Portuguese Phlebitis Scale: cross-cultural adaptation, validity and reliability for use in Brazil

Escala Portuguesa de Flebite: adaptação transcultural, validade e confiabilidade para uso no Brasil

Escala Portuguesa de Flebitis: adaptación transcultural, validez y confiabilidad para uso en Brasil

Luciene Muniz Braga[1] ◉
Dalete Delalibera Correa de Faria Mota[2] ◉
Ana Carolina de Castro Mendonça Queiroz[3] ◉
Fernando Cordeiro Ribeiro[4] ◉
Herica Silva Dutra[5] ◉
Cristina Arreguy-Sena[5] ◉
Pedro Parreira[6] ◉
Silvana de Lima Vieira dos Santos[3] ◉

[1] Universidade Federal de Viçosa (UFV), Viçosa, Minas Gerais, Brasil.

[2] University of Wisconsin - Eau Clair (UWEC), Eau Clair, Wisconsin, United States of America.

[3] Universidade Federal de Goiás (UFG), Goiânia, Goiás, Brasil.

[4] Hospital e Maternidade Therezinha de Jesus (HMTJ), Juiz de Fora, Minas Gerais, Brasil.

[5] Universidade Federal de Juiz de Fora (UFJF), Juiz de Fora, Minas Gerais, Brasil.

[6] Escola Superior de Enfermagem de Coimbra (ESEnfC), Coimbra, Portugal.

Corresponding author:
Dalete Delalibera Correa de Faria Mota
E-mail: motadd@uwec.edu

ABSTRACT

Objectives: To adapt the Portuguese Phlebitis Scale to the Brazilian culture and verify the adapted version's psychometric properties. **Methods:** Methodological study involving analysis of semantic, cultural, and idiomatic equivalence for cross-cultural adaptation, cognitive debriefing, verification of internal consistency, and construct validity. The equivalence was analyzed considering the percentage of agreement among experts. Exploratory factor analysis was used to test construct validity. Reliability was assessed by internal consistency (Cronbach's α and McDonald's Ω). **Results:** In the cross-cultural adaptation process involving ten experts, two items did not reach an agreement ≥ 80% and underwent adjustments according to the suggestions received. Twelve cognitive debriefing participants approved the adapted version. Adults (n = 244) using a peripheral venous catheter participated in the reliability and construct validation analysis. Exploratory factor analysis identified a single factor, including all tested items (pain, erythema, edema, streak formation along the course of the vein, and palpable venous cord) and factor loading > 0.743. Internal consistency of the set of items was high (Cronbach's α = 0.771 and McDonald's Ω = 0.853). **Conclusion:** The Portuguese Scale of Phlebitis - Version adapted for Brazil proved valid and reliable. It achieved properties that allow use in Brazil's clinical practice, teaching, and research.

Descriptors: Nursing; Validation Study; Phlebitis; Catheterization, Peripheral.

RESUMO

Objetivos: Adaptar a Escala Portuguesa de Flebite para a cultura brasileira e verificar as propriedades psicométricas da versão adaptada. **Métodos:** Estudo metodológico envolvendo análise da equivalência semântica, cultural e idiomática para adaptação transcultural, cognitive debriefing, verificação da consistência interna e validade de construto. Equivalência foi analisada utilizando percentual de acordos. Validade de construto foi testada utilizando análise fatorial exploratória. A confiabilidade foi avaliada pela consistência interna (α de Cronbach e Ω de McDonald). **Resultados:** No processo de adaptação transcultural, envolvendo dez especialistas, dois itens não alcançaram concordância ≥ 80% e sofreram ajustes conforme as sugestões recebidas. Doze participantes do cognitive debriefing aprovaram a versão adaptada. Participaram da análise de confiabilidade e de validação do construto 244 adultos em uso de cateter venoso periférico. Análise fatorial exploratória identificou um único fator incluindo todos os itens testados (dor, eritema, edema, rubor no trajeto da veia e cordão venoso palpável) e carga fatorial > 0,743. Consistência interna do conjunto de itens foi alta (α de Cronbach = 0,771 e Ω de McDonald = 0,853).

Rev. Eletr. Enferm., 2023; 25:74036, 1-11

1

Conclusão: *A Escala Portuguesa de Flebite – Versão adaptada para o Brasil mostrou-se válida e confiável. Alcançou propriedades que permitem sua utilização na prática clínica, no ensino e pesquisas no país.*

Descritores: *Enfermagem; Estudo de Validação; Flebite; Cateterismo Periférico.*

RESUMEN

Objetivos: *Adaptar la Escala de Flebitis Portuguesa a la cultura brasileña y verificar las propiedades psicométricas de la versión adaptada.* **Métodos:** *Estudio metodológico que involucró análisis de equivalencia semántica, cultural e idiomática para adaptación transcultural, debriefing cognitivo, verificación de consistencia interna y validez de constructo. Para el análisis de la concordancia de la equivalencia se utilizó el porcentaje de concordancias. Para probar la validez de constructo, se utilizó el análisis factorial exploratorio. La fiabilidad se evaluó mediante la consistencia interna (α de Cronbach e Ω de McDonald).* **Resultados:** *En el proceso de adaptación transcultural, en el que participaron diez expertos, dos ítems no alcanzaron un acuerdo ≥ 80% y se ajustaron de acuerdo con las sugerencias recibidas. Doce participantes en el debriefing cognitivo aprobaron la versión adaptada. Usuarios de catéter venoso periférico (n = 244) participaron en el análisis de confiabilidad y la validación de constructo. El análisis factorial exploratorio identificó un solo factor que incluía todos los ítems probados (dolor, eritema, edema, enrojecimiento en la vena y el cordón venoso palpable) y una carga factorial > 0,743. La consistencia interna de los ítems fue alta (α de Cronbach = 0,771 y Ω de McDonald = 0,853).* **Conclusión:** *La Escala Portuguesa de Flebitis – Versión adaptada para Brasil demostró ser válida y confiable. Alcanzó propiedades que permiten su uso en la práctica clínica, la docencia e la investigación en Brasil.*

Descriptores: *Enfermería; Estudio de Validación; Flebitis; Cateterismo Periférico.*

INTRODUCTION

Phlebitis is a peripheral vascular trauma that results in an inflammatory process in the layers of the vein, evidenced by signs and symptoms at the catheter insertion site or in the vein pathway, such as pain, erythema, edema, streak formation along the course of the vein, palpable venous cord and drainage of purulent exudate through the catheter insertion site[1,2]. It is an important indicator of the quality of care nursing provides[2] and is intrinsically related to patient safety[3].

