

# Clinic validation protocol for venous ulcers in high complexity

*Validação clínica de protocolo para úlceras venosas na alta complexidade*

*Validación clínica para el protocolo de úlceras venosa en alta complejidad*



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## ABSTRACT

**Objective:** To perform clinical validation of a clinical protocol for treatment of individuals with venous ulcers in highly complex health services.

**Method:** Methodological quantitative study conducted by four specialist nurses who evaluated 32 patients with venous ulcers, at the Onofre Lopes University Hospital, in Natal/Rio Grande do Norte. Data was collected between July and December/2013 and analysis was carried out using Kappa test (K), considering  $K \geq 0.61$ .

**Results:** Items with unsatisfactory Kappa coefficients were excluded and the experts suggested changes in the categories anamnesis; examinations; verification of pain and pulse signs; surgical treatment of chronic venous disease; prevention of recurrence; reference and counter-reference.

**Conclusions:** The protocol was validated in the clinical setting and, after adjustments, it contained 15 categories and 76 items. Validation optimized the instrument regarding applicability and relevance.

**Keywords:** Varicose ulcer. Tertiary healthcare. Clinical protocols. Validation studies.

## RESUMO

**Objetivo:** Realizar a validação clínica de um protocolo assistencial para pessoas com úlceras venosas em serviços de saúde de alta complexidade.

**Método:** Estudo metodológico, quantitativo, que incluiu quatro enfermeiros especialistas, que avaliaram 32 pacientes com úlceras venosas, no Hospital Universitário Onofre Lopes, em Natal/Rio Grande do Norte. A coleta de dados foi realizada entre julho e dezembro/2013 e a análise ocorreu por meio do teste Kappa (K), considerando  $K \geq 0,61$ .

**Resultados:** Os itens com Kappa insatisfatórios foram excluídos, e os especialistas sugeriram modificações nas categorias: anamnese; exames; verificação da dor e pulsos; tratamento cirúrgico da doença venosa crônica; prevenção de recidiva; referência e contrarreferência.

**Conclusões:** O protocolo foi validado no contexto clínico, e sua composição, após os ajustes, foi de 15 categorias e 76 itens. A validação otimizou o instrumento quanto à aplicabilidade e à pertinência.

**Palavras-chave:** Úlcera varicosa. Atenção terciária à saúde. Protocolos clínicos. Estudos de validação.

## RESUMEN

**Objetivo:** Realizar la validación clínica de un protocolo clínico para las personas con úlceras venosas en los servicios de salud de alta complejidad.

**Método:** Estudio metodológico, cuantitativo, que incluía cuatro enfermeras especialistas que evaluaron a 32 pacientes con úlceras venosas, el Hospital Universitario Onofre Lopes, en Natal/Rio Grande do Norte. La recolección de datos se llevó a cabo entre julio y diciembre/2013 y el análisis se realizó en octubre a través de la prueba de Kappa (K) Considerando  $K \geq 0,61$ .

**Resultados:** los ítems con Kappa insatisfactorios fueron excluidos y los expertos sugirieron modificaciones a las categorías: anamnesis; exámenes; verificación de dolor y pulsos; tratamiento quirúrgico de la enfermedad venosa crónica; prevención de recidiva; referencia y contrarreferencia.

**Conclusiones:** El protocolo fue validado en el ámbito clínico y su composición después de los ajustes fue de 15 categorías y 76 ítems. La validación optimizó el instrumento a la aplicabilidad y relevancia.

**Palabras clave:** Úlcera varicosa. Atención terciaria de salud. Protocolos clínicos. Estudios de validación.

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## ■ INTRODUCTION

Venous ulcers (VUs) are injuries caused by inadequate flow of blood through the veins and are related to chronic venous insufficiency, venous valve malfunction abnormalities and venous thrombosis. These complications are more common in older female individuals, but affect both genders at different ages. These wounds account for 70% to 90% cases of lower extremity wounds and usually occur on the distal third of the medial side of the leg, typically around the medial malleolus<sup>(1-3)</sup>.

Venous leg ulcers have a high rate of recurrence (30%) when they are not properly treated in the first year, and may reach 78% after two years<sup>(2-5)</sup>. The complication is estimated to affect 0.5% to 2% of the world population. According to Brazilian studies<sup>(3-6)</sup> venous ulcers constitute the 14th cause of absence from work and the 32nd cause of permanent inability of an employee to return to work, and are hence a public health issue.

