

Management of totally implanted vascular access device in cancer patients: methodological research to validate a procedures manual

Manejo do cateter totalmente implantado em pacientes oncológicos: estudo metodológico para validação de manual de procedimentos

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ABSTRACT

Objective: To perform an appearance, content and semantics validation of a procedures manual for the management of totally implanted vascular access device in cancer patients. **Materials and Method:** This is methodological research that used item response theory originated from the Psychometrics Theory in its validation process. This study was carried out in two steps: validation of appearance and content by expert nurses, and semantic validation by nurses who handle the catheter. The Concordance Index was considered valid with at least 80% of agreement among the assessors. **Results:** In the validation of appearance and content, only the item regarding to procedure in case of complications about the catheter reached concordance index of less than 80% and was rewritten according to the literature recommendations. In the semantic validation all items had a 100% of agreement. **Conclusion:** The manual was considered validated in terms of appearance, content and semantics, and it can be used as a teaching strategy for professional training of nurses who deal with cancer patients.

Keywords: Central Venous Catheters; Validation studies; Nursing Care; Oncology Nursing; Nursing.

RESUMO

Objetivo: Realizar validação de aparência, conteúdo e semântica de um manual de procedimentos para o manuseio de cateter totalmente implantado em pacientes com câncer. **Materiais e Método:** Trata-se de pesquisa metodológica, cujo processo de validação foi realizado com base na teoria da resposta ao item, originada da Psicometria. Este estudo foi realizado em duas etapas: validação da aparência e conteúdo por enfermeiros especialistas e validação semântica pelos enfermeiros que manuseiam o cateter. O Índice de Concordância foi considerado válido com pelo menos 80% de concordância entre os avaliadores. **Resultados:** Na validação de aparência e conteúdo, apenas o item referente a conduta em caso de complicações sobre o cateter atingiu índice de concordância inferior a 80% e foi reescrito de acordo com as recomendações da literatura. Na validação semântica todos os itens tiveram 100% de concordância. **Conclusão:** O manual foi considerado validado em termos de aparência, conteúdo e semântica, podendo ser utilizado como estratégia de ensino para a formação profissional de enfermeiros que lidam com pacientes oncológicos.

Palavras-chave: Cateteres Venosos Centrais; Estudos de validação; Cuidados de enfermagem; Enfermagem Oncológica; Enfermagem.

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INTRODUÇÃO

Totally implanted vascular access device (TIVAD) is a device widely used in oncology because it allows prolonged access to the vascular system, allowing infusion of various types of intravenous fluids and collection of blood samples for laboratory tests (XIN-YAN et al., 2018; HSIEH et al., 2022). In addition, it provides a higher quality of life to patients by reducing pain and anxiety generated by repeated punctures to receive the indicated therapy, and provides greater freedom and security to develop activities of daily living (BURBRIDGE et al., 2016).

Despite representing a safe vascular access, some complications related to the use of TIVAD may happen due to improper management as infection, obstruction, infiltration or leakage (GRANIC et al., 2014; VERMEULIN et al., 2018; VELIOGLU et al., 2019). The management of TIVAD is a nursing procedure that requires skill and knowledge to avoid adverse events (PACHECO et al., 2014; OLIVEIRA et al., 2019). There is a need that nurses, who manage the device, have technical and scientific knowledge and are trained for its management, in a precise and standardized way (CONLEY et al., 2017; GORSKI et al., 2021).

Many doubts between nurses exist about how to handling the TIVAD (PIRES; VASQUES, 2014; PINTO et al., 2015). The results of a study conducted in Brazil (PIRES; VASQUES, 2014) showed a significant knowledge deficit among nurses of the Medical Clinic and Emergency Service at a university hospital about TIVAD management regarding to different aspects: indication and purpose of the TIVAD, puncture technique, heparinization and maintenance of the device. These knowledge gaps guided the development of an evidence-based procedures manual, which can guide the clinical practice of professionals about the management of the device.