In general clinical practice, the most apparent signs and symptoms of phlebitis, such as hyperemia and redness along the vein, are considered without instruments that allow a more accurate assessment, which can lead to underreporting. Effective management of phlebitis requires its rapid, safe, and reliable identification. Thus, it is essential to use appropriate instruments that are easy to apply to assess the presence and severity of phlebitis, including subjective aspects such as the patient's pain. In addition, the phlebitis assessment instrument should be valid, reliable, and adapted to the cultural conditions and language of the setting where it will be used, as recommended by good practices for using and validating health scales. Instruments with such characteristics increase the quality of phlebitis assessment, contribute to patient safety, and can be adopted by healthcare institutions to promote a culture of patient safety[3].

Several phlebitis assessment tools are available in the literature[4] and are commonly used by researchers in the area, such as the Visual Infusion Phlebitis Assessment (VIP scale)[5], Peripheral Venous Catheter Assess (PVC Assess)[6], Maddox Scale[7] and Infusion Nursing Society - Phlebitis Scale (INS Phlebitis Scale)[8-12]. These scales make it possible to characterize phlebitis progressively in degrees, ranging from zero (absence of clinical signs of phlebitis) to degrees 4 or 5 (signs of greater severity). The scales generally consider pain as one of the first signs of phlebitis (grade 1) and the presence of purulent exudate and palpable venous cords as the most severe symptoms, corresponding to grades 4 or 5. Detecting signs and symptoms, and implementing nursing interventions as soon as possible can prevent complications such as bloodstream infection and tissue injury[2,9,13].

There is no consensus on phlebitis measures or reference scales[9,10,12,14]. This may contribute to the wide variations in the cumulative incidence of phlebitis reported in the literature[9,12,15-17] (4.6% to 36.7%), depending on the definition of phlebitis and scale used, and prevents comparison at the national or international level. Consequently, without standardized, valid, and consistent measures, it becomes more challenging to determine the magnitude of phlebitis in clinical practice and the effectiveness of prevention and treatment measures.

In Brazil, authors have performed loose translations of scales published in other countries and other languages, or they have used their own definitions and criteria for evaluating phlebitis, or the authors do not describe the scale used in the study[10-12,18].

The Phlebitis Scale[19] is one of the most widely used scales (inter)nationally. It has been adapted to Portuguese from Portugal (*Escala Portuguesa de Flebite*)[2]. The verification of clinical parameters determines the occur-

Rev. Eletr. Enferm., 2023; 25:74036, 1-11

2

rence of phlebitis and its degree of severity, where 0 is the absence of phlebitis, and 4 is the highest degree of severity. The application of the adapted scale in Portugal made it possible to identify phlebitis in 11.5%[2] and 36.7%[17] of adults using short peripheral venous catheters in that country.

The Portuguese Phlebitis Scale[2] has been used in Brazil without cross-cultural adaptation[12]. It was possible to identify the occurrence of 6.1% of phlebitis in a study conducted in the country[12]. Despite the standardization of Portuguese writing through the orthographic agreement between Brazil and Portugal in 2009, many words have different meanings or are not similarly used when comparing Portuguese and Brazilian culture[20]. Thus, it is necessary to conduct studies to adapt measurement instruments, considering the cultural differences between these countries[21]. In addition, to date, no adapted and validated version of any other phlebitis assessment scale has been identified for use in Brazil.

In summary, we recognize the need to provide a valid and reliable phlebitis assessment scale to evaluate and document this event in clinical practice, teaching, and research in Brazil. Thus, considering that the *Escala Portuguesa de Flebite* has good psychometric properties in Portuguese culture[2], the possible differences between the meanings of some words/expressions of Portuguese and Brazilian cultures and, also, considering the possibility of standardizing the nursing language for phlebitis assessment and comparing the cumulative incidence of phlebitis in the Brazilian context, the present study aimed to adapt the *Escala Portuguesa de Flebite* to Brazilian culture and verify the reliability and validity of the adapted version.

METHODS

A three-step methodological study was developed[21] modified from Beaton's (2007) method including: 1) assessment of idiomatic, semantic, cultural and conceptual equivalence for cross-cultural adaptation; 2) cognitive debriefing[22], 3) verification of psychometric properties of the *Escala Portuguesa de Flebite* – Version adapted for Brazil[23]. Of note, the cross-cultural adaptation did not require translation since it is a scale already in the same language.

Cross-cultural adaptation

Cross-cultural adaptation was performed through idiomatic, semantic, cultural and conceptual equivalence of the *Escala Portuguesa de Flebite*[2]. Idiomatic equivalence verifies whether idiomatic or colloquial expressions are corresponding. Semantic equivalence seeks to identify whether the meaning of the words corresponds in the original and adapted versions, considering vocabulary and grammatical aspects[21]. Cultural equivalence reflects the adequacy to situations related to the experiences of the target culture, in this case, the Brazilian culture. Conceptual equivalence explores whether the concept reflected in the instrument is compatible with situations and events experienced in the target culture[21].

