

ORIGINAL ARTICLE

AMPUTATION DUE TO COMPLICATIONS OF DIABETES: NURSING CARE PROTOCOL

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ABSTRACT

Objective: to produce and validate a Nursing care protocol for people amputated due to diabetic complications. Methods: a methodological research study conducted in Recife-PE between February 2019 and October 2020, comprising the following stages: 1) Theoretical phase: integrative literature review; 2) Production phase; 3) Validation by specialists; and 4) Validation by the target population. The Content Validity Index was used in the validation by specialists. The Agreement Index was employed in the validation by the target population. Results: the items included in the instrument permeate the following care dimensions: Biological, Psychological and Socio-educational. Validation by the evaluators was in charge of 13 specialists. The instrument presented an index of 0.94. Validation by the target population was conducted with 33 participants; all the items achieved an agreement index \geq 80%. Conclusion: the protocol enables comprehensive and humanized care, encouraging autonomy and assisting in rehabilitation; it also allows for a reflection regarding individualization of Nursing care.

DESCRIPTORS: Nursing Protocols; Nursing Care; Amputation; Complications of Diabetes; Validation Study.

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INTRODUCTION

Diabetes Mellitus (DM) represents a global problem due to habits detrimental to health such as sedentary lifestyle and obesity, which promote non-control of the disease, leading to vascular and neurological complications – precursor conditions of diabetic foot¹. This represents a public health problem that can lead to amputation of the lower limbs (LLs). It has significant incidence in the Brazilian population, with repercussions in quality of life and in higher financial costs for its treatment².

It is verified that 85% of the people with diabetic foot suffer amputations, with an estimate of two amputations due to complications of diabetes, every minute and at the global level. This fact reveals the social and economic impact of diabetic foot for people with the disease, which makes them vulnerable when trying to reintegrate into society, either through participation in social events that do not provide accessibility to people with disabilities or through re-entering the labor market and having to deal with prejudice towards disability³.

People amputated due to diabetic complications have a lower life expectancy when compared to those with DM without amputations. This risk is associated with an important burden of cardiovascular diseases in these patients and that predisposes to the occasion. Thus, assistance should be seen in a comprehensive health context⁴. It is necessary to strengthen the implementation of effective health education measures by the multiprofessional team, by promoting the professionals' awareness and improving resoluteness in the health prevention actions – which should be directed at preventing new injuries and infections, encouraging the people involved by making them co-responsible for the treatment⁵.

From this perspective, Nursing care is indispensable to strengthen healthcare through health education, in order to improve patients' adherence to the treatment and achieve effectiveness in glycemic control, thus reducing amputations and reamputations⁶. Protocols are understood as paramount tools in health care, identified by the specification of the care measures, which encompasses a series of operational indications on the practice, in order to provide care guidelines to the professionals, provide effective understanding and reduce errors⁷. They also increase precision of the guidelines for the patients, contributing to a more dynamic and efficient rehabilitation⁵.

The scientific production of the Nursing protocols devoted to patients with diabetic complications proves to be effective. However, there is a gap in the knowledge about the Nursing care protocols targeted at amputated people. It is necessary to prepare a specific Nursing care protocol, with a view based on humanized and comprehensive care⁸ and that encompasses safe interventions with positive results. The objective of the current research study was to prepare and validate a Nursing care protocol for people amputated due to diabetic complications.

METHOD

This is a methodological research study⁹ developed according to the recommendations set forth by Pasquali¹⁰⁻¹¹, through the following stages: 1) Theoretical phase: integrative literature review; 2) Production phase; 3) Validation by specialists; and 4) Validation by the target population. The research was developed between February 2019 and October 2020 in Recife-PE.

In the theoretical phase, and integrative literature review was conducted aimed at identifying the Nursing care for people amputated due to diabetic complications. The

Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations were followed. The search for the research studies was conducted in the following portals and databases: LILACS, Medline, PubMed, Scopus and Web of Science; using the descriptors and Boolean operators specified below: Nursing Care AND Amputation; Nursing Care AND Diabetes Complications; as well as the following filters: language (English, Portuguese and Spanish), and year (from 2015 to 2019). Of 2,389 research studies, 12 answered the guiding question.

In the elaboration phase, the protocol elements obtained in the review were prepared, with the constitutive definitions represented by the domains and the operational definitions represented by Nursing care. The operational definitions were in accordance with the most concrete and comprehensive concepts in the construct, in order for the definition to move from abstract to concrete and represent the construct's physical behavior, enabling elaboration of the items related to operationalization of the instrument¹¹.