Education technologies, such as manual and protocols can be adopted to improve clinical practice performance (HONÓRIO et al., 2011; KRAUZER et al., 2018; FONSECA et al., 2019). The standardization of procedures by means of manuals and protocols is one of the strategies that can be used to ensure qualified clinical practices, since it allows professionals to clarify doubts on this topic, guides the implementation of actions and provides increased safety during the procedure (WALTER et al., 2016). It is noteworthy that the development of educational materials such as manuals, must involve the following steps: bibliographical search, development of educational materials and, finally, material validation by experts on the subject and representatives of the target

audience, as described by Echer (2005). The validation of an educational manual will ensure that there is scientific credibility enough to make it effective for the proposed purpose (OLIVEIRA et al., 2014; FARIAS et al., 2018). Considering this context, this study aimed to validate appearance, content and semantics of a procedures manual for the management of TIVAD.

MATERIALS AND METHOD

Study design

This is methodological research with quantitative approach, since it involves the development, evaluation and validation of a procedures manual for the management of TIVAD (POLIT; BECK, 2017).

To perform the validation, it was used the Psychometrics Theory, which proposes the item response theory (PASQUALI, 1998). This analysis includes validation of content and appearance and can be performed by two different groups of judges. A group of judges, considered experts with experience in the content to be assessed, performs the analysis on the relevance of the items in relation to the represented construct, judging whether these items refer or not to the subject at issue. This analysis is called two-judge analysis or content analysis (PASQUALI, 1998). The content validation is the determination of the representativeness and extent that each item of the analyzed material adapts to the purpose of a given phenomenon under study (POLIT; BECK, 2017).

The appearance validation assesses whether the instrument under analysis seems to be measuring, in an appropriate way, what it proposes. This is a validation concerning the analysis of legibility, clarity and organization of the instrument content (PASQUALI, 1998; POLIT; BECK, 2017). Another validation step, called semantic validation, must also be performed by a sample of the instrument target audience. Such analysis aims to verify if all the items are understandable for the target audience, and can be carried out individually or in a group (PASQUALI, 1998).

For the validation, a concordance index of more than 80%, among the judges serves as a decision criteria on the importance of the item to the topic to which it refers theoretically (PASQUALI, 1998). In order to carry out the analysis, the judges received an instrument to assess the content of the material to be validated so that they can judge each item according to the expected purpose of the material at issue. According to Pasquali (1998), six judges are sufficient for such purpose. Items that do not show a

concordance index of more than 80% indicate problems and it is recommended that they are excluded (PASQUALI, 1998).

Selection of experts for validation of appearance and content

The selection of the experts was performed by non-probabilistic intentional sampling, with a stipulated number of 6 participants. To be considered as experts, some eligibility criteria were established based on what was proposed by Fehring (1987): to hold a master's degree, to have theoretical knowledge on the subject at issue, proven through scientific publications, clinical practice and specialization in the subject under analysis. On this basis, the individual should reach a minimum score of 5 points to be considered as an expert for this study.

Thus, for the selection of experts, the following criteria were established: degree, scientific production and a minimum of one year of work experience in the field of study. The analysis of the eligibility criteria was performed through the analysis of the Curriculum Lattes, available on the website of the National Council for Scientific and Technological Development (CNPq), of the individuals working with the topics covered in the procedures manual.

Selection of nurses who are representatives of the target audience

Nurses who worked in the medical clinic at a teaching hospital in Brazil and who had no experience in the management of totally implanted vascular access device were selected. The researchers approached these nurses personally during the work shift and invited them to participate in the study.

Data collection instruments

An assessment instrument was developed based on the study by Oliveira (2006) to enable the validation of the manual in terms of content and appearance by experts. The first part of this instrument contained information on the characteristics of the experts, such as gender, age, work experience time, area of expertise, academic degree, and topics of their publications. The second part contained evaluative items about the manual, including the analysis on the coverage, clarity, coherence, criticality of the items,

objectivity, scientific writing, relevance, sequence, and uniqueness. These items were organized on a Likert-type scale with five response alternatives: 1 - inappropriate (I), 2 - partially appropriate (PA), 3 - not sure (N), 4 - appropriate (A), and 5 - totally appropriate (TA).

For the semantic validation by the representatives of the target audience, an assessment instrument was developed with items that evaluated the objectives of the manual, its organization, writing style, appearance and motivation ability, and each item should be judged according to the following parameters: 1 - inappropriate (I), 2 - partially appropriate (PA), 3 - not sure (N), 4 - appropriate (A), and 5 - totally appropriate (TA). For those items considered as inappropriate or partially appropriate, a justification of the reason for such assessment was requested. At the end of the instrument, it was given the option of providing additional suggestions about the manual.

Data collection

After selection, the experts were invited to participate in the study by email. After acceptance, the Informed Consent Form (ICF), the data collection instrument and the procedures manual to be validated were also sent. Those experts who did not respond to the contact within 30 days were excluded.

After analyzing the results presented by the experts and making the necessary adjustments in the manual, the semantic validation was performed with the nurses, which are the representatives of the target audience of the manual. At this stage, the nurses were contacted during the work shift to receive the ICF, data collection instrument and the manual, and the latter remained with the nurses for a period of seven days in order to analyze the material.

Data analysis

A minimum concordance index of 80% was considered as a criteria for the permanence of the assessed item, as recommended by Pasquali (21). The item of the Likert-type scale “1 - inappropriate (I)” was classified as degree of disagreement; the items “2 - partially appropriate (PA)” and “3 - not sure (N)” were classified as degree of indecision and the items “4 - appropriate (A)” and “5 - totally appropriate (TA)” as degree of agreement (OLIVEIRA, 2006). Among the items analyzed, only those, whose sum of

the responses “A” and “TA” corresponded to at least 80% of the total responses were maintained.

For the semantic validation, an individual analysis was performed, since it is not possible to stratify the sample by level of education because it is about health professionals, not patients. In this analysis, it was also considered a concordance index of 80%.

Items with percentages lower than 80% were reformulated, considering the suggestions and the evidence available in the literature. Suggestions that reached a concordance index greater than or equal to 80% were also considered, since they were relevant for the adaptation of the manual.

Ethical aspects

This study was approved by the Research Ethics Committee of the Faculty of Medicine at the University of Brasilia.

RESULTS

Validation of content and appearance by experts

Seven professionals were selected to compose the sample of experts in this study, and six responded the contact within the expected time. The sample was composed, therefore, of six experts, all nurses, females, aged between 33 and 38 years. The average time of work experience of these professionals was nine years, ranging from 4 to 15 years. All of them had specialization and scientific publications in oncology and/or validation of health technologies and/or TIVAD , according to Table 1.

Table 1- Characterization of the experts in relation to the area of professional performance, degree and scientific production.

Characteristics	n* = 6	%
Area of professional performance		
Hospital/outpatient	2	33.4
Academic/teaching	3	50.0
Both	1	16.6

Degree		
Specialist	6	100.0
Masters	4	66.6
PhD	3	50.0
Subject of the Scientific Production		
Oncology	6	100.0
TIVAD	2	40.0
Validation of health technologies	2	33.3

*number of experts

The instrument for assessment of the manual included 41 items, and was subdivided into two parts. The first part contains 18 topics for the overall assessment of the manual, with assessment items on the objectives, structure, presentation and relevance of the manual. The second part concerned a more specific assessment, with 23 items to assess the topics listed throughout the manual: concept; indications and purpose; puncture technique for TIVAD; heparinization of the TIVAD for needle removal and observations; management technique and procedures in case of complications. The results of this section were presented in tables, following the order of the items described above. The 18 items on the general assessment of the manual reached a concordance index equal to or greater than 80% among the assessors (Table 2).

Table 2 - Distribution of the responses of the experts in relation to the general assessment of the manual and in relation to the concordance index.

General assessment						
Assessment items	n* =6					%**
	I†	PA††	N§	A 	TA¶	
1-Objectives						
1.1 Consistent with the needs of nurses	0	0	0	3	3	100.0
1.2 Consistent with the teaching-learning process	0	0	0	2	4	100.0
1.3 Promotes behavior and attitude change	0	0	1	2	3	83.3
1.4 Can be disseminated to the scientific community	0	0	0	1	5	100.0
1.5 Meets the objectives of institutions that serve patients with TIVAD	0	0	0	0	6	100.0
2-Structure and appearance						
2.1 Appropriate for nurses who manage TIVAD	0	0	0	0	6	100.0

2.2 Appropriate to the socio-cultural level of the target audience	0	0	0	0	6	100.0
2.3 There is logical sequence of content	0	0	0	2	4	100.0
2.4 Appropriate subject-verb agreement	0	1	0	2	3	83.3
2.5 Wording accessible to the target audience	0	0	0	1	5	100.0
2.6 There is coherence between the information of the front cover, back cover, summary and presentation	0	1	0	1	4	83.3
2.7 Appropriate size of titles and topics	0	1	0	1	4	83.3
2.8 Appropriate number of pages	0	0	1	0	5	83.3
3-Relevance						
3.1 Themes present relevant key aspects	0	0	0	3	3	100.0
3.2 Allows the transfer and generalization of learning to other contexts	0	0	0	2	4	100.0
3.3 Allows the learner to acquire knowledge on the management of TIVAD	0	0	0	1	5	100.0
3.4 Addresses the issues necessary for the management of TIVAD	0	0	0	4	2	100.0
3.5 Appropriate for use by any nurse	0	0	1	1	4	83.3
Total	0	3	3	26	76	94.4

*number of assessors; †Inappropriate; ††Partially appropriate; §Not sure; ††Appropriate; †††Totally appropriate; **Concordance Index calculated by the sum of the number of appropriate and totally appropriate judgments considered by the judges: $(TA+A/\text{total responses}) \times 100$.

Only one of the 23 items reached a concordance index of less than 80% among the assessors and was reformulated (Table 3). After analysis of the suggestions, corrections were made taking into account the evidence available in the literature on the management of TIVAD.

Table 3- Distribution of the responses of the experts in relation to the topics of the manual and to the concordance index.

PART 2 - Specific Assessment						
Assessment items	n* =6					%**
	I†	PA††	N§	A 	TA†††	
1-Concepts, Indications and Purpose						

1.1 Proper scientific writing	0	0	0	2	4	100.0
1.2 Clear and objective messages	0	0	0	1	5	100.0
1.3 There is a logical sequence of content	0	0	0	1	5	100.0
1.4 Sufficient illustrations that facilitate understanding	0	0	0	2	4	100.0
1.5 All relevant information is displayed	0	0	0	4	2	100.0
2-Puncture Technique for the TIVAD						
2.1 Proper scientific writing	0	0	0	2	4	100.0
2.2 Clear and objective messages	0	0	0	1	5	100.0
2.3 There is a logical sequence of content	0	1	0	1	4	83.3
2.4 Sufficient illustrations that facilitate understanding	0	0	0	1	5	100.0
2.5 All relevant information is displayed	0	1	0	2	3	83.3
3- Heparinization of the TIVAD for needle removal						
3.1 Proper scientific writing	0	0	1	1	4	83.3
3.2 Clear and objective messages	0	1	0	2	3	83.3
3.3 There is a logical sequence of content	0	0	0	0	6	100.0
3.4 Sufficient illustrations that facilitate understanding	0	0	0	1	5	100.0
3.5 All relevant information is displayed	0	1	0	1	4	83.3
4- Management technique						
4.1 Proper scientific writing	0	0	1	1	4	83.3
4.2 Clear and objective messages	0	1	0	2	3	83.3
4.3 There is a logical sequence of content	0	0	0	0	6	100.0
4.4 All relevant information is displayed	0	1	0	2	3	83.3
5-Procedures in case of complications						
5.1 Proper scientific writing	0	1	0	0	5	83.3
5.2 Clear and objective messages	0	0	0	4	2	100.0
5.3 There is a logical sequence of content	0	0	0	3	3	100.0
5.4 All relevant information is displayed	0	2	0	3	1	66.6
Total	0	9	2	37	90	92

*number of assessors; †Inappropriate; ††Partially appropriate; §Not sure; ‖Appropriate; ¶Totally appropriate; **Concordance Index calculated by the sum of the number of appropriate and totally appropriate judgments considered by the judges: (TA+A/total responses) x 100.

Semantic validation by nurses

The sample consisted of six nurses, five of whom were females, with a mean age of 32 years and an average work experience of four years. Only one of the nurses had previous experience in oncology as a nursing technician, but none of them had previous experience in the management of TIVAD or training on the device.

The assessment instrument provided to this group of nurses covered a total of 22 items and all items reached a concordance index of 100%, as described in Table 4.

Table 4 - Distribution of the responses of the nurses in relation to the items of the assessment instrument and to the concordance index.

Assessment items	n* = 6					%**
	I [†]	PA ^{††}	N [§]	A	TA	
1-Objectives						
1.1 Consistent with the needs of nurses	0	0	0	2	4	100
1.2 Manual appropriate for use by any professional who manage TIVAD	0	0	0	2	4	100
2-Organization						
2.1 Attractive front cover that indicates the contents of the manual	0	0	0	2	4	100
2.2 Appropriate size of topics and title	0	0	0	2	4	100
2.3 Topics have sequence	0	0	0	2	4	
2.4 There is coherence between the information of the front cover, back cover, summary and presentation	0	0	0	0	6	100
2.5 Appropriate paper and printing	0	0	0	1	5	100
2.6 Appropriate number of pages	0	0	0	2	4	100
2.7 Themes address important key aspects	0	0	0	1	5	100
3-Writing style						
3.1 It is possible to understand all information	0	0	0	3	3	100
3.2 Interesting text that encourages moving on with reading	0	0	0	1	5	100
3.3 Plain language	0	0	0	2	4	100

3.4 There is an association between the themes of each section and the text	0	0	0	1	5	100
3.5 Clarity of the text	0	0	0	2	4	100
3.6 Writing style compatible to the target audience	0	0	0	1	5	100
4-Appearance						
4.1 The sections are organized	0	0	0	0	6	100
4.2 The illustrations allow a greater understanding of the techniques	0	0	0	0	6	100
4.3 The illustrations serve to supplement the text	0	0	0	0	6	100
4.4 The illustrations are expressive and sufficient	0	0	0	1	5	100
5-Motivation						
5.1 The manual is logically presented	0	0	0	3	3	100
5.2 The manual promotes behavioral and attitude changes	0	0	0	4	2	100
5.3 The manual proposes to nurses the acquisition of knowledge and interest in the subject	0	0	0	1	5	100
Total	0	0	0	33	99	100

*number of assessors; †Inappropriate; ††Partially appropriate; §Not sure; †††Appropriate; ††††Totally appropriate; **Concordance Index calculated by the sum of the number of appropriate and totally appropriate judgments considered by the judges: $(TA+A/\text{total responses}) \times 100$.

DISCUSSION

Validation of content and appearance by experts

The academic degree and time of work experience are fundamental issues so that a person can be considered as an expert in a certain area. To be considered as an expert, the professional should have expertise in a given subject and clinical practice, which can be proven through his academic degree, publications and time of work experience (FEHRING, 1987). In this study, having experience in validation and/mastery in the management of TIVAD was of fundamental importance for the validation, since the experts provided constructive and relevant suggestions for the improvement of the procedures manual for the management of TIVAD, based on the theoretical-practical skills they have.

The only item that reached a concordance index of less than 80% was related to the procedures in case of complications with the TIVAD, with regard to the item 5.4, shown in Table 3. The experts did not consider any of the items related to this topic as inappropriate. However, some of the recommended suggestions were accepted because they were also found in the available literature.

The first suggestion of the experts was to replace the title of the first sub-item, regarding this section, namely “Infection” by “Suspicion of Infection”, since the recommendation to collect blood for blood culture in the manual is indicated when there is suspicion of infection and not when it is already confirmed. It was also suggested to describe the signs of infection related to TIVAD and the guidelines on blood collection technique for blood culture.

The infection related to TIVAD is a major problem in oncologic patients in need of early diagnosis and treatment (TABATABAIE et al., 2017). Signs such as fever, chills and phlogistic signs at the device insertion site may indicate catheter-related infection. To confirm the infection, a blood culture test should be performed using blood samples collected from the catheter and from a peripheral vein. Collection of blood samples through the catheter requires a sterile technique and routing of the first 5 mL of collected blood for analysis (WINOKUR et al., 2014).

Given its importance, this information was included in the manual and the item was reformulated. It should be noted that, aware of this information, the nurse could act to prevent infections related to the use of the catheter, preventing further damages, such as early removal of the device.

The second sub-item of the manual, regarding the topic “procedures in case of complications”, concerns the obstruction. It has been suggested to add the unclogging method with ascorbic acid using a three-way plastic wrench. This method was validated in a clinical trial that evaluated ascorbic acid for the unclogging of TIVAD (VASQUES, 2010). Such an unclogging procedure is intended to create a negative pressure inside the catheter to allow the entry of ascorbic acid without the displacement of possible thrombus that may be inside the catheter or at its tip. The technique involves the use of two 10-mL syringes that are coupled to a three-way plastic wrench, and the third port must be attached to the catheter. In order to facilitate understanding, photos of the performance of this technique were also added. It should be noted that ascorbic acid is a weak acid with

antioxidant action, which has been used by some national institutions to unclog TIVAD due to its pro-fibrinolytic properties (OLAS; WACHOWICZ, 2002).

Although other items have reached a concordance index greater than or equal to 80%, it has also been suggested a modification in the presentation of the puncture techniques for the TIVAD, as well as in the needle removal technique and in the catheter management technique. They have been reformulated according to the suggestions considered as relevant and that concerned to the sequence of steps to carry out each procedure, as well as a more detailed description of the materials to be used.

Semantic validation by nurses

The semantic validation of the manual by the representatives of the target audience is also fundamental, since it makes it possible to verify if this is intelligible for this population (PASQUALI, 1998).

The nurses who performed the semantic validation of the manual stated that it met the objectives and assessed it as a useful tool to train professionals dealing with patients with TIVAD.

One of the nurses in the validation group, as well as one of the experts, pointed out that the manual is an important instrument for acquiring knowledge about TIVAD, but this alone is not able to lead to a complete change of attitude in relation the management of the device. In fact, the information has consistency considering that, initially, there should be an interest in the acquisition of knowledge by the nurse and it is necessary that the professional who carries out any activity related to central vascular access devices participates in a training course (PÉREZ-GRANDA et al., 2015; CONLEY et al., 2017; FONSECA et al., 2019). This will help the professional to memorize the contents addressed in the manual, as well as to have greater safety during the management of the catheter.

Technology-mediated health education is an important action for the acquisition of knowledge by nursing professionals. Provision of a manual, in the clinical scenario, addressing the guidelines on nursing care for the management of the TIVAD is crucial, since it allows the clarification of doubts that may arise in clinical practice, which gives greater security to the professional.

Limitations

This study has some limitations. Professionals who work in Publicity and Languages were not included as experts on the phase of validation of content and appearance. Other aspect is related to the small sample size of nurses who represented the target audience during the semantic validation. The authors suggest that future studies be conducted with larger sample size on the phase of semantic validation and including experts from Publicity and Languages field. The inclusion of these professionals is important as they can assess the linguistic and didactical aspects of the manual.

CONCLUSION

The validation made it possible to adapt the structure and presentation of the manual, in order to guarantee the reliability of the information, greater clarity, objectivity and adequacy of the content for the purposes for which it was developed. Therefore, the manual turned an appropriated education technology to standardize technical procedures. This way, the manual can help to ensure qualified clinical practices, since it allows professionals to clarify doubts, guides the implementation of actions and provides safety during the management of the totally implanted vascular access device. It is concluded, therefore, that after validation by experts and representatives of the target audience, the manual was considered validated and it is suggested its use as a teaching strategy in the professional qualification processes of nurses dealing with patients with TIVAD in future studies.

Conflict of interest: None declared.

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