to the need for comprehensive care recommended by the Brazilian public health system (SUS). Primary care is the preferred entrance to the health system for the person with venous ulcers. However, many of the primary level professionals are not prepared to provide comprehensive care to this population, which is due, among others factors, to the absence of protocols systematizing this assistance[3]. The result of these weaknesses in primary care is the high demand in the secondary and tertiary levels of care.

In this sense, the use of a specific assistance protocol for people with venous ulcers (VU) can help primary care professionals both in patient assessment and in the establishment of quality care, since the treatment of people with venous ulcers requires specific knowledge, technical skills, multidisciplinary activities, adoption of a protocol and coordination between complexity service levels and active participation of people with VU and their families[2-4].

In the previous step of this study, a specific assistance protocol for people with VU based on an integrative literature review was made, and is still in the process of publication. Care protocols must pass through validation processes that include several steps, including content validation, which considers the opinion/agreement of professional experts in the field involved in assisting this population. In this context, this study aimed to verify the content validity of a multidisciplinary protocol, previously developed to meet the needs of people with venous ulcers in primary care.

METHOD

This is a methodological study with a quantitative approach, carried out from September to November 2012. To identify health professionals in Brazil who could act as judges for the instrument, we conducted a search into the Lattes platform of the National Council for Scientific and Technological Development (CNPq), using the advanced search by subject, followed by the application of the inclusion and exclusion criteria and invitation to potential participants (Figure 1).

The inclusion criteria used were: graduate and/or post-graduate (broad and strict sense) degree in health; previous clinical practice with people with venous ulcers for at least one year, or to have developed a published/course--completion study (specialization, masters or doctorate degree) related to the care practices to venous ulcers, or have academic guidance in the area. Exclusion criteria were: only information in Lattes curriculum being completion of work of the graduation course on the subject.

Using this strategy, 102 professionals (doctors, nurses, nutritionists and physical therapists) were selected and invited via e-mail to participate in the study in September 2012. The messages were sent in order to explain the purpose of their participation as judges of the research through an invitation letter with a link to the research from a form built via Google Docs (<docs.google.com>). From the 102 selected professionals, 51 agreed to participate, signed the Informed Consent and became the judges of the study.

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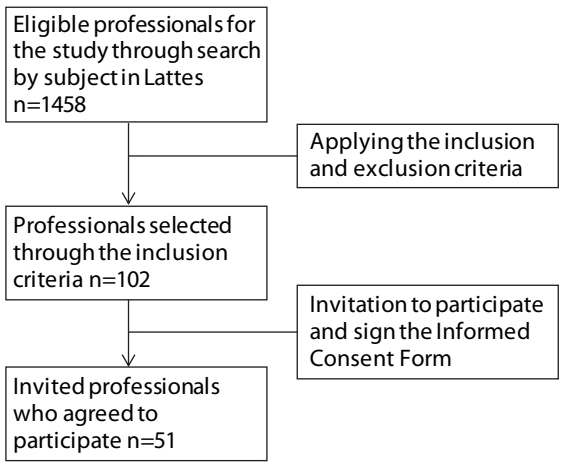
Figure 1 - Study flowchart.



Source: Authors' study

The data collection instrument sent to the judges contained two parts: one for identifying items of professional characterization and the other about the proposal for a multidisciplinary care measures protocol for people with venous ulcers in primary care, designed based on an unpublished integrative review. The content of the protocol was composed of the following categories:

- Social-demographic data (12 items): Name, Public Health ID card number, medical record number, age, sex, address, health unit, health agent, marital status, education level, profession/occupation, family income in minimum wages.
- Medical history (25 items): Person who applies bandage during the week, bandage application venue during the week, person who applies bandage at the weekend, dressing application venue at the weekend, diabetes, heart disease, arterial insufficiency, arteriosclerosis, neurological disease, venous insufficiency, leprosy, hypertension, allergies, medications currently in use, alcohol consumption, smoking, personal hygiene, activities performed during the day, resting, hours/days of sleep, time from first ulcer in months, time from current ulcer in months, recurrence.
- Risk factors (12 items): Family history of venous disease, obesity, varicose veins, previous venous surgery, multiparity, phlebitis, episodes of chest pain, tumor-like mass that blocks blood flow, leg fracture or surgery, work activities requiring long standing or sitting periods, proven or suspected history of deep vein thrombosis (DVT), investigate duration, recurrence and age.
- Tests request/performance/results (07 items): Complete blood count, fasting blood glucose, serum albumin, urine type I, ankle-brachial index, eco doppler, phlebography.
- Verification of pain, vital signs (SSVV), signs of infection, lesion location and edema (12 items): Pain, pedial pulse, tibial pulse, popliteal pulse, edema, signs of infection, body mass index (BMI), blood pressure, temperature, pulse, respiratory rate, location of the lesion.
- Ulcer characteristics (09 items): rate, exudate, exudate amount, odor, lesion edge, perilesional area, wound bed, change rate, ulcer measurement in the course of treatment.
- Care actions to perilesional and lesional area (05 items): Cleaning of perilesional area, products used in perilesional area, lesion cleaning, lesion coverage indication (related to the predominant type of tissue), products used in lesion.
- Drugs currently in use related to the treatment of the lesion (02 items): Antibiotic, fhlebotropic.
- Pain Treatment (06 items): Absent, present, physical therapy measures, which physiotherapy measures, painkillers, what painkillers.
- Compression therapy (08 items): Absent, present, which compression therapy, does apply appropriate compression, which ones?; Advised about use of compression stockings, advised about resting with legs elevated (2 to 4 hours/day) and raising feet 10 to 15 cm above bed, advised about use of calf flexion and

contraction exercises and walking, elevating legs 30min before compression.

- Clinical relapse prevention strategies (03 items): venous and surgical research, compression therapy throughout entire life, regular follow-up to monitor skin conditions for recurrence.
- Educational relapse prevention strategies (06 items): Importance of adherence to the use of compression stockings, skin care, prevention of accidents or injuries in the lower limbs, advice for early seeking of skilled care to interruption of possible recurrence of any skin signals, encouraging mobility and exercise, elevation of affected limb when resting.
- Reference/referral of patients (02 items): Absent or present, which professional? (specify).
- Counter reference (02 items): Where from, indication.
- Quality of life (Chronic Venous Insufficiency Questionnaire - CIVIQ)[5].

The evaluation of the protocol items was conducted after the classification of each one according to the opinion of the judges about the agreement or disagreement on the item's permanence in the protocol. In addition, suggestions could also be made in an open manner, so that the items could be modified and/or improved.

Kappa index (K) was applied for checking the level of agreement and level of consistency (reliability) of the opinion of the judges, in addition to the Content Validity Index (CVI). The K index measures the proportion of concordance, ranging from "minus 1" to "plus 1"; the closer to 1, the better the level of agreement between observers. As acceptance criteria, a higher agreement was set to 0.80 among the judges, with this level considered optimal[6]. The CVI evaluates the analysis of the judges as to the representativeness of the measure in relation to the analyzed content, which is calculated by dividing the number of judges who agreed with the item by the total of judges (CVI per each item). CVI values greater than 0.80 were considered appropriate[7].

The data collected were organized in a computer data sheet and subsequently exported to SPSS version 20.0. After being coded and tabulated, the elements were analyzed using descriptive statistics with absolute and relative frequencies, mean scores of variables and application of K test via the Online Kappa Calculator[8] and CVI.

After the initial analysis of K and CVI indexes, the protocol items that did not reach the adopted values were excluded, and some were reformulated in accordance with the suggestions of the judges. Subsequently, the K and CVI values were recalculated.

The study followed the ethical and legal principles governing research with human beings contained in the Declaration of Helsinki of the World Medical Association and in the National Health Council Resolution Nr. 466/12[9]. This research project was approved by the Research Ethics Committee / UFRN in 11/09/12 with the approval opinion number 147 452 (CAAE: 07556312.0.0000.5537).

RESULTS

According to Table 1, 43 nurses (84.3%), and eight angiologist physicians (15.7%) participated as judges. Of the nurses, the majority were female (86.0%), aged between 31 and 40 years (41.9%), working in the assistance care area (55.8%), with time of experience treating people with venous ulcers up to five years (46.5%), domiciled and exercising activities in the Brazilian Northeast region (55.8%). Of the doctors, all were male (100.0%), with a predominance of the "over 50 years" age group (62.5%), working in the education area (62.5%) with time of experience

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treating people with venous ulcers greater than 10 years (75.0%), domiciled and exercising activities in the Brazilian Southeast region (62.5%).

Table 1 - Research Participants' characteristics distribution. Natal, 2013.