Venous ulcer management require early diagnosis, interdisciplinary approach, adoption of a protocol, specific knowledge on the subject, technical expertise and coordination at the different levels of service of the Unified Health System (SUS), permanent education and participation of people with venous ulcers and their families, within the context of comprehensive healthcare<sup>(3,7-9)</sup>.

The importance of the use of clinical protocols consists in the need for standardization of healthcare actions aimed to promote the healing process. Poor management of ulcers may result in injuries that take years to heal, resulting in high social and emotional cost<sup>(3,7-9)</sup>. Brazilian studies showed that lack of standardization in the management of venous ulcers at the several levels of service of the SUS is one difficulty faced in VU treatment<sup>(3,6)</sup>.

Standard protocols for the treatment of venous ulcer are useful tools for helping health professionals perform their actions, systematizing the care to be provided to patients with venous ulcers, based on humanistic and ethical principles of conduct<sup>(3,7-9)</sup>. The use of a standard protocol facilitates teamwork and adds to the body of scientific knowledge<sup>(3,7-8)</sup>.

Validation studies are aimed to assess the quality of the tools, being essential to ensure their legitimacy and credibility. Therefore, two steps are key for testing these tools: relevance and clinical applicability.

Relevance seeks to identify whether the investigated tool, i.e., the protocol, is relevant and meets the intended purpose<sup>(10)</sup>. Regarding clinical applicability, relevance concerns the feasibility and/or usefulness of the tool in a given clinical context, contributing to the improvement of the

protocol, by selecting items with clinical usefulness to ensure its reliability and validity<sup>(10)</sup>.

Therefore, the following guiding question was selected for this study: "Which categories and items of the protocol for the treatment of patients with venous ulcers in high complexity services will be validated for relevance and clinical applicability?" The present study aimed to perform the clinical validation of a protocol for the treatment of patients with venous ulcers in high complexity services.

## ■ METHOD

Methodological study of clinical validation with quantitative approach conducted from July to December 2013, at Hospital Universitário Onofre Lopes (HUOL), in Natal/Rio Grande do Norte (RN).

In this study, the protocol for venous ulcers was submitted to the assessment of four specialist nurses trained to evaluate the items and categories for relevance and applicability of the protocol to the clinical context. Thus, each one of the 32 patients was assessed by four nurses who acted in pairs (paired), corresponding to 64 observations.

In each pair, one nurse was judge 1 and the other was judge 2. One of the pairs assessed 20 patients and the other pair assessed 12 patients using the protocol. The criteria used to select these nurses were specialization in dermatology, experience in the development of protocols and minimum experience of 1 year in care to patients with venous ulcer.

The Protocol for the Treatment of Venous Ulcers (PUV), previously validated for its content, is composed of 15 categories and 91 items. The construction of these categories and items was based on integrative literature review and subjected to content validation by 53 specialists in vascular wounds (44 nurses, eight physicians and one physiotherapist)<sup>(3)</sup>.

For this purpose, the 15 categories and 91 items below, identified by the four specialist nurses who selected the options "I agree" or "I disagree" and "If you do not agree, would you like to make any suggestions?":

- Sociodemographic data: Name, number of SUS card and record, referenced (Family Health Unit, Basic Health Unit, specialized or non-specialized care), age (in years), gender, address, marital status (single/widowed, divorced/separated, married/stable union), educational level (illiterate, primary education, secondary education and higher education), profession/occupation, religion, family income (in minimum wages, number of people living in the house).
- Anamnesis: Who changes wound dressings (nurse, nursing technician/assistant, patient, caregiver, other

(who?)), Where wound dressings are changed (Family Health Unit, Basic Health Unit, at the patient's home and other (where?)), chronic diseases (which?), allergies (no, yes (which?)), drugs used (name, indication, for how long, dose/day), alcohol (no, yes (how long has been drinking, type of drink and drinking frequency)), smoking (no, yes), personal hygiene (adequate and inadequate), activity/day (household activity, work activity and household/work activity, how many hours per day?), daily rest (no, yes (with or without elevating the legs? how many times? For how long?)), sleep (in hours/day), onset of the first venous ulcer (in months), duration of the current venous ulcer (in months), relapse (in number of times) and risk factors (which?).

