

# Transcultural adaptation of the Infiltration Scale into the Portuguese culture

Adaptação transcultural da *Infiltration Scale* para o português

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## Abstract

**Objective:** To translate, adapt and evaluate the psychometric properties of the Infiltration Scale for the Portuguese culture.

**Methods:** A methodological study of trans-cultural adaptation to evaluate the psychometric properties of the Infiltration Scale, conducted in a cohort study with 110 adults undergoing intravenous therapy.

**Results:** In the translation and cultural adaptation, language adjustments were discussed by researchers and a panel of experts, achieving an agreement of 85.71% for clinical criteria, except for "Possible numbness". The scale identified infiltration in 48 patients (60% prevalence). Edema was the most evident sign in the insertion site and areas adjacent to the venous catheter. The internal consistency, determined by Cronbach's alpha, was 0.85.

**Conclusion:** The scale adapted to the Portuguese culture presented linguistic equivalence to the original, proved valid and reliable, with good internal consistency for assessing infiltration. The systematic evaluation of infiltration using the scale can support decision-making and the implementation of preventive measures.

## Resumo

**Objetivo:** Traduzir, adaptar e avaliar as propriedades psicométricas da *Infiltration Scale* para a cultura portuguesa.

**Métodos:** Estudo metodológico de adaptação transcultural com avaliação das propriedades psicométricas da *Infiltration Scale* em uma coorte com 110 adultos submetidos à terapia intravenosa.

**Resultados:** Na tradução e adaptação cultural, as adequações linguísticas foram discutidas pelos investigadores e um painel de especialistas, havendo concordância em 85,71% dos critérios clínicos, exceto "Possible numbness". A escala captou infiltração em 48 pacientes (prevalência de 60%). O edema foi o principal sinal evidenciado na inserção e áreas adjacentes ao cateter venoso. A consistência interna, determinada pelo alfa de Cronbach, foi de 0,85.

**Conclusão:** A escala adaptada para a cultura portuguesa apresentou equivalência linguística em relação à original, mostrou-se válida e fidedigna, com boa consistência interna para avaliar a infiltração. A avaliação sistemática da infiltração com recurso a escala poderá subsidiar a tomada de decisão e implementação de medidas preventivas.

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## Introduction

Infiltration is a complication related to intravenous therapy, and has been a major cause for removal of peripheral venous catheters prior to completing treatment.<sup>(1-3)</sup> It is defined as the inadvertent administration of solutions and non-vesicant medications into tissue close to the venous catheter insertion, due to breakage or perforation of the vein. A leakage is an infiltration that occurs due to inadvertent administration of solution or vesicant medication, which represents a risk for progressive tissue damage, and which may become apparent within days or weeks after exposure.<sup>(4-7)</sup> Regardless of the causal mechanism of tissue injury, the intervention is determined by the pharmacological characteristics of the infused solution, and involves an interdisciplinary team of nurses, physicians and pharmacists.<sup>(7,8)</sup>

Some problems hamper the process of infiltration management, such as failure to identify the problem, due to insufficient number of professionals, high staff turnover and lack of knowledge about effective treatments, related to limitations of research, among others.<sup>(7)</sup>

However, in order to reduce the risk of infiltration, best practices for intravenous therapy must be implemented. Among these, the following stand out: monitoring the catheter insertion site, implementing guidelines and protocols for prevention, early detection of the first signs and symptoms, and properly intervening on the problem, to limit damage and prevent serious adverse effects.<sup>(4-6,8-11)</sup>

A rating scale is recommended for assessing and determining the extent, standardizing the description of the infiltration, documenting the severity of the problem, and evaluating the degree and prevalence of infiltration.<sup>(5,6,9,10)</sup> Currently, scales have also been used as indicators to assess the outcomes of care and to support the implementation of interventions.<sup>(12)</sup> This same logic is proposed by the *American Nurses Association*, in the safety aspects related to intravenous therapy, especially in the evaluation of the infiltration rate of peripheral ve-

nous catheters in pediatrics, and the catheter-related infection rate.<sup>(13)</sup>

The *Infusion Nurses Society*<sup>(5)</sup> published the *Infiltration Scale*, organized into four levels, to classify infiltration. Level zero represents the absence of infiltration, and level four represents the most severe. The scale describes the clinical criteria to be evaluated for each level of infiltration, such as skin color, skin temperature to touch, pain, extent and depth of edema, abnormal sensitivity, circulatory impairment and infiltration of blood, irritant solution or vesicant. The identification of one clinical criterion is sufficient to characterize the level of infiltration, and the recommendation for the removal of a peripheral venous catheter.<sup>(5)</sup>

An investigation assessed the psychometric properties of the *Infiltration Scale* based on the following dimensions: feasibility, acceptability, reliability and concurrent validity. It was found that the scale was easy to administer, with rapid implementation (mean of 1.3 minutes), and was clinically appropriate.<sup>(14)</sup> The authors also indicated the need to make other psychometric studies to assess the validity and reliability of the scale.

To date, studies have not been identified on the transcultural adaptation of the *Infiltration Scale* for the Portuguese population. Thus this investigation was conducted, in order to translate, adapt and evaluate the psychometric properties of the *Infiltration Scale* to the Portuguese culture.