It is important to emphasize and clarify that translation and back-translation are the first steps in the process of adapting a scale[21]. These steps were developed during the adaptation process of the original Phlebitis Scale (in English)[19] into Portuguese (Portuguese version) and described in a previous publication[2]. The translation and back-translation steps are dispensable when the instrument is already in the language used by the target population[21], in this case, the Portuguese language. Therefore, in the present study, we proceeded to the equivalence evaluation stage by a committee of experts. The study was conducted after authorization from the authors of the *Escala Portuguesa de Flebite*[2] for the adaptation and use of this scale in Brazil.

Cross-cultural adaptation was performed by a committee of expert nurses with clinical, teaching and/or research experience in the process of peripheral vein puncture. The experts were selected using typical-case sampling and snowball technique[24]. The number of committee participants met the recommendations for studies of this nature[25].

Initially, three nurses/professors from a Nursing School in Minas Gerais, Brazil, were invited to participate in the expert committee through personal contact, as they are scholars on the subject. Next, each one was asked to nominate three other experts who met the following criteria: be a nurse, and have at least two years of clinical, teaching and/or research experience on the peripheral vein puncture process. The nine indicated specialists (three from Minas Gerais, two from Rio de Janeiro, two from São Paulo, one from Acre, and one from Rio Grande do Sul) were invited by e-mail to participate in the study. The message described the study's objectives and included the Informed Consent and the data collection instrument.

The instrument described the criteria for evaluating the items of the *Escala Portuguesa de Flebite* regarding equivalence: idiomatic, semantic, cultural and conceptual. For each item, there were two response options of agreement (agree and disagree)[2,26] and a space for suggestions. Modification proposals were accepted when the agreement between experts was ≥ 80.0%[2,26]. The

Rev. Eletr. Enferm., 2023; 25:74036, 1-11

3

verification of agreement among experts considered the total number of "agree" answers divided by the total number of experts in the committee multiplied by 100. After analysis by the research team, version 1 of the Portuguese Phlebitis Scale - Version adapted for Brazil was developed.

Cognitive Debriefing

After completion of the previous stage, a focus group composed of a second committee of experts reviewed the first version of the *Escala Portuguesa de Flebite* - Version adapted for Brazil. Researchers selected to form this second committee were considered references in the area. The criteria for indication/inclusion to participate in the focus group were: being a nurse and having at least two years of clinical experience, or experience in teaching, or in research related to the process of peripheral vein puncture. The invitation was made in person, and the group met in a room with privacy and chairs arranged in a circle.

The focus group participants evaluated version 1 of the *Escala Portuguesa de Flebite* – Version adapted for Brazil, for clarity, comprehension, and coherence of terms or expressions. Simultaneously, they compared this version with the *Escala Portuguesa de Flebite* and, when relevant, with the original version[19]. Comments and suggestions were expressed verbally and recorded in report format by one of the researchers. To determine the consensus of the group (minimum of 80.0%), votes were taken to accept modification, replacement, or exclusion of any item from the scale. All items were accepted, and there were no changes. After the consensus of the experts in the focus group, the *Escala Portuguesa de Flebite* - Version adapted for Brazil was sent to the authors of the Portuguese version for evaluation as to its correspondence with the original meaning. The authors agreed with the proposal of the Brazilian version, and there were no suggestions for changes.

Verification of the psychometric properties of the Escala Portuguesa de Flebite - Version adapted for Brazil

The construct validation and internal consistency test of the version adapted for Brazil was performed in a non-probabilistic convenience sample, consisting of women treated in a surgical/obstetric clinic of a public hospital in Minas Gerais (MG) and patients treated in a chemotherapy clinic (outpatient clinic) of a public hospital in Goiás (GO). These settings were chosen because of the common use of peripheral venous devices during treatment and because they were the researchers' places of work. The recommendations regarding the minimum size of participants to enable factor analysis[27] were considered, of at least five to ten times the number of variables, ensuring, for small scales, a total of 100 or more participants.

The criteria for inclusion of participants in this stage were: age greater than or equal to 18 years, being in intravenous therapy by short peripheral venous catheter over needle. Diverse populations exposed to different risks of phlebitis were included in order to capture signs and symptoms of phlebitis with potentially distinct evolution.

Patient data were collected by members of the research team, who were previously trained to assess the clinical criteria for phlebitis. Recording was performed electronically ([Open Data Kit](#)) or on printed instruments, identical to the electronic forms, depending on the resource available in the research setting.

The first 30 patients from Minas Gerais were considered as pre-test. Given that the instrument was well understood, data collection was continued. Also, considering that there were no changes, the 30 patients of the pre-test were used in the evaluation of the total sample.

The collected data were: age (years), sex (male or female), catheter caliber (gauge), insertion site (dorsum of the hand, forearm, antecubital fossa, arm), length of catheter stay (hours), signs and symptoms of phlebitis and degree of phlebitis (0 to 4) according to the *Escala Portuguesa de Flebite* - Version adapted for Brazil. There were no losses or refusal of patients to participate in the study. Descriptive statistical analysis (absolute and relative frequencies) was performed for demographic, catheter and phlebitis data.

The psychometric properties tested were reliability and construct validity. Data were processed using R software (version 4.3.0, R Core Team, 2020, Vienna, Austria). Signs and symptoms of phlebitis are dichotomous items (present *versus* absent). Bartlett's test of sphericity tested the suitability of the data for factoring and the Kaiser-Meyer-Olkin (KMO) test verified the suitability of the sample for factor analysis. Significant Bartlett's test of sphericity values ($p < 0.05$) indicate that exploratory factor analysis can proceed[28], KMO values above 0.6 are considered reasonable[29] and the minimum factor loading to consider an item fit for the domain was 0.50[26].