Professionals characteristics	Nurses		Physicians		Total	
	n	%	n	%	n	%
Female	37	86	-	-	37	72,5
Male	6	14	8	100	14	27,5
Age Group						
21 to 30 years	13	30,2	-	-	13	25,5
31 to 40 years	18	41,9	2	25	20	39,2
41 to 50 years	10	23,2	1	12,5	11	21,6
> 50 years	2	4,7	5	62,5	7	13,7
Work Institution						
Assistance Care	24	55,8	3	37,5	27	52,9
Education Institution	19	44,2	5	62,5	24	47,1
Time of experience with VU patient						
1 to 5 years	20	46,5	-	-	20	39,2
6 to 10 years	11	25,6	2	25	13	25,5
> 10 years	12	27,9	6	75	18	35,3
Region of work						
Northeast	24	55,8	2	25	26	51
Southeast	15	34,9	5	62,5	20	39,2
South	2	4,7	-	-	2	3,9
Middle-west	1	2,3	1	12,5	2	3,9
North	1	2,3	-	-	1	2
Total	43	84,3	8	15,7	51	100

The suggestions made by the judges are shown in Table 1, which shows whether they were accepted or not, and also the justifications. It was found that, of the twelve suggestions made by the judges, nine were accepted after analysis and comparison with the literature, and three were rejected.

Thus, the suggestions were distributed as follows: eight refer to the increase in the protocol items (five were accepted, three were not); two allude to the removal of items found to be repetitive or redundant; one refers to a change in nomenclature, facilitating the understanding of the protocol; and one refers to the best specification of one of the items (edema).

The analysis of K and CVI indexes of the Protocol showed excellent rates of agreement between the judges on the following categories: "ulcer characteristics", "care measures to perilesional and lesional area", "drugs related to the treatment of the injury", "compression therapy", "clinical and educational strategies for prevention", "reference and counter-reference" and "quality of life" (Table 2).

Table 2 - Opinion of the judges about the categories of composition the initial protocol and after removal of the items that had low agreement scores. Natal, 2013.

Protocol category composition	Initial analysis		Final analysis	
	KAPPA	CVI	KAPPA	CVI
Sociodemographic data	0,83	0,9	0,93	0,96
Anamnesis	0,92	0,95	0,94	0,97
Risk Factors	0,85	0,89	0,93	0,96
Tests Request / performance / results	0,72	0,74	0,87	0,93
Pain verification, SSVV, pulse, signs of infection, lesion location and edema	0,83	0,89	0,91	0,95
Ulcer characteristics	0,9	0,95	0,9	0,95
Care measures to perilesional and lesional area	0,96	0,98	0,96	0,98
Drugs related to the treatment of the lesion in use today	0,89	0,94	0,89	0,94
Pain treatment	0,79	0,87	0,92	0,96
General care and compression therapy	0,87	0,93	0,87	0,93
Relapse prevention (clinical strategies)	0,91	0,95	0,91	0,95
Relapse prevention (educational strategies)	0,92	0,96	0,92	0,96
Reference / referral of patients	0,89	0,94	0,89	0,94
Counter-reference	0,89	0,94	0,89	0,94
Aspects related to quality of life	0,96	0,98	0,96	0,98
Protocol general score	0,88	0,92	0,91	0,95

Chart 1 - Suggestions of judges, acceptance of the suggestions by the researchers and reason for acceptance or rejection of suggestions. Natal, 2013.

Protocol category	Judges' suggestion (n)	Acceptance	Reason
Socio-demographic data	Include religions and beliefs (04)	Yes	Religion/belief can be a source of relief or discomfort, depending on how the person relates to it(4).
Anamnesis	Include nutritional assessment (05)	Yes	There are reports of the need for nutritional assessment(10).
	Include diuresis and bowel habits (01)	No	No reason found in literature.
	Mobility (01)	No	It is evaluated in the quality of life instrument(5).
Risk factors	Items "episodes of chest pain", "tumor blocking blood flow" and leg fracture/surgery are caused by or suspected deep-vein thrombosis, and therefore, repetitive (01).	Yes	The items will be reduced to facilitate the implementation of the Protocol.
Tests Request / Implementation / Results	Swab in case of infection signs (02)	No	Not accepted due to controversy in the literature on this item because a study(10) reported that the Swab provides information on the colonization of the wound surface, with little value in choosing the treatment, while another(11) reports that just the Swab is enough.
Pain verification / SSVV / pulse / signs of infection / location of the lesion / edema	Specify the extent of edema (01)	Yes	Measuring the circumference of the leg edema in 10cm above the ankle (medial malleolus)(10).
Ulcer characteristics	Change the term "edge" by "margin" - most current (01)	Yes	Latest terms improving the quality of protocol.
Care measures to perilesional and lesional area	Add: how do you protect wound during bath? (01)	Yes	Foreseen in another protocol(12).
	Do make use of ointment in bandage (which one)? (01)	Yes	Foreseen in another protocol(12).
Drugs related to the treatment of the lesion in use today	Anti-inflammatory (03)	Yes	Investigate the use and frequency of this medication as it may delay the healing process(10).
Pain treatment	"Pain" is repeated in two items. Remove one of them (07)	Yes	The items will be reduced to facilitate the implementation of the Protocol.