- Tests (request/completion/results): complete blood count, fasting blood glucose, serum albumin, ankle brachial index, biopsy (in case of suspected infection) and echo-doppler.
- Different checks: Pain (visual analogical scale), pulses (absent and present for pedial, tibial and popliteal pulses), edema (measure ankle circumference 10 cm from the bottom of the heel and calf (medial malleolus)), signs of infection (absent and present (which?)), body mass index (BMI), vital signs (blood pressure, respiratory rate, pulse and temperature) and location of the wound (inform in which part of the right or left leg the wound is located).
- Characteristic of the ulcer: degree (1 to 4), exudate (type, amount), odor (absent, mild, strong), margin (characteristics), characteristics of perilesional area, prevalence of wound bed (tissue), measurement of ulcer in the treatment (no, yes).
- Care of perilesional and lesional area: Cleaning of perilesional area and wound (technique used), products used in perilesional area and wound, wound coverage required (wound tissue) and frequency of dressing change (number of times/week).
- Medications used: Use of antibiotics (no, yes (which?)), phlebotropic drugs (no, yes (which?)) and anti-inflammatory drugs (no, yes (which?)).
- Pain treatment: Absent/present, non-pharmacological measures (types), takes painkillers (which?).
- Surgical treatment of chronic venous disease (CVD): Absent/present, venous valve malfunction (which?), venous obstruction (which?), method of incompetent perforating veins ligation (which?), compressive therapy after surgery (which?).
- Compression treatment: Absent/present, use of adequate compression (which?), use of compression stockings recommended (no, yes), elevation of legs

during rest recommended (2 to 4 h/day) (no, yes) and elevating the feet of the bed 10 to 15 cm (no, yes), calf muscle contraction (no, yes) and flexing exercises and walking (no, yes) recommended and elevation of legs 30 minutes before compression recommended (no, yes).

- Prevention of recurrence (clinical strategies): venous and surgical procedures used in the investigation (no, yes), lifetime compression treatment (no, yes) and regular monitoring of the skin surrounding the ulcer (no, yes).
- Prevention of recurrence (educational strategies): importance of adherence to compression stockings (no, yes), skin care (no, yes), prevention of accidents or injuries in the legs (no, yes), guidance on early search for specialized care if possible signs of possible broken skin are detected (no, yes), encouragement of mobility and exercises and elevation of the affected limb at rest (no, yes).
- Reference: Absent/present, unit of origin, referenced for professional X (name).
- Counter-reference: Absent/present, destination, clinical summary, tests results, diagnosis, conduct.
- Quality of life: Chronic Venous Insufficiency Questionnaire – CIVIQ<sup>(11)</sup>.

In clinical validation, data collection includes information directly obtained from the patients, in the clinical context. This process allowed verifying the relevance and applicability of the proposed protocol.

The 32 people with VU signed the Free Informed Consent Form and were selected according to their availability and the following inclusion criteria: individual with at least one venous ulcer; well informed on the study and able to be interviewed; minimum age of 18 years. The exclusion criteria were presence of oncological wounds, since clinical cancer patients have often severe impairment of their bodily functions, which represents a different sample profile; individuals with wounds of mixed arterial venous or venous/leprosy origin. The justification for this criterion is that these wounds differ from typical venous ulcers.

The patients were assessed once by one pair of nurses when they reported to the outpatient unit for appointment with the angiologist and/or changing dressing.

For assessment of level of agreement and level of consistency (reliability) of the judges (specialist nurses) regarding the items and categories of the protocol, Kappa (K) index was used. This index was also used in the assessment of inter-rater agreement regarding each item.

The Kappa coefficient measures the percentage of agreement ranging from "minus" to "plus 1": the closer to 1,

the better the level of agreement between the observers. A level of agreement  $\geq 0.61$  among the judges (considered a good level) was established as criterion of acceptance<sup>(12-13)</sup>.

The study met the ethical principles of Resolution no 466/2012 and was approved by the Research Ethics Committee of Universidade Federal do Rio Grande do Norte (UFRN) (CAAE: 07556312.0.0000.5537).

The data collected was organized in an electronic spreadsheet and after double data entry procedure was exported to the Statistical Package for Social Science (SPSS), version 20.0 Windows. After coding and tabulation, data were analyzed by reflective reading and statistics with the use of Kappa test through Online Kappa Calculator<sup>(14)</sup>.

## ■ RESULTS

The results were distributed in three parts, as follows: description of specialists; relevance of categories and items of the protocol; applicability of protocol categories and items to clinical practice.

### Description of specialists

The nurses who acted like judges of the protocol were aged 20 to 30 years old, female and specialists in dermatology with 1 to 5 years of experience in caring for patients with venous ulcer.

### Relevance of the categories and items of the protocol

The Protocol for the treatment of venous ulcers (PUV) was first assessed for the relevance of the categories (Chart 1).

Most categories were assessed with Kappa coefficient  $\geq 0.61$  (acceptable). However, some categories such as clinical strategies for prevention of recurrence ( $K = 0.41$ ), reference ( $K = 0.31$ ) and counter-reference ( $K = 0.53$ ), obtained Kappa coefficients below the acceptable values.

Moreover, 13 items of categories of the protocol obtained Kappa coefficients lower than 0.61, in inter-rater assessment (Chart 2).

Categories of the protocol	Relevance		
	Judge 1	Judge 2	Inter-raters
	Kappa	Kappa	Kappa
Sociodemographic data	0.99	0.98	0.92
Anamnesis	0.84	0.89	0.64
Tests (Request/completion/results)	0.84	0.82	0.79
Different checks: pain, pulses, edema, signs of infection, body mass index (BMI), vital signs (SSW) and site of the wound.	0.92	0.89	0.78
Characteristics of the ulcer	1.00	1.00	1.00
Care with the wound and perilesional area	0.97	0.96	0.89
Drugs for treating the wound taken by the patient	1.00	1.00	1.00
Pain treatment	0.97	0.97	0.83
Surgical treatment of CVD	0.76	0.67	0.62
Compression treatment	0.84	0.83	0.64
Prevention of recurrence (clinical strategies)	0.44	0.61	0.41
Prevention of recurrence (educational strategies)	1.00	1.00	1.00
Reference	0.37	0.59	0.31
Counter-reference	0.73	0.57	0.53
Quality of life	0.99	0.95	0.91
General score	0.84	0.85	0.79

**Chart 1** – Assessment of the relevance of the categories of the protocol. Natal/RN, 2014

Source: Research data, 2014.

## Applicability of the protocol categories and items for clinical practice

In addition to relevance, the protocol categories were assessed for their applicability to clinical practice, obtaining acceptable scores (Chart 3).

Although all the categories had high Kappa values regarding clinical applicability, two items did not obtain acceptable coefficients and were excluded (Chart 4).

The protocol version validated for content included 15 categories and 91 items. Clinical validation allowed improvement of the protocol. The final version had 15 categories and 76 items.

## DISCUSSION

Regarding relevance and clinical applicability, most categories obtained Kappa coefficient  $\geq 0.61$  (acceptable) in the assessments.

The first step in care to patients with venous ulcer includes collection of sociodemographic data, anamnesis and

physical examination for the establishment of an accurate diagnosis and effective management of the condition<sup>(3)</sup>.

During physical examination, patient's vascular status, diseases, risk factors for CVD, history of the ulcer, pain complaints, drugs used to treat the wound, surgical treatments and compression<sup>(7-8)</sup>.

Appropriate care to individuals with venous leg ulcers involves preventive strategies and a multidisciplinary<sup>(15)</sup>. According to some authors<sup>(7-8)</sup> the reference and counter-reference system should involve proper coordination between health services, which improves care efficiency and effectiveness, minimizing failures and gaps and reducing the chances of recurrence.

Therefore, these protocols contribute to accelerate the healing process, improving the quality of life of people with venous ulcer, by standardizing care and optimizing the time of health professionals<sup>(3-5,16)</sup>.

Regarding relevance, some items of category anamnesis obtained Kappa coefficients below the acceptable values, such as: chronic diseases ( $K = 0.45$ ), drugs currently used ( $K = 0.31$ ), daily activities ( $K = 0.33$ ) and risk factors ( $K$

Category	Item	Judge 1	Judge 2	Inter-raters
		Kappa	Kappa	Kappa
Anamnesis	Chronic diseases	0.53	0.66	0.45
	Drugs used by the patient	0.37	0.53	0.31
	Daily activities	0.37	0.66	0.33
	Risk factors	0.47	0.66	0.42
Tests (Request/completion/results)	Serum albumin	0.44	0.50	0.33
Different checks	Pain	0.57	0.27	0.29
Surgical treatment of CVD	Valve malfunction	0.74	0.40	0.38
	Venous obstruction	0.66	0.45	0.41
	Method of incompetent perforating veins ligation	0.66	0.51	0.43
Compression therapy	Rest with elevated legs recommended (2 to 4 h/day) and elevating the feet of the bed 10 to 15 cm	0.59	0.91	0.58
Prevention of recurrence (clinical strategies)	Venous and surgical procedures in the investigation	0.37	0.59	0.34
	Lifetime compression treatment	0.53	0.66	0.45
	Regular monitoring of the skin surrounding the ulcer	0.42	0.59	0.40

**Chart 2** – Assessment of relevance of the items that obtained Kappa coefficient  $< 0.61$  (inter-rater assessment). Natal/RN, 2014

Source: Research data, 2014.

Category of the protocol	Applicability		
	Judge 1	Judge 2	Inter-raters
	Kappa	Kappa	Kappa
Sociodemographic data	0.99	0.98	0.97
Anamnesis	1.00	1.00	1.00
Tests (Request/ completion/results)	0.81	0.81	0.80
Different checks: pain, pulses, edema, signs of infection, body mass index (BMI), vital signs (SSVV) and site of the wound.	0.94	0.94	0.92
Characteristic of the ulcer	0.95	0.92	0.91
Care with the wound and perilesional area	1.00	1.00	1.00
Drugs related to the treatment of the wound taken by the patient	1.00	1.00	1.00
Pain treatment	1.00	1.00	1.00
Surgical treatment of CVD	0.90	0.93	0.89
Compression treatment	0,89	0,95	0,82
Prevention of recurrence (clinical strategies)	0.88	0.88	0.86
Prevention of recurrence (educational strategies)	0.86	0.88	0.85
Reference	1.00	0.87	0.88
Counter-reference	1.00	0.87	0.88
Quality of life	0.89	0.99	0.95
General score	0.94	0.93	0.92

**Chart 3** – Assessment for clinical applicability of the categories of the protocol. Natal/RN, 2014

Source: Research data, 2014.

Category	Item	Judge 1	Judge 2	Inter-raters
		Kappa	Kappa	Kappa
Tests (request/ completion/results)	Serum albumin	0.54	0.76	0.51
Different checks	Tibial pulse	0.46	0.37	0.30

**Chart 4** – Assessment regarding clinical applicability of the items that obtained Kappa coefficient < 0.61 (inter-rater assessment). Natal/RN, 2014

Source: Research data, 2014.

= 0.42). These items were considered relevant if some suggested changes were made, as follows: in chronic diseases remove the number of years; in drugs used, remove for how long the patient has been taking them; in activities/day, remove the number of hours; in risk factors, remove duration, recurrence and time. These suggestions were accepted because they do not impact the effectiveness of the ulcer venous protocol and make it easier to understand and use.

Regarding the tests (request/completion/results), serum albumin dosage was considered not very relevant (K = 0.33) to care, according to the experts. Some authors<sup>(3,7-8,17)</sup> affirmed that laboratory tests such as complete blood count, biochemistry (triglycerides and cholesterol), fasting blood glucose, protein dosages (total and fractions) and albumin and transferrin levels are key aspects of a high quality care. However, the suggestion made by the experts was accepted, since the other tests had already

provided elements to guide the conducts of the health team, and the lack of albumin dosage would not jeopardize the care process.

For pain assessment, an analogical scale ranging from 0 (no pain) to 10 (insufferable pain) was proposed. In their assessment of 40 observations, the judges found that the item was relevant if some changes were made ( $K=0.29$ ), since the patients found it difficult to indicate their pain intensity. Thus, the use of verbal descriptor was suggested in pain assessment: mild pain, moderate pain or intense pain, which was accepted and included in the protocol.

It should be stressed that effective control of pain significantly improves the quality of life of patients with venous ulcers, and appropriate control of pain also contributes to wound healing<sup>(18)</sup>. Despite the relevance, few studies have explored pain in patients with venous ulcers<sup>(19)</sup>. However, an international study<sup>(18)</sup> reported that patients who used compression treatment and were told to elevate their legs had lower pain intensity and less impact on daily activities.

Concerning the drugs used to treat the wound, antibiotics should only be used in case of infections and with results of biopsied tissue cultures, given the large number of patients who develop resistance. Phlebotropic drugs act on macrocirculation, improving venous tone and microcirculation, reducing capillary hyperpermeability, and can be an alternative for patients with pain and edema. However, the anti-inflammatory action of these drugs may interfere with the natural process of tissue repair<sup>(5)</sup>.

Regarding surgical treatment of CVD, some judges found not relevant the item cause of disease – valve malfunction ( $K=0.38$ ) or venous obstruction ( $K=0.41$ ) – and type of surgery method of incompetent perforating veins ligation ( $K=0.43$ ), which had Kappa coefficients lower than the acceptable value. The surgical treatment of venous hemodynamic abnormalities to heal venous ulcers aims to eliminate or reduce high venous pressure to the ulcerated areas, leading to a good prognosis overtime<sup>(17)</sup>. Therefore, it is agreed that knowing the cause or type or surgery is not essential, as suggested by the experts.

Regarding compression therapy, the experts found not relevant assessing rest with elevated legs recommended (2 to 4 h/day) and elevating the feet of the bed 10-15cm ( $K=0.58$ ). The judges suggested excluding this item from the category compression treatment and leave it only in the category prevention of recurrence (educational strategies). The suggestion was accepted.

Regarding the category prevention of recurrence (clinical strategies), the items venous and surgical procedures used in the investigation ( $K=0.34$ ), lifetime compression treatment ( $K=0.45$ ) and regular monitoring of the skin surrounding the ulcer ( $K=0.40$ ), despite been considered of low relevance, were maintained in the protocol because they are essential in the prevention of new wounds<sup>(3,15,20)</sup>.

Regarding the relevance of categories reference ( $K=0.31$ ) and counter-reference ( $K=0.53$ ) that obtained Kappa coefficients below the acceptable values, some changes were suggested, as follows: for category reference, its maintenance with all the items and removal of the item “reference” from category “sociodemographic data” was suggested. Regarding counter-reference, maintenance of all the items and arranging the items “test results”, “diagnosis” and “conduct” in one topic named “clinical summary” was suggested<sup>(16)</sup>. The suggestions were welcome and accepted in the protocol.

Regarding clinical applicability, the categories obtained high Kappa coefficients. However, the items “serum albumin dosage” ( $K=0.51$ ) in the category “tests (request/completion/results)” and “tibial pulse check” ( $K=0.30$ ) had poor Kappa coefficients. The suggestion of removal of “serum albumin dosage check” had already been accepted in the assessment of relevance.

Regarding “tibial pulse check”, 10 observations mentioned this item as not applicable because since it is the site of the venous ulcer measurement cannot be made. Considering that the “check of central and peripheral pulses” contributes to the assessment of perfusion in the vascular network and on determination of associated arterial disease<sup>(3,15)</sup>, the experts suggested including the observation “not applicable because of the wound” for the several pulses to be measures. This suggestion was also accepted.

It should be stressed that the quality of life of people with venous ulcers is also impaired by pain, physical limitation, impossibility of performing leisure activities, absence from work, and these factors can also be aggravated by poor adherence to medical treatment, contributing to chronicity in non-healing wounds, and worsening of quality of life. It is essential to assess the quality of life of these patients every three months. This factor was confirmed by a systematic literature review of studies on quality of life that obtained significant results in the period between three and six-month evaluations<sup>(9)</sup>.

This stage of clinical validation of the protocol of care to venous ulcers stressed the importance of the relevance and applicability of categories and items,

since the judges observed that the concepts involved are relevant and appropriate to achieve the goals related to care and monitoring of patients with venous ulcer. Moreover, the experts can make suggestions to improve the protocol.