Construct validity was assessed by exploratory factor analysis, since it was the first evaluation of the scale in Brazil, and it was decided not to establish restrictions on the estimation or number of components/factors. Thus, exploratory factor analysis was conducted with factor extraction by principal components and rotation by the varimax method to identify the number of factors. The

minrank factorial method and rotation by the orthogonal varimax method were used to calculate the factor loadings of the proposed model. Reliability was assessed using Cronbach's alpha (α) and McDonald's omega (Ω) coefficients. Cronbach's alpha coefficient values between 0.60 and 0.75 were considered moderate and above 0.75 considered high and very high[30]. The significance level was 5%.

The study was approved by the Research Ethics Committees of the institutions involved (opinion numbers 4.433.582 and 3.643.747).

RESULTS

Cross-cultural adaptation

Of the twelve nurses invited to participate in the expert committee, ten responded to the instrument: two were studying for a master's degree, two for a doctorate degree, and six hold PhD in Nursing with published studies on peripheral venous catheters, and all had clinical experience in peripheral vein puncture and phlebitis evaluation. Some terms or expressions did not present agreement ≥ 80.0% (Table 1). In these cases, the experts' suggestions were analyzed by the researchers, and version 1 of the *Escala Portuguesa de Flebite* - Version adapted for Brazil was developed.

Table 1 - Comparison between the Portuguese Scale and Version 1, in relation to terms or expressions with agreement lower than 80.0% among experts and their suggestions for changes, Viçosa, Minas Gerais, Brazil, 2019

Grade	Terms or expressions - Portuguese Phlebitis Scale	Experts' suggestions for version 1
1	Pain at access site or areas adjacent to the catheter during administration of solution or medication OR	Pain at access site or areas adjacent to **the** catheter **insertion** during administration of solution or medication OR
2	Pain at access site AND edema and erythema	Pain at access site AND **Erythema AND/OR edema**
3	Pain at access site AND erythema OR edema, AND Streak formation along the vein pathway	Pain at access site AND **Erythema AND/OR edema AND** Streak formation along the **course of the vein**
4	Streak formation along the vein pathway	Streak formation along the **course of the vein AND**

Note: in bold the adapted items.

Cognitive Debriefing

In this stage, Version 1 of the *Escala Portuguesa de Flebite* - Version adapted for Brazil was evaluated by focus group (n = 12). Three nursing professors and nine nurses participated. The professors were PhDs in nursing, with 14 to 18 years of training, with clinical experience in venipuncture and teaching in nursing. The nine nurses had an average of 6.5 years of nursing training (2-11 years), with two working in intensive care unit (22.2%), four in emergency departments (44.4%) and three in medical-surgical unit (33.3%). The 12 participants reported no difficulty in understanding the terms or expressions of the scale (100%) and did not make any suggestions for changes.

The authors of the Portuguese version analyzed the version adapted for Brazil (Table 2) and agreed with the modifications, considering that the changes were understandable, preserving the original meaning.

Psychometric properties of the Escala Portuguesa de Flebite - Brazilian adapted version

A total of 244 patients took part in this phase, whose demographic data and characteristics related to venipuncture, presence and signs of phlebitis are shown in Table 3.

Bartlett's test of sphericity was statistically significant (p < 0.001), suggesting that factor analysis is applicable to the study's data. The sample was adequate for the factor analysis of the scale (KMO = 0.603).

One of the aims of exploratory factor analysis is to reduce the number of parameters for the number of psychological constructs, allowing both the extraction of factors and the selection of the number of items in each factor. When extracting factors, methods are used that examine the correlation/covariance between all variables and seek to extract a latent variable from the measured variables. Since it is possible to extract as many factors as the number of items, other analyses must be used to know which factors will be retained for subsequent analyses. Thus, in this study, the eigenvalues of the main factors for the questionnaire items were evaluated (Figure 1).

According to the Kaiser criterion[31,32], there is only one factor, since only the first factor has an eigenvalue greater than one. When considering the other methods, both by reading the graph (*Scree Plot*) and parallel analysis, methods proposed by Horn[33], we have that the ideal number of factors is also one.

Table 4 presents the factor loadings, which were greater than 0.70, indicating that the items belong to the factor. The proportion of variance explanation was 0.809.

Rev. Eletr. Enferm., 2023; 25:74036, 1-11

5

Table 2 - Phlebitis Scale, *Escala Portuguesa de Flebite* and the Version adapted for Brazil

Grade	Phlebitis Scale* Clinical criteria	Escala Portuguesa de Flebite** Clinical criteria	Escala Portuguesa de Flebite - Version adapted for Brazil Clinical criteria
0	No symptoms	No symptoms	No symptoms
1	Erythema at access site with or without pain	Pain at access site or areas adjacent to the catheter during administration of solution or medication¥ OR Erythema at the access site with or without pain	Pain at access site or areas adjacent to **the** catheter **insertion** during administration of solution or medication OR Erythema at the access site with or without pain
2	Pain at access site with erythema and/or edema	Pain at access site with erythema or edema	Pain at access site AND **Erythema AND/OR edema**
3	Pain at access site with erythema Streak formations Palpable venous cord	Pain at access site with erythema or edema Streak formation along the vein pathway Palpable venous cord	Pain at access site AND **Erythema AND/OR edema AND** Streak formation along the **course of the vein AND** Palpable venous cord
4	Pain at access site with erythema Streak formations Palpable venous cord greater than 1 inch in length Purulent drainage	Pain at access site with erythema and/or edema Streak formation along the vein pathway Palpable venous cord > 2.5 cm long Purulent drainage	Pain at access site AND **Erythema AND/OR edema AND** Streak formation along the **course of the vein AND** Palpable venous cord > 2.5 cm long E Purulent drainage

Note: * Infusion Nurses Society (Norwood, Massachusetts, The United State of American);** Braga, Salgueiro-Oliveira, Henriques, Rodrigues, Rodrigues, Pereira et al. (2016);¥ In the adaptation of the Phlebitis Scale to European Portuguese, it was considered that the original scale presented a limitation, since it raised doubts of interpretation in relation to grade 1 and 2 of phlebitis, since all other descriptions begin with a reference to pain.

Table 3 - Characterization of patients (n = 244) regarding demographic data and data related to venipuncture, presence and signs of phlebitis, Juiz de Fora, Minas Gerais, Goiânia, Goiás, Brazil, 2019 – 2020

Variables	Surgical/Obstetric Clinic (MG) (n=189) n (%)	Chemotherapy Clinic (GO) (n=55) n (%)	Total (n=244) n (%)
Age (years)			
< 40	127 (67.2)	7 (14.6)	134 (54.9)
40 – 59	57 (30.2)	30 (54.5)	87 (35.7)
60 - 79	5 (2.6)	17 (30.9)	22 (9.4)
Mean (SD), min-max	34.4 (10.9), 18 – 73	52.8 (12.0), 26 – 76	38.0 (17.0), 18 – 76
Median (IQ - 3IQ)	32 (IQ 25 - 41)	52 (IQ 43 - 61)	37 (IQ28-46)
Sex			
Female	189 (100)	35 (63.6)	224 (91.8)
Male	0 (0.0)	20 (36.4)	20 (8.2)
Catheter Gauge			
16G	6 (3.2)	0 (0.0)	6 (2.4)
18G	107 (56.6)	0 (0.0)	107 (43.9)
20G	48 (25.4)	0 (0.0)	48 (19.7)
22G	10 (5.3)	26 (47.3)	36 (14.8)
24G	0 (0.0)	29 (52.7)	29 (11.9)

Table 3 - Characterization of patients (n = 244) regarding demographic data and data related to venipuncture, presence and signs of phlebitis, Juiz de Fora, Minas Gerais, Goiânia, Goiás, Brazil, 2019 – 2020

Conclusion.

Variables		Surgical/Obstetric Clinic (MG) (n=189) n (%)	Chemotherapy Clinic (GO) (n=55) n (%)	Total (n=244) n (%)
Insertion site				
Back of hand		105 (55.6)	44 (80.0)	149 (61.1)
Forearm		39 (20.6)	10 (18.2)	49 (20.1)
Antecubital fossa		40 (21.2)	1 (1.8)	41 (16.8)
Arm		5 (2.6)	0 (0.0)	5 (2.0)
Length of stay of the catheter at the time of data collection - Hours				
0 < 6		0 (0.0)	12 (21.8)	12 (4.9)
6 < 12		32 (16.9)	28 (50.9)	60 (24.6)
12 < 24		147 (77.8)	9 (16.4)	156 (63.9)
24 < 36		5 (2.6)	0 (0.0)	5 (2.0)
36 < 48		3 (1.6)	0 (0.0)	3 (1.2)
48 < 60		2 (1.1)	0 (0.0)	2 (0.8)
Signs & Symptoms of phlebitis				
Pain	No	68 (35.98)	25 (45.45)	93 (38.11)
	Yes	121 (64.02)	30 (54.55)	151 (61.89)
Edema	No	90 (47.62)	53 (96.36)	143 (58.60
	Yes	99 (52.38)	2 (3.64)	101 (41.40)
Erythema at the access site	No	70 (37.04)	51 (92.73)	121 (49.60)
	Yes	119 (62.96)	4 (7.27)	123 (50.40)
Palpable venous cord	No	171 (90.48)	55 (100.00)	226 (92.62)
	Yes	18 (9.82)	0 (0.00)	18 (7.38)
Streak formation along the course of the vein	No	175 (92.59)	55 (100.00)	230 (94.26)
	Yes	14 (7.41)	0 (0.00)	14 (5.74)
Purulent drainage	No	189 (100.00)	55 (100.00)	244 (100.0)
	Yes	0 (0.00)	0 (0.00)	0
Grade of phlebitis				
0		63 (33.33)	23 (41.82)	86 (35.25)
1		28 (14.81)	31 (56.36)	59 (24.18)
2		68 (35.98)	1 (1.82)	69 (28.28)
3		30 (15.87)	0 (0.00)	30 (12.30)
4		0 (0.00)	0 (0.00)	0 (0.00)

Rev. Eletr. Enferm., 2023; 25:74036, 1-11

7

Figure 1 - Eigenvalues of the main factors of the items under study (n = 244)
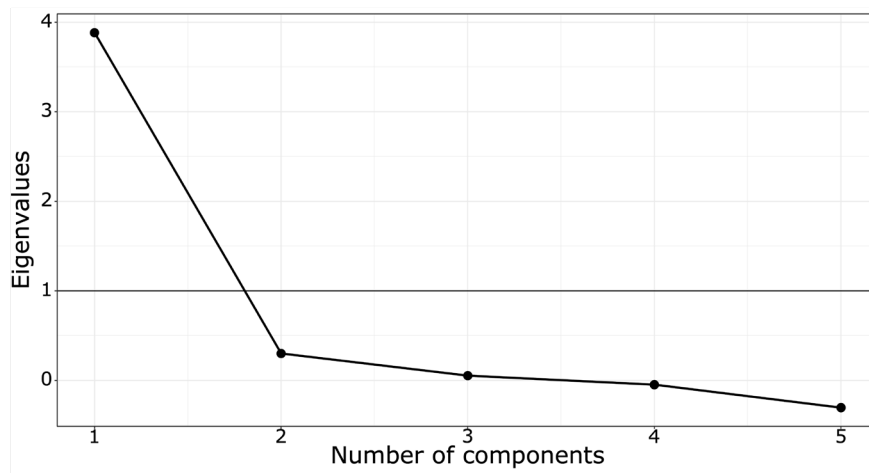
Table 4 - Factor loadings, communities, KMO and internal consistency values of the items under validation (n = 244)