Some categories of the protocol showed excellent K or CVI rates, although some items displayed values below those previously set, which were removed as described below.

In socio-demographic data, the items "health agent" (K = 0.52; CVI = 0.62), "public health card number" (K = 0.71), "medical record number" (K = 0.74), "address" (K = 0.74) and "health unit" (K = 0.74) were removed. In the anamnesis category, the items "neurological disease" (K = 0.61; CVI = 0.75) and "leprosy" (K = 0.61; CVI = 0.75) were removed.

Among the risk factors, the items "episode of chest pain" (K = 0.49; CVI = 0.45), "tumor blocking blood flow" (K = 0.66; CVI = 0.79) and "leg fracture or surgery" (K = 0.74) were removed.

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In the category tests request/performance/results, the following contents were removed: "urinalysis" (K = 0.49; CVI = 0.53), "echo Doppler" (K = 0.50; CVI = 0.57) and "venography" (K = 0.56; CVI = 0.32).

However, the categories of the protocol that did not reach excellent K and CVI scores among the judges of the research were: "tests request/performance/results" (K = 0.72; CVI = 0.74) and "pain treatment" (K = 0.79), as shown in Table 2. In relation to tests performance, the items "respiratory rate" (K = 0.51; CVI = 0.60), "heart rate" (K = 0.59; CVI = 0 , 72) and "temperature" (K = 0.61 CVI = 0.74) were removed. In the category "pain management" the item "physiotherapy measures" was removed (K = 0.59; CVI = 0.72).

After removal of items that did not reach optimal K and/or CVI rates, there were higher values in those categories and in the overall evaluation of the protocol (Table 2).

DISCUSSION

The selection of judges was guided by the search for all professionals in the area of Brazil with experience and known for their excellence in health care, education and research, which demonstrates technical and scientific knowledge and strengthens the reliability of the results of this study.

The predominance of female nurses reflects the process of feminization of nursing, with high numbers of women in the labor market[13].

With regard to the quantity of angiologists in the research, this number (eight) reflects the ratio of these professionals in Brazil, which is 1: 81,561 inhabitants, although the World Health Organization (WHO) recommends 1: 17,000 people in developed countries and 1: 35,000 in developing countries[14]. It is also relevant to note that most of these professionals are concentrated in the Southeast region, in the capital cities, and are men (87.0%)[15]. These data corroborate this study, since the majority of respondent angiologists were working in the Southeast and all of them were male.

With regard to the treatment of injuries, we believe that the nursing professional has a primary role, playing an extremely important part in monitoring the evolution of the lesion. In addition, nurses provide advice and apply bandages, as this is one of their duties[15].

In addition to the relevance of nurses in the care practice to people with wounds, the physician, especially the angiologist, is critical in the diagnosis and treatment of venous ulcers. This specialist is responsible, in addition to the anamnesis and physical examination, for conducting and interpreting laboratory tests, as well as for the prescription of treatment with medication use, elastic compression and surgery for valve disease correction and venous insufficiency[16] - hence the multidisciplinary aspect of the protocol.

In a study that evaluated the sociodemographic, health and assistance characteristics to the elderly with VU in Natal/RN, we could observe low (39.8%) access to angiologists[3], a fact that reflects the low number of this professionals in Brazil and especially in the Northeast region, which hinders access to care.

The clinical course of people with venous ulcers must be monitored by a multidisciplinary team in order to plan the actions to be implemented, following the logic of primary and later secondary and tertiary care. Continuity of care actions must be assured with a continuous flow at all levels of assistance, fulfilling the principle of completeness of the Brazilian Public Health system[3,10,14].