## Methods

A methodological, transcultural adaptation study of the *Infiltration Scale*<sup>(5)</sup> to the Portuguese of Portugal was conducted, to evaluate psychometric properties and to assess its validity and reliability in clinical practice.

The process of translation and transcultural adaptation met international guidelines,<sup>(15,16)</sup> following five phases: translation into Portuguese; version synthesis; back translation; preliminary version in Portuguese; proposal for a final version by panel of

experts. This process followed the authorization of the *Infusion Nurses Society*.<sup>(5)</sup>

### Phase I and Phase II

The Infiltration Scale was independently translated from the original language into the Portuguese of Portugal by two bilingual translators, whose native language was Portuguese. The translations obtained were compared and the items that did not reach consensus on translation regarding the terms were discussed by the research team (two professors with doctorates in nursing, with experience in research on vascular trauma; two professors, with doctorates in nursing with experience in the process of scale validation, and one master's-prepared professor, who was a doctoral student in nursing, with experience in intravenous therapy) and the translators. After achieving linguistic appropriateness, the first version of the Infiltration Scale translated into Portuguese (synthetic version) was developed. Two bilingual translators (English as native language) back-translated this version into English, independently. The translations and back-translations were analyzed by the same research team to evaluate ambiguities and discrepancies; to achieve cross-cultural equivalence of the scale into the Portuguese context; and to achieve consensus; a draft was developed.

### Phase III and IV

The preliminary version in Portuguese, and the original in English, were analyzed and compared by a panel of seven experts (three nurses from a medical clinic service, with between 10 and 20 years experience in the venipuncture process; one Brazilian nursing professor and one professor of Portuguese, both doctorally prepared, with experience in vascular trauma research; a doctorally prepared professor of Portuguese, with expertise in management and research, and one of the translators, who participated in the back translation phase, and who had a nursing degree) for semantic, idiomatic, experiential and conceptual verification into the Portuguese. The final version of the "*Portuguese Infiltration Scale*" achieved a level of agreement of 85.71% from the panel.

### Phase V and VI

The final version was applied in a cohort of 110 patients of a medical service in the central region of Portugal. The study included patients older than 18 years with intravenous therapy for peripheral venous catheter; those with central venous catheter or who refused to participate were excluded. The patients were followed from admission into the service until the end of intravenous therapy (July-September, 2015).

The data were organized and analyzed using the Statistical Package for the Social Sciences, version 21.0. A descriptive and factor analysis were performed of main components to assess the dimensionality and analysis of the internal consistency of the scale for determining the Cronbach's alpha. The significance level for the tests was 5% ( $\mu = 0.05$ ).

The study was approved by the Hospital and University of Coimbra (C.H.U.C.) Under the registration number 4907 PCA - University of Coimbra.

## Results

Two translators performed the *Infiltration Scale* translation process into the Portuguese of Portugal. Both translations approached the literal *Infiltration Scale* sense except on four criteria, requiring evaluation and adjustments by the research team, namely: "*No symptoms*", "*Gross edema > 6 inches in any direction*", "*Possible numbness*" and "*Moderate-severe pain*". This step produced the synthesized version, which was approved by the translators and submitted to back translation. Of the 16 clinical criteria, only the criterion "*Possible decreased sensitivity*" ("*Possible numbness*" and "*Possible reduction in sensitivity*") required reassessment.

The research team and one translator examined the original version, the summary version in Portuguese, the back translation, and approved the translation of "*Possible numbness*" to "*Possível dormência*".

Consensus on the draft was obtained following these steps. This version was analyzed for conceptual, semantic, idiomatic, experiential and operational equivalence, by a panel of seven experts with

clinical experience in the venipuncture process. All items of the scale were analyzed and compared with the *Infiltration Scale*. Because of clinical judgment, the translation of “Possible numbness” was changed to “Possible decreased sensitivity”. Chart 1 presents the proposed version of the Portuguese scale infiltration.

**Chart 1.** Version proposed of the Portuguese Infiltration Scale

Grau	Crítérios clínicos
0	Sem sinais e sintomas
1	Pele pálida Edema <2,5cm em qualquer direção Frio ao toque Com ou sem dor
2	Pele pálida Edema entre 2,5 e 15cm em qualquer direção Frio ao toque Com ou sem dor
3	Pele pálida, translúcida Edema extenso >15cm em qualquer direção Frio ao toque Dor leve a moderada Possível diminuição da sensibilidade
4	Pele pálida, translúcida Pele tensa, com perda de fluidos Pele descorada, com hematoma e edema Edema extenso >15 cm em qualquer direção Edema depressível dos tecidos Comprometimento circulatório Dor moderada a severa Infiltração de qualquer quantidade de produtos derivados do sangue, irritantes, ou vesicantes

The *Portuguese Infiltration Scale* version was subjected to evaluation in clinical settings with 110 patients receiving intravenous therapy, who used 517 peripheral venous catheters. The sample consisted predominantly of people over 60 years (95.5%), with a mean age of 80 years and mode of 79 years (range 18-96 years). The mean length of stay of the 517 catheters was 2.5 days (range 1 to 16 days).