Item	Factor Load	Commonalities	KMO[a]	Cronbach's α [b] (95% CI)	McDonald's Ω[c] (95% CI)
Pain	0.985	0.971	0.699	0.674 (0.602; 0.736)	0.812 (0.770; 0.848)
Erythema at the access site	0.989	0.978	0.670	0.618 (0.533; 0.691)	0.736 (0.677; 0.7861)
Edema	0.924	0.854	0.609	0.656 (0.580; 0.722)	0.806 (0.763; 0.843)
Palpable venous cord	0.743	0.553	0.490	0.799 (0.755; 0.838)	0.866 (0.837; 0.892)
Streak formation along the course of the vein	0.831	0.691	0.510	0.802 (0.758; 0.840)	0.863 (0.832; 0.889)
Total				0,771 (0,723; 0,814)	0,853 (0,822; 0,881)

Note: [a] KMO - Kaiser-Meyer-Olkin; [b] Cronbach's α – alfa of Conbach; [c] McDonald's Ω – omega of McDonald.

Cronbach's alpha (α) coefficient for all items within the domain was 0.771 (95% CI = 0.722 - 0.813). As for McDonald's ômega (Ω), the overall coefficient was 0.853 (95% CI = 0.822- 0.880). In both tests, the coefficients reflect high reliability values.

DISCUSSION

The process of cross-cultural adaptation of scales is essential for their use in clinical practice and research in another country, even if the language is the same, as in the case of Portuguese in Portugal and Brazil. The aim is to ensure the quality of the scales and achieve idiomatic, conceptual, semantic, and cultural equivalence[23]. In the present study, two expert committees were involved in the cross-cultural adaptation of the *Escala Portuguesa*

de Flebite, allowing a robust process of adequacy for use by nurses and other health professionals in this country.

The profile of the Brazilian experts who served on the committees involved in the cross-cultural adaptation stage in the present study is similar to that of those who participated in the adaptation of the original instrument into Portuguese from Portugal, including representatives of teaching, research and nursing care, contributing to validation from different perspectives[2]. This diversity of expertise is essential to ensure the quality of cross-cultural adaptation. In this study, the experts provided a small semantic adjustment by including the words "catheter insertion" in grade 1 (Pain at access site or areas adjacent to the catheter insertion during the administration of solution or medication) and replacing the word "pathway" (Streak formation along the

vein pathway) with "course of the vein" in the signs of phlebitis in grades 3 and 4 (Streak formation along the course of the vein). These changes are essential to ensure correct understanding and assessment of the signs and symptoms of phlebitis in patients with a peripheral venous catheter.

Considering patient safety, using a validated scale for the periodic and systematized assessment of the insertion site of a venous catheter may assist nurses in clinical reasoning. That is, the use of the scale offers parameters for decision-making regarding catheter removal when the first signs and symptoms of phlebitis (pain, erythema, and edema) are identified, preventing progression to degrees of more significant tissue impairment. Additionally, the analysis of phlebitis incidence rates and their respective degrees can be used as an indicator of quality of care, directing the implementation of quality improvement projects that promote patient safety through educational actions.

The patients and professionals who participated in this adaptation and validation study represent individuals from two Brazilian regions, from different clinical settings (inpatient and outpatient units), and exposed to different risk factors for the development of phlebitis (for example, considering the solutions or medications administered by venous catheters). This diversity increases the external validity of the scale. Despite the differences, it is worth noting that the patients who participated in the evaluation of the psychometric properties of the scale resemble the profile of those in other Brazilian studies that evaluated phlebitis in terms of age, sex, and location (hospital and clinic)[7,8,10-12]. The instrument must be valid for use in different clinical settings and among patients with different risks.

The psychometric tests indicate evidence of construct validity and internal consistency of the *Escala Portuguesa de Flebite* - Version adapted for Brazil. When performing exploratory factor analysis, it was observed that the factor analysis was adequate and that the items grouped into a single factor. The high factor loading values for all items indicate that the items belong to the same factor. Together, the items explain the variance in an excellent value (cumulative variance equal to 0.809). Also, the communality values of the items, all above 0.5, indicate the high explanatory power of the items by the factor. The result of the exploratory factor analysis confirms what is observed in the clinic, namely that the signs of inflammation observed in cases of phlebitis are strongly related.

The good internal consistency stands out, reinforcing the reliability of the scale. The Cronbach's α coefficient may have presented a moderate-high value due to the small number of items in the scale. However, it is noteworthy that the value of McDonald's Ω coefficient was high. Examining the reliability of the pain, erythema, and edema items individually, reasonable values were noted. It was observed that the value of Cronbach's alpha coefficient could be better if the other items (palpable venous cord and streak formation along the course of the vein) were excluded. However, the improvement in reliability by excluding the items palpable venous cord and streak formation along the course of the vein may be related to the low identification of these items in the sample studied. Once again, reflecting on the clinical relevance of the signs and symptoms of phlebitis, the removal of one or another symptom may interfere with the quality of the nursing assessment and identification of phlebitis.

It is understood that, when conducting the present study, the frequent evaluation of the peripheral venous catheter insertion site in patients has caused bias since the researchers followed strict protocol for data collection. However, this frequent evaluation is positive for patients, as the progression of phlebitis was avoided by identifying the first signs and symptoms. From the scientific/statistical point of view, this possible bias due to frequent evaluation made the analysis difficult because there were no cases of patients with purulent drainage and few cases with palpable venous cords and streak formation along the course of the vein. Similar results were reported by researchers in a study conducted in Portugal[17] using the *Escala Portuguesa de Flebite* and another study conducted in Brazil[10] using another scale, freely translated by the authors, but with the same criteria for grade 4. Future studies should be conducted to confirm the unidimensional theoretical model identified in the present study through confirmatory factor analysis, and it is suggested to evaluate the intra and interobserver reliability of the signs and symptoms of phlebitis. Also, due to the extension of Brazil, participants representing different regions of Brazil are encouraged.