The care guidelines for amputated people set forth by the Ministry of Health¹² was used in this stage, serving as the basis to elaborate the instrument. The protocol was prepared including the following domains: identification data, pain, stump, dressing, motor difficulties, DM control, emotional care, self-care and care measures after discharge, adaptation to the prosthesis, and referral.

The search for the specialists for content validation was conducted in the Lattes Platform and, after due analysis, they were invited to participate via email contacts. After their acceptance, they received instructions related to filling in the Free and Informed Consent Form (FICF) and diverse information to characterize the evaluators.

Assessment was performed using a Likert scale prepared on Google Forms, with values from one to four for each item of the instrument, namely: totally adequate (four), adequate (three), partially adequate (two), and inadequate (one)¹³.

Thirteen Brazilian nurse-evaluators specialists in the content who underwent training in the North, Northeast and South regions of the country were the study participants, in addition to 33 clinical nurses working at hospitals in the city of Recife, Pernambuco, Brazil, for validation by the target population. The content specialists were selected according to the adapted Fehring criteria¹⁴, including those who obtained at least five points (Chart 1).

Chart 1 – Adapted criteria to assemble the committee to validate the Nursing care protocol for people amputated due to diabetic complications. Recife, PE, Brazil, 2020

Criteria	Score
MSc in the health area as minimum degree	1
Having developed a dissertation and/or thesis in the Nursing area with a theme targeted at Nursing care, amputation and/or DM.	3
Having at least one year of experience in the provision of guidelines for people amputated due to diabetic complications in the clinical practice.	2
Having at least two years of professional experience in care targeted at people amputated due to diabetic complications.	3
Having a specialization in the Nursing area with a course conclusion paper on Nursing care for people with Diabetes Mellitus and/or amputated individuals, and/or production and validation of instruments.	2

Having published scientific papers in the health area on Nursing care for people with Diabetes Mellitus and/or amputated individuals, and/or production and validation of instruments.	2
Having participated in research groups/projects in the last 12 months, involving Nursing care for people with Diabetes Mellitus and/or amputated individuals, and/or production and validation of instruments.	2
Maximum score	15

Source: Adapted from Fehring (1994).

Validation by the target population was conducted according to the recommendations set forth by Pasquali¹⁰, with a sample comprised by 30 to 40 clinical nurses who worked in reference hospitals for trauma and vascular care. The inclusion criteria were as follows: being a Nursing graduate and having worked/being currently working in care provision for patients amputated due to diabetic complications. The exclusion criteria in both validation processes were the following: not completing the entire instrument and answering the instrument more than once – in this case, one of the instruments was excluded and the other was included in the research.

The data referring to the content evaluators were analyzed based on the Content Validity Index (CVI). The CVI score was calculated by adding up the agreement level of the items marked with "three" or "four", divided by the total number of answers to the items. The criterion for validation adopted was as follows: As a first step, each item of the instrument was assessed individually; in this evaluation, all the items that obtained CVI values above 0.70 were considered valid. In the second phase, the instrument was evaluated as a whole, i.e., the entire instrument, which should have a minimum agreement level of 0.80¹³; therefore, all the CVI values calculated separately were added up and the result was subsequently divided by the number of items included in the instrument.

Validation by the target population was conducted with 33 clinical nurses working in two reference hospitals for trauma and angiology care located in the city of Recife, Pernambuco, Brazil, and affiliated to the Unified Health System (Sistema Único de Saúde, SUS). The contacts were made via phone calls and those interested were sent an access link with the FICF, the data collection instrument and instructions to fill it in Google Forms. The form included two components: items to characterize the participants; and evaluative items for the protocol (domains: organization, writing style, appearance and motivation).

In relation to the data evaluated by the target population, items with a minimum agreement level of 80% in the positive answers were considered valid. Items with an agreement index below 80% were considered worthy of change, as indicated in the literature¹⁵. Calculation of the overall adequacy score was performed by adding up the scores obtained, dividing by the total scores and multiplying by 100, presenting the ratio as a percentage.

The research was approved by the Research Ethics Committee of Universidade Estadual da Paraíba, under favorable opinion No. 4,174,186.

RESULTS

The literature review stage allowed identifying the Nursing care for people amputated due to diabetic complications, grounding elaboration of the protocol. Thus, the technology was produced in order to provide comprehensive care, minimizing the predominant care fragmentation found in the current biomedical model.

The protocol should be applied by clinical nurses in hospital clinical units that treat the researched population, and should be used in the period following amputation. The protocol addresses the following domains: patient's identification data; care measures related to pain; stump; dressing; motor difficulties; DM control; emotional care; self-care and care measures after discharge; adaptation to the prosthesis; and referral. Figures 1 and 2 show the technology that was produced.

NURSING CARE PROTOCOL FOR PEOPLE AMPUTATED DUE TO DIABETIC COMPLICATIONS						
IDENTIFICATION DATA						
0301	oru	ie nearth service.				
Motl	her's	name:				
Date of birth: Age: Skin color:			Skin color:			
Schooling level: Occupation: Marital status:			Marital status:			
		DOMAINS:		CARE:		
DOMAINS: CAI Pain - Verify pain report: () Yes () No - Evaluate its characteristics (onset, frequency, int • Description: - - Pain classification from 0 to 10: 0-1-2-3-4-5 • Perform non-pharmacological techniques for p massage): • () Yes () No Description: • Administer analgesics according to the medical - Administer analgesics according to the medical - Verify the amputation level: - Assess stump characteristics: • Location • Location • Shape: () Globular () Conical • Presence of stitches: () Yes () No • Burning sensation on the stump () Yes • Grafting: () Yes () No • Bony spikes: () Yes () No • Investigate stump position: • Remain in functional position: () Yes () No			 Verify pain r Evaluate its c Descr Pain classific Perform non massage): () Y Descr Administer a Identify the t Verify the an Assess stump Locat Shapp Prese Sensi Burni Grafti Bony Investigate st Remaa () Y Analyze sutu of contraindica Indica Presence of s 	eport: () Yes () No haracteristics (onset, frequency, intensity): iption:	intensity): 5-6-7-8-9-10 pain relief (relaxation, heat and cold application, Il prescription: () Yes () No) Closed 	
		Dressing Motor difficulties	 Exchange drevelocity Dress Type Identi Descr Perform band Band proxin Note: If a tinglight Identify the c Select and in Instruct the p possible: () Indicate moto Preve the clipht 	c dressing: ressing exchange frequency:		

Figure 1 – Protocol corresponding to the Nursing care for people amputated due to diabetic complications, third version. Recife, PE, Brazil, 2020Source: The authors ,2020.

	Strengthen and move the unaffected limb by means of passive or according to the clinical evaluation Encourage early walking with aids, in case of lower limb amputation Provide support for the stump when sitting, for patients who suffered transtibial a lower level, with the knee extended: () Yes () No Provide guidelines about: Adequate diet and referral to a nutritionist: () Yes () No Pharmacological treatment as prescribed (medication, schedule, dosated () Yes () No Application of the insulin injections as recommended: () Yes () No Capillary glycemia check when necessary: () Yes () No Investigate access to self-monitoring devices () Yes () No					
	Psychological	Emotional care	 Verified mood swings (samess, anxiety, fear): () Yes () No Evaluate difficulty accepting the amputation: () Yes () No Description: Investigate support network (family/friends): () Yes () No Description: Provide emotional support and refer to monitoring with a specialist: () Yes () No Provide guidelines on patient's/family's doubts and questions: () Yes () No 			
Care dimensions	Socio-educational	Self-care and care measures after discharge Adaptation to the prosthesis	 Provide guidelines about: Stump: () Yes () No With removal of the stitches, the stump should be cleaned with warm water and neutral soap (avoid leaving it immersed in order to prevent maceration) Dry by compression, searching for irritated areas Massage with an emollient product. Start from the proximal end of the stump towards the suture line If bandaging could not be performed, and it is indicated by a vascular physician, a compressive mash can be used, if available. Activities of daily living: () Yes () No Bathing should be done in the shower, with the patient sitting on a firm seat. The patients should sit on a chair to take off their clothes and the prosthesis again Patients amputated at the level of the femur: Sit down for dressing. Firstly, put on the shirt and the socks, then adjust the prosthesis and fix the pelvic belt over the shirt Put on underwear over the prosthesis. () Yes () No Guidelines: Protect stump skin when using the prosthesis: () Yes () No Cover the stump with a sock made of a soft and comfortable fabric and appropriate to its shape and size Change the socks twice a day, in order to prevent moisture on stump skin The sock should be intact, with no folds or seams in contact with the skint, in order to prevent discomfort and development of pressure ulcers 			
		Referral Date: /	For upper limb prostheses, it is relevant to provide guidelines on grip, getting accustomed with the weight of the objects, and sensitivity Referral indicated: () Yes. Place:			
		Signature:				

Figure 2 – Protocol corresponding to the Nursing care for people amputated due to diabetic complications, third version. Recife, PE, Brazil, 2020

Source: The authors ,2020.

The validation by specialists stage was conducted with the participation of 13 nurseevaluators who assessed the protocol in relation to its content. The variables included in the form to characterize the evaluators are organized in Table 1.

Variables	n	%
Gender		
Female	12	92.3
Male	1	7.7
Race/Skin color		
White	08	61.5
Brown	04	30.8
Asian	01	7.7
Degree		
MSc	09	69.2
PhD	03	23.1
Post-PhD	01	7.7
Have you already provided care to people amputated due to diabetic complications?		
Yes	10	76.9
No	03	23.1
Have you already worked in production and validation of instruments?		
Yes	11	84.6
No	02	15.4
Place of training		
Northeast	09	69.2
North	1	7.7
South	3	23.1

Table 1 – Variables included in the form to characterize the evaluators. Recife, PE, Brazil, 2020

Source: The authors ,2020.

The evaluators' age varied from 26 to 55 years old, with a mean of 34.92. Their training time was between four and 35 years, with a mean of 11.76. There was a variation from nine to 15 points in the score obtained according to the adapted Fehring criteria: seven evaluators obtained 15 points (maximum recommended score), three obtained 12 points, two obtained 13 points, one obtained 10 points, and one specialist obtained nine points, totaling the sample of 13 specialists who took part in the research.

With regard to the evaluation of the instrument, all items were validated, with $CVI \ge 0.70$, as well as the entire protocol, which presented CVI = 0.94, a value above the one recommended for validation of the entire instrument ($CVI \ge 0.80$). Thus, Table 2 presents the domains included in the protocol and the respective CVI values for each domain.

Table 2 – Domains included in the protocol and their respective CVI values. Recife, PE, Brazil, 2020

DOMAINS	CVI
Patient's identification data	0.95
Pain	0.90
Stump	0.96
Dressing	0.96
Motor difficulties	0.88
Emotional care	0.88
Diabetes control	0.92
Self-care and care measures after discharge	0.97
Adaptation to the prosthesis	0.94
Referral	1

Source: The authors ,2020.

A total of 33 clinical nurses took part in the validation by the target population stage. The participants evaluated the organization, writing style, appearance and motivation domains, based on an agreement level \geq 80%. Table 3 shows the categories corresponding to validation of the instrument by the target population, as well as the agreement index. According to the target population, the instrument proved to be valid in terms of semantics.

Table 3 – Agreement index in the evaluation by the target population Recife, PE, Brazil, 2020

CATEGORIES	AGREEMENT INDEX (%)
Organization	96
Writing style	95
Appearance	97
Motivation	90
OVERALL AGREEMENT INDEX	94

Source: The authors ,2020.

DISCUSSION

Care protocols are organized guidelines based on the literature that emphasize crucial aspects in the patient care process, i.e., they represent what needs to be performed while providing care to patients¹⁶.

The need was identified to develop individualized care protocols for Nursing professionals during care for patients amputated due to diabetic complications; furthermore,

the importance of validating these protocols as tools to customize and standardize Nursing care was revealed¹⁷. The Nursing care protocol for patients amputated due to diabetic complications was developed due to the need to standardize/unify care by means of a scientifically validated instrument.

Corroborating with the above, a research study that assessed nurses' perspectives in the treatment of patients amputated due to diabetic complications in eight hospitals from Spain and Portugal evidences that individuals amputated due to diabetic complications become physically and psychologically vulnerable¹⁷. Care based on the biological, psychological and social aspects is necessary. The authors emphasize the need for a multidisciplinary approach to these patients. Therefore, the protocol indicates the need for assessment and referral to other health professionals, such as nutritionist, physiotherapist and psychologist, in order to provide the recommended multiprofessional care.

The other aspects addressed in the protocol, such as patient's identification data, pain management, stump, dressing, motor difficulties, emotional care, self-care and care measures after discharge, adaptation to the prosthesis and referral, are listed in the literature¹⁵⁻²⁰. Pain is a frequent problem in the aforementioned population segment; however, few research studies address the semiology and targeted Nursing care, thus limiting professional care²¹. The protocol addresses this domain when investigated and treated in a particular way. The last component of the protocol encompasses referral of the patients to other services, according to each patient's needs.

The importance of standardization in the readaptation process of the researched population is verified. Nursing professionals should provide appropriate care to patients through referral and counter-referral, as shown in a research study found in the literature that aimed at identifying referral and counter-referral activities of amputated individuals in the city of Florianópolis, Brazil¹⁸.

It is worth noting a research study in which a protocol was prepared to direct nurses for performing the red reflex test in children during growth and development consultations in basic health units from the state of Rio Grande do Norte, Brazil. The authors indicate that production of the protocol represented a challenge due to the scarcity of updated articles on the theme, which demanded a search for other sources to produce the technology²². It is noticed that, in this research, the difficulty elaborating the protocol was also evidenced, as the studies found reported fragmented Nursing care, based on the biomedical model that only sees the patients by parts, not treating them as a whole.

Elaboration of the protocol needs to be associated with the patients' requirements and with the particularities of the treatment. Participation of the professionals in production of this instrument improves adherence and the success level in its implementation process²³. It is noted that such participation in production of the protocol was through the validation process, conducted both by the evaluators and by the target population.

Validation studies address analysis measures to verify the most appropriate writing style to be employed when producing the instrument; thus, the results collaborate to the analysis of improvements in the health measures and can define changes in care actions²⁴.

The validation stage proved to be a challenge due to the difficulty finding specialists on the theme and to the delay in filling out the validation instrument via email. This stage also represented a challenged in a research study conducted in Brazil with the participation of 15 evaluators with the purpose of validating the content of a Nursing intervention checklist for the angioplasty pre-operative period. In the research, the authors refer to the difficulty finding evaluators to comprise the sample²⁵.

In content validation by the evaluators, all the items reached the CVI recommended in the individual analysis: ≥ 0.70 . The instrument also presented an adequate CVI (0.94), where ≥ 0.80 is the recommended value for overall validation. Therefore, representativeness of the protocol and the evaluators' agreement regarding validity of the material are verified.

The CVI was also used in previous methodological research studies to determine validity of the instruments elaborated, which also reached an adequate CVI: $\geq 0.80^{25-27}$.

With regard to validation by the target population, the protocol was positively assessed, as all items analyzed obtained an agreement index \geq 80%, which enabled establishing that instrument validation by the target population was achieved. The suggested changes, both in instrument content and face, were crucial because they improved the protocol writing style and appearance, which will encourage Nursing professionals to use the tool. Changes related to face and content were also identified in the other research studies, which was useful to improve the instrument²⁸.

Nursing care provision to the patients should offer safety during the assistance, as well as result in positive results due to the care measures applied, reducing pain and suffering. Therefore, it is pointed out that Nursing should promote health actions in a holistic way at all care level²⁹. Standardization of the care provided to patients amputated due to diabetic complications by means of a validated protocol will systematize Nursing care and guide scientific evidence-based professional practice.

Regarding the public health policies, the Health Care Network in the SUS devoted to chronic conditions stands out. There is an evident need to apply the SUS principles and guidelines in the health care activities³⁰. Using the tool elaborated in this research in the care provided to people with chronic diseases, more specifically to people amputated due to diabetic complications, involves the application of some principles, such as comprehensiveness, as the protocol provides for comprehensive patient care, meeting the need for multiprofessional care.

The research evidences the development of a new tool to improve Nursing care for people amputated due to DM, addressing the necessary demands and having implications on the professional practice. It was also verified that development of this research encouraged the capacity to deepen knowledge on issues related to clinical Nursing care, in addition to health education for the provision of comprehensive care to the target population, based on instruments with scientific evidence.

In relation to management, application of the protocol by Nursing professionals will promote knowledge on the tool developed and a possible investment on its use, in order to reduce expenses with complications/hospitalizations due to DM.

As for the study limitation, it is noted that, due to the time proposed for conduction of the research, it was not possible to evaluate the instrument with regard to its clinical applicability, an essential stage in methodological research. It is suggested that future research studies assess clinical applicability of the instrument, which will be the objective of the doctoral research by the author of the protocol, by means of a clinical trial to be conducted in the hospitals participating in this research. Another important factor related to the limitation lies in the data collection phase, which would initially be conducted inperson at the participating hospitals. However, due to the COVID-19 pandemic it was necessary to change the strategy and collection was performed at a distance.

CONCLUSION

Development of this research allowed elaborating and validating a Nursing care protocol for people amputated due to diabetic complications based on the literature, addressing domains that are cross-sectional to the comprehensive care approach. Both the evaluators and the target population validated the instrument. It presented CVI = 0.94 in the validation by the evaluators, and an agreement index \geq 80% in the validation by the target population. Therefore, the protocol stands out as a valid tool to apply it in the

Nursing care practice.

This research shows to be relevant for the provision of comprehensive and humanized care, encouraging autonomy and assisting in the rehabilitation process, in addition to promoting a reflection on the standardization and customization of Nursing care provided to individuals amputated due to diabetic complications, thus motivating the production of scientifically validated instruments to improve care delivered by Nursing professionals.

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