## ■ CONCLUSION

The items and categories of the protocol for the treatment of venous ulcers were clinically validated. The contributions of the experts allowed improving/optimizing the protocol regarding its relevance and clinical applicability. The final composition after some adjustments was 15 categories and 76 items.

The items that obtained unsatisfactory Kappa and Content Validity Index (CVI) coefficients and needed changes were in the categories anamnesis, tests (request/completion/results); assessment of pain and pulses checks; surgical treatment of CVD; prevention of recurrence (clinical strategies); reference and counter-reference. Under this perspective, the protocol will be implemented after the first contact with the patient and re-fed each time the patient is assisted, whenever necessary.

Implementation of the protocol for the treatment of individuals with venous ulcers is a feasible measure that supports the guidance of the health team in high complexity services, aiming not only to ensure wound healing but full health recovery. Further studies are needed to assess the clinical impact of the use of this protocol in other health units. It is believed that the referred protocol will bring benefits to patients, family members and health teams, providing standardization of care.

## ■ REFERENCES

1. Taverner T, Closs SJ, Briggs M. Painful leg ulcers: community nurses' knowledge and beliefs, a feasibility study. *Prim Health Care Res Dev*. 2011 [cited 2012 Feb 15];12(4):379-92. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21787447>.
2. Abbade LPF, Lastoria S, Rollo HA. Venous ulcer: clinical characteristics and risk factors. *Int J Dermatol*. 2011 [cited 2013 Nov 10];50(4):405-11. Available from: [www.ncbi.nlm.nih.gov/pubmed/21413949](http://www.ncbi.nlm.nih.gov/pubmed/21413949).
3. Dantas DV, Dantas RAN, Costa IKF, Torres GV. Protocolo de assistência a pessoas com úlceras venosas: evidência de validação de conteúdo. *Rev Rene*. 2013 [citado 2013 nov 10];14(3):588-99. Disponível em: <http://www.revistarene.ufc.br/revista/index.php/revista/article/view/1204/pdf>.
4. Azoubel R, Torres GV, Silva LWS, Gomes FV, Reis LA. Efeitos da terapia física descompressiva na cicatrização de úlceras venosas. *Rev Esc Enferm USP*. 2010 [citado 2013 nov 10];44(4):1085-92. Disponível em: [http://www.scielo.br/scielo.php?script=sci\\_arttext&pid=S0080-62342010000400033](http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0080-62342010000400033).
5. Borges EL, Caliri MHL, Haas VJ. Revisão sistemática do tratamento tópico da ulcera venosa. *Rev Latino-Am Enfermagem*. 2007 [citado 2013 nov 10];15(6):1163-70. Disponível em: [http://www.scielo.br/scielo.php?pid=S0104-11692007000600017&script=sci\\_arttext&lng=pt](http://www.scielo.br/scielo.php?pid=S0104-11692007000600017&script=sci_arttext&lng=pt).
6. Macedo EAB, Oliveira AKA, Melo GSM, Nóbrega WG, Costa IKF, Dantas DV, et al. Caracterização sociodemográficos dos pacientes com ulcera venosa atendidos em um hospital universitário. *Rev Enferm UFPE on line*. 2010 [citado 2013 nov 10]; 4(spe):1863-7. Disponível em: <http://www.revista.ufpe.br/revistaenfermagem/index.php/revista/article/download/1475/1689>.
7. Belo Horizonte. Secretaria Municipal de Políticas Sociais. Secretaria Municipal de Saúde. Gerência de Assistência. Coordenação de Atenção a Saúde do Adulto e do Idoso. Protocolo de assistência aos portadores de feridas. Belo Horizonte (MG): SMS; 2010. Disponível em: <http://www.pbh.gov.br/smsa/biblioteca/atadulto/protocoloferidas.pdf>.
8. Ribeirão Preto. Prefeitura Municipal. Secretaria Municipal da Saúde de Ribeirão Preto. Programa de Educação Continuada da Secretaria Municipal da Saúde de Ribeirão Preto. Manual de assistência integral as pessoas com feridas crônicas. Ribeirão Preto (SP): SMS; 2011. Disponível em: [http://dms.ufpel.edu.br/ares/bitstream/handle/123456789/184/manual\\_feridas\\_%202011.pdf?sequence=1](http://dms.ufpel.edu.br/ares/bitstream/handle/123456789/184/manual_feridas_%202011.pdf?sequence=1).
9. Costa IKF, Nóbrega WG, Costa IKF, Torres GV, Lira ALBC, Tourinho FSV, et al. Pessoas com úlceras venosas: estudo do modo psicossocial do Modelo Adaptativo de Roy. *Rev Gaúcha Enferm*. 2011 [citado 2013 nov 10];32(3):561-8. Disponível em: [http://www.scielo.br/scielo.php?script=sci\\_arttext&pid=S1983-14472011000300018](http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1983-14472011000300018).
10. Ribeiro MAS, Vedovatto TG, Lopes MHBM, Monteiro MI, Guirardello EB. Estudos de validação na enfermagem: revisão integrativa. *Rev Rene*. 2013 [citado 2014 ago 10];14(1):218-28. Disponível em: <http://www.revistarene.ufc.br/revista/index.php/revista/article/view/54/pdf>.
11. Creason SN. Clinical validation of nursing diagnoses. *Int J Nurs Terminol Classif*. 2004 [cited 2014 Aug 10];15(4):123-32. Available from: <http://onlinelibrary.wiley.com/doi/10.1111/j.1744-618X.2011.01194.x/pdf>.
12. Wynd, CA, Schmidt B, Schaefer MA. Two quantitative approaches for estimating content validity. *West J Nurs Res*. 2003 [cited 29 Aug 2016];25(5):508-18. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/12955968>.
13. Pilatti LA, Pedroso B, Gutierrez GL. Propriedades psicométricas de instrumentos de avaliação: um debate necessário. *R.B.E.C.T.* 2010 [citado 23 out 2013];3(1):81-91. Disponível em: <http://revistas.utfpr.edu.br/pg/index.php/rbect/article/view/619/469>.
14. Randolph JJ. Online Kappa Calculator. 2008 [cited 2013 Jan 22]. Available from: <http://justusrandolph.net/kappa/>.
15. Costa IKF, Salvetti MG, Souza AJG, Dias TYAF, Dantas DV, Torres GV. Assistance protocol to people with venous ulcers: a methodological study. *Online Braz J Nurs*. 2015 [cited 2015 Oct 10];14(1):5-15. Available from: <http://www.objnursing.uff.br/index.php/nursing/article/view/4692>.
16. Sellmer D, Carvalho CMG, Carvalho DR, Malucelli A. Sistema especialista para apoiar a decisão na terapia tópica de úlceras venosas. *Rev Gaúcha Enferm*. 2013 [citado 2013 dez 22];34(2):154-62. Disponível em: [http://www.scielo.br/scielo.php?script=sci\\_arttext&pid=S1983-14472013000200020](http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1983-14472013000200020).
17. Conferencia Nacional de Consenso sobre Úlceras de la Extremidad Inferior. Documento de consenso C.O.N.U.E.I. Barcelona: Kamed; 2009.
18. Woo KY, Sibbald RG. The improvement of wound-associated pain and healing trajectory with a comprehensive foot and leg ulcer care model. *J Wound Os-*



- tomy Continence Nurs. 2009 [cited 2013 Dec 22]; 36(2):184-91. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19287267>.
19. Salvetti M G, Costa IKF, Dantas DV, Freitas CCS, Vasconcelos QLDAQ, Torres GV. Prevalência de dor e fatores associados em pacientes com úlcera venosa. Rev Dor. 2014 [citado 2014 dez 22];15(1):245-8. Disponível em: [http://www.scielo.br/scielo.php?pid=S1806-00132014000100017&script=sci\\_arttext](http://www.scielo.br/scielo.php?pid=S1806-00132014000100017&script=sci_arttext).
20. Malaquias SG, Bachion MM, Sant'Ana SMSC, Dallarmi CCB, Lino Junior RS, Ferreira PS. Pessoas com úlceras vasculogênicas em atendimento ambulatorial de enfermagem: estudo das variáveis clínicas e sociodemográficas. Rev Esc Enferm USP. 2012 [citado 2012 out 12];46(2):302-10. Disponível em: <http://www.scielo.br/pdf/reeusp/v46n2/a06v46n2.pdf>.

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