Despite the rigor in assessing the idiomatic equivalence process and the considerable sample for testing psychometric properties, the cross-cultural adaptation of the Phlebitis Scale from the Portuguese version and not from the original English version can be considered a limitation of the study. In addition, the recruitment of experts can be seen as a limitation since it mainly occurred in one region of the country, which may be a weakness of the study due to possible cultural differences between Brazilian regions and intentional sampling. However, it is noteworthy that the terms of the phlebitis scale are technical, reducing the impact of this issue. Furthermore, the similarities between Brazilian and

Rev. Eletr. Enferm., 2023; 25:74036, 1-11

9

Portuguese are greater than the differences, and, considering that the *Escala Portuguesa de Flebite* followed the translation and back-translation steps from the original English instrument, it reduces the risk of misunderstandings regarding the object of the original scale.

Systematic use of this tool could help to identify evidence of phlebitis and establish a baseline for interventions and comparative studies at national and international levels.

CONCLUSIONS

The *Escala Portuguesa de Flebite* - Version adapted for Brazil, presents construct validity and good internal consistency. Thus, nursing and health professionals working in practice, teaching and research now have an instrument for the assessment of phlebitis properly adapted to the country's culture.

Financing

This research received financial support from Blugold Commitment/University of Wisconsin - Eau Claire Student-Faculty International Fellows Program for Research, Service and Creative Activity.

Conflict of Interest

None.

Author contributions - CRediT

LMB: conceptualization; data curation; formal data analysis; methodology; project administration; supervision; validation; visualization; writing - original draft and writing - review and editing.

DDCFM: conceptualization; data curation; formal data analysis; funding acquisition; investigation; methodology; project administration; supervision; validation; visualization; writing - original draft and writing - review and editing.

ACCMQ: conceptualization; writing - original draft and writing - review and editing.

FCR: data curation; formal data analysis; resources; writing - original draft and writing - revision and editing.

HSD: conceptualization; data curation; formal data analysis; investigation; methodology; project administration; resources; supervision; validation; visualization; writing - original draft and writing - review and editing.

CAS: conceptualization; data curation; formal data analysis; investigation; project administration; resources; supervision; writing - original draft and writing - review and editing.

PP: formal data analysis; visualization; writing - original draft and writing - revising and editing.

SLVS: data curation; formal data analysis; investigation; project administration; resources; supervision; writing - original draft and writing - review and editing.

REFERENCES

1. Maki DG, Ringer M. Risk factors for infusion related phlebitis with small peripheral venous catheters: a randomized controlled trial. Ann. Intern. Med. 1991;114(10):845-54.

2. Braga LM, Salgueiro-Oliveira AS, Henriques MAP, Rodrigues MA, Rodrigues CJV, Pereira SAG, et al. Tradução e adaptação da *Phlebitis Scale* para a população portuguesa. Revista de Enfermagem Referência. 2016 Oct/Nov;IV(11):101-9. https://doi.org/10.12707/RIV16048

3. Nickel B. Peripheral Intravenous Access: Applying Infusion Therapy Standards of Practice to Improve Patient Safety. Crit. Care Nurs. 2019;39(1):61-71.

4. Ray-Barruel G, Polit DF, Murfield JE, Rickard CM. Infusion phlebitis assessment measures: a systematic review. J. Eval. Clin. Pract. 2014;20(2):191-202.

5. Atay S, Sen S, Cukurlu D. Phlebitis-related peripheral venous catheterization and the associated risk factors. Niger J Clin Pract. 2018;21(7):827-31.

6. Göransson KE, Johansson E. Prehospital peripheral venous catheters: A prospective study of patient complications. J. Vasc. Access. 2012;13(1):16-21.

7. Silva WCR, Waisberg J, Silva GM, Araújo SAN. Indicador de flebite e cuidados de enfermagem em crianças e adolescentes com cateter central de inserção periférica. Glob Acad Nurs. 2020 Dec 31;1(3):e44. https://doi.org/10.5935/2675-5602.20200044

8. Jacinto AKL, Avelar AFM, Wilson AMMM, Pedreira MLG. Phlebitis associated with peripheral intravenous catheters in children: study of predisposing factors. Esc. Anna. Nery. 2014 Apr-June;18(2):220-6. https://doi.org/10.5935/1414-8145.20140032

9. Lee S, Kim K, Kim JS. A model of phlebitis associated with peripheral intravenous catheters in orthopedic inpatients. Int J Environ Res Public Health. 2019;16(18):3412.

10. Urbanetto JS, Muniz FOM, Silva RM, Freitas APC, Oliveira APR, Santos JCR. Incidência de flebite e flebite pós-infusional em adultos hospitalizados. Rev. Gaucha Enferm. 2017;38(2):e58793. https://doi.org/10.1590/1983-1447.2017.02.58793

11. Rodrigues CC, Guilherme C, Costa Júnior ML, Carvalho EC. Fatores de risco para trauma vascular durante a quimioterapia antineoplásica: contribuições do emprego do rsico relativo. Acta paul. enferm. 2012 July 12;25(3):448-52. https://doi.org/10.1590/S0103-21002012000300020

12. Simões AMN, Vendramim P, Pedreira MLG. Fatores de risco para flebite relacionada ao uso de cateteres intravenosos periféricos em pacientes adultos. Rev. esc. enferm. USP.

2022 June 10;56:e20210398. https://doi.org/10.1590/1980-220X-REEUSP-2021-0398pt

13. Ray-Barruel G, Cooke M, Mitchell M, Chopra V, Rickard CM. Implementing the I-DECIDED clinical decision-making tool for peripheral intravenous catheter assessment and safe removal: protocol for an interrupted time-series study. BMJ Open. 2018;8(6): e021290. https://doi.org/10.1136/bmjopen-2017-021290

14. Lind J, Danski MTR, Lenzi L, Pedrolo E, Schwanke AA, Johann DA. Cateter periférico com sistema fechado de infusão: implementação de tecnologia. Rev enferm UFPE on line. 2019 May;13(5):1208-15. https://doi.org/10.5205/1981-8963-v13i5a239008p1208-1215-2019

15. Miliani K, Taravella R, Thillard D, Chauvin V, Martin E, Edouard S, et al. Peripheral Venous Catheter-Related Adverse Events: Evaluation from a Multicentre Epidemiological Study in France (the CATHEVAL Project). PloS One. 2017 Jan 3;12(1):e0168637. https://doi.org/10.1371/journal.pone.0168637

16. López-López C, Collados-Gómez L, García-Manzanares ME, Segura-Paz AM, López-Gutierrez AM, Pérez-García S. Estudio de cohortes prospectivo sobre el manejo y lascomplicaciones del catéter venoso periférico en pacientes ingresados en Medicina Interna. Rev. Clin. Esp. 2021 Mar;221(3):151-6. https://doi.org/10.1016/j.rce.2020.05.005

17. Nobre ASP, Martins MDS. Prevalência de flebite da venopunção periférica: fatores associados. Revista de Enfermagem Referência. 2018 Jan/Feb/Mar;IV(16):127-38. https://doi.org/10.12707/RIV17058

18. Furlan MS, Lima AFC. Avaliação da ocorrência do evento adverso flebite em pacientes de uma Unidade de Internação Clínica. Rev. esc. enferm. USP. 2021;55:e03755. https://doi.org/10.1590/S1980-220X2020017103755

19. 53. PHLEBITIS. J Infus Nurs [Internet]. 2006 Jan [cited 2023 Mar 14];29(1):S58-9. Available from: https://journals.lww.com/journalofinfusionnursing/Citation/2006/01001/53__PHLEBITIS.58.aspx

20. Marôco JP, Campos JADB, Vinagre MG, Pais-Ribeiro JL. Adaptação Transcultural Brasil-Portugal da Escala de Satisfação com o Suporte Social para Estudantes do Ensino Superior. Psicol. Reflex. Crit. 2014;27(2):247-56. https://doi.org/10.1590/1678-7153.201427205

21. Beaton D, Bombardier C, Guillemin F, Ferraz MB. Recommendations for the Cross-Cultural Adaptation of the DASH & QuickDASH Outcome Measures. Institute for Work & Health [Internet]. 2002, 2007 [cited 2023 Mar 14]. Available from: https://dash.iwh.on.ca/sites/dash/files/downloads/cross_cultural_adaptation_2007.pdf.

22. Meadows K. Cognitive interviewing methodologies. Clinical Nursing Research. 2021 May;30(4):375-9.

23. Echevarría-Guanilo ME, Gonçalves N, Romanoski PJ. Psychometric properties of measurement instruments: conceptual basis and evaluation methods - Part II. Texto contexto - enferm. 2019 Dec 9;28:e20170311. https://doi.org/10.1590/1980-265X-tce-2017-0311

24. Costa BRL. Bola de Neve Virtual: O uso das redes sociais virtuais no processo de coleta de dados de uma pesquisa científica. RIGS [Internet]. 2018 Jan-Apr [cited 2022 Nov 18];7(1):15-37. Available from: https://periodicos.ufba.br/index.php/rigs/article/view/24649

25. Yusoff MSB. ABC of content validation and content validity index calculation. Education in Medicine Journal. 2019 June 28;11(2):49–54. https://doi.org/10.21315/eimj2019.11.2.6

26. Perroca MG, Gaidzinski RR. Sistema de classificação de pacientes: construção e validação de um instrumento. Rev. Esc. Enf. USP. 1998 Aug;32(2):153-68. https://doi.org/10.1590/S0080-62341998000200009

27. Hair Jr. JF, Black WC, Babin, BJ, Anderson RE. Multivariate Data Analysis. 8th ed. Independence, Kentucky: Cengage Learning EMEA; 2018.

28. Tabachnick BG, Fidell LS. Using multivariate statistics. 5th ed. Boston: Allyn and Bacon; 2007.

29. Kaiser HF, Rice J. Little jiffy, Mark IV. Educ Psychol Meas. 1974.34.111-7.

30. Freitas ALP, Rodrigues SG. Avaliação da confiabilidade de questionários: uma análise utilizando o coeficiente alfa de Cronbach. In: Anais do 12º Simpósio de Engenharia de Produção, 2005, Bauru-SP, Brasil [Internet]. 2005 [cited 2023 Mar 14]. Available from: https://simpep.feb.unesp.br/anais/anais_12/copiar.php?arquivo=Freitas_ALP_A%20avalia%E7%E3o%20da%20confiabilidade.pdf

31. Kaiser HF. The application of electronic computers to factor analysis. Educ Psychol Meas. 1960 Apr;20(1):141-51. https://doi.org/10.1177/001316446002000116

32. Kaiser HF. A second generation little jiffy. Psychometrika. 1970 Dec;35(4):401-15. https://doi.org/10.1007/BF02291817

33. Horn JL. A rationale and test for the number of factors in factor analysis. Psychometrika. 1965 June;30(2):179–85. https://doi.org/10.1007/BF02289447

Rev. Eletr. Enferm., 2023; 25:74036, 1-11

11