Regarding the suggestions of the judges, most were accepted based on the related literature[4,10,12]. Thus, items related to religion/beliefs,

nutritional assessment, use of anti-inflammatory and care measures to lesion and perilesional area were included. The term "edge" was replaced by "margin". The edema measurement became more specific, and redundant or repetitive items related to risk factors and pain were removed.

Some suggestions of the judges, however, were not followed. The idea of including an item on bowel habits and diuresis did not find justification in the literature. The proposal to include an item about culture/swab in the case of infection also had no support, and the recommendation to evaluate mobility was not accepted since it already was part of the questionnaire on quality of life used in the protocol.

A study reports that a complete history with demographics and risk factors in the clinical evaluation of patients with UV, such as cardiovascular disease, body mass index, mobility, diabetes, and history of leg injury or deep vein thrombosis[17] must be collected. Information about the ulcer, such as when the first one occurred, the location of the previous ones, quantity of recurrences, time free of ulcers and types of treatment are also important[17], confirming the opinion of the judges of this research about the items of the protocol.

By analyzing judges' agreement regarding risk factors proposed in the protocol, we observed an alignment between them and the literature with regard to associated diseases such as diabetes mellitus, hypertension and cardiovascular diseases, which exert negative impact on healing, mainly in angiogenesis, requiring, therefore, research and control[18-19].

The clinical diagnosis of chronic venous disease and VU is made by history, physical and clinical examination[12,19]. For these, we should perform a physical examination and lesion assessment in addition to the tests. In this study, however, the items related to phlebography and Echo Doppler were considered too specific and difficult to access in primary care by the judges, and unnecessary in a protocol to this level of assistance. The items urine test, respiratory rate, heart rate and temperature also did not obtain optimal rates of acceptance among the judges, owing to being non-specific, so they were removed.

Regarding the physical examination, this should be directed to evaluating the vascular status and characteristics of the lesions. The evaluation of vascular status refers to the identification of specific signs of chronic venous disease: edema, eczema, hyperpigmentation, increased ankle diameter, varicose veins, lipodermatosclerosis, pain and others[19]. Regarding the characteristics of the lesions, the location, depth, margins, wound bed, exudate, injured area and pain should be observed[3,19]. Pain assessment is important because it has a negative impact on the quality of life of patients and also affects healing[20]. There was an agreement among the judges of this research on the importance of this item.

In the aspects relating to prevention of injury, we observed an excellent score of agreement in clinical and educational strategies, such as improving venous return with the use of compression therapy, advice on resting and lifting members, skin care, prevention of accidents and fractures of the lower limbs (LL), patient education with advice for early referral to health system in case of signs of possible skin lesion continuity, encouraging mobility and exercise, and elevation of the affected limb when at rest[3-4 , 10].

The presence of an ulcer affects work productivity, generating disability pensions, and restricts daily living and leisure activities. For the patients, venous disease means pain, loss of functional mobility and decreased quality of life[4], which may explain the consensus of the

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judges about the need to assess the quality of life of people with venous ulcers.

In addition, we emphasize the importance of referral to professionals as well as counter--referencing items that achieved excellent scores among the judges of this study, reaffirming the fact that the better structured this flow between health services, the better their efficiency and effectiveness[3].

The study results permitted the refinement and confirmed the validity of content of the proposed clinical protocol. The limitation of this study was the judge selection technique, which was restricted to the Lattes platform. The adoption of other strategies of inclusion in the study, such as the snowball technique, could have increased the sample.

Other validity tests can be performed in future studies to confirm their psychometric properties, after its clinical application. It is expected that the implementation of this protocol for people with venous ulcers will contribute to the systematization of care actions for these patients, increasing safety and reorienting the health team in primary care, aimed at healing the injury and the overall health.

CONCLUSION

The categories of the protocol with items that did not reach optimal K rates were: Tests application/performance/results, socio-demographic data, medical history, risk factors, verification of pain/SSVV/pulse/signs of infection/ location of the lesion/edema and treatment of pain.

After removal of the items that had K or CVI rates disagreement between judges, we observed an increase in the scores of the six categories, elevating K indexes and general CVI protocol to 0.91 and 0.95 respectively, achieving excellent rates in all categories. The suggestions of the judges were accepted in most of the cases.

The proposed protocol was validated and may facilitate the systematization, standardization of actions and continuity of care of people with venous ulcers in primary care through a multi-disciplinary, objective and easy-to-apply instrument, which will contribute to the reduction in healing time and the improvement in patients' quality of life.

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