The observation performed of the catheter insertion site and surrounding areas, using the *Portuguese Infiltration Scale*, enabled the identification and removal of 80 peripheral venous catheters due to infiltration (prevalence of 15.7%) in 48 patients (prevalence of 60% infiltration per patient). Sixty-seven infiltrations were documented as Grade One (83.8%), and 13 as Grade Two (16.2%). There were no Grade Three or Four infiltrations. The 48 patients presented between one to six infiltrations throughout the intravenous treatment; 28 patients

had only one infiltration, 15 had two infiltrations, two had four infiltrations, one had five infiltrations, and another had six infiltrations.

The length of stay of the catheter in the patient, beginning with the insertion of the venous catheter until the identification of infiltration, was a mean of 1.7 day (from less than a day, to 8 days), the mode was one day (40%), with a standard deviation of 1.5. Almost half of the catheters remained at least one day, or 24 hours, in the patient (55%); only 32.5% remained two or three days.

Edema was the clinical sign that differentiated the degree of infiltration (edema <2.5 cm, or from 2.5 - 15 cm in any direction); it was present in all assessments and was the essential condition to characterize the infiltration. The other clinical criteria alone did not characterize infiltration without the presence of any amount of edema.

In the evaluation of the psychometric properties of the *Portuguese Infiltration Scale*, the analysis of the adequacy of the sample was performed using the *Kayser-Meyer-Olkin Measure of Sampling Adequacy (KMO)* test, obtaining a value of 0.72 (considering a mean value between 0.7 - 0.8) with a Bartlett sphericity test ( $X^2(6) = 1066.64, p < 0.000$ ), which was statistically significant. Next, a solution with Varimax rotation was generated. Items with commonalities > 0.30 and loadings  $\geq 0.45$  were accepted, and it was not necessary to eliminate any items. The extracted solution was one-dimensional and explained 69.13% of the total variance. Thus, it was possible to state that the scale is valid and reliable for assessing the degree of infiltration (Table 1).

**Table 1.** Loadings, percentage of explained variance, commonalities (h<sup>2</sup>) and internal consistency of the Portuguese Infiltration Scale

Clinical criteria of the Portuguese Infiltration Scale	Factors, % explained variance and commonalities	
	F1 71.2%	h <sup>2</sup>
Edema <2,5cm ou entre 2,5 e 15cm em qualquer direção	0.90	0.804
Pele pálida	0.87	0.758
Frio ao toque	0.84	0.707
Dor	0.73	0.529
Cronbach's alpha	0.85	

F1 - nurse assessment

## Discussion

The limitation of this study is the lack of an evaluation strategy by two independent professionals, in order to confirm the judgment of the degree of infiltration. The sample size may also have influenced the results, as the sample ( $n$ ) may have been low and have not captured the Grade Three and Four infiltrations. In addition, this is the first study on the translation and adaptation of the *Infiltration Scale* in Portugal, and few studies on the subject were available in the literature, particularly on the method of assessment and documentation of infiltration. This fact limits the comparison of results and restricts the discussion.

The process of transcultural adaptation of the scale required grammatical adjustments, due to the cultural context and use in clinical practice, to ensure repeated measurement and to preserve the meaning of the original version. In this sense, the clinical criteria should be self-explanatory without generating doubts or ambiguities. In this regard and in accordance with the consensus reached by the research team and the expert panel, the criterion “*No symptoms*” was translated as “Sem sinais e sintomas”. It facilitates the understanding regarding the absence of signs and/or symptoms of infiltration, while “*Assintomático*” refers to the absence of symptoms of a disease, and did not make sense when translated.

For the criterion “*Moderate-severe pain*”, the terminology used by nurses in clinical practice to characterize the intensity of pain supported the translation to “*Dor moderada a severa*”, excluding the “grave” term, which does not characterize pain intensity.

The clinical criterion “*Deep pitting tissue*” was translated as “*Edema depressível dos tecidos profundos*.” According to the analysis of the research team and the translators, the word “profundo” was not appropriate. According to one of the translators, “*Deep pitting edema*” is an idiom referring to the depression created in the tissues when evaluating the depth of edema. From this discussion, the “profundo” word was then excluded.

The analysis of the scale by the panel of experts enabled the necessary adjustment in the translation of the criterion “*Possible numbness*” to “*Possível diminuição da sensibilidade*”. For the remaining items of the scale, 100% agreement in semantic, idiomatic, conceptual and experimental equivalence of the terms was achieved.

The participation of a translator with knowledge of the technical health terms, nurses and nursing professors/researchers with expertise in intravenous therapy was extremely important to make changes or eliminate insignificant terms, during the process of trans-cultural adaptation of the *Infiltration Scale* to the Portuguese culture.

A scale translated and adapted to the Portuguese context that characterized the infiltration as relevant is important, in particular due to the risk that inadvertent administration of medications or solutions in the tissues may generate. Therefore, the use of valid and reliable scales based on well-designed clinical criteria should be the strategy followed to monitor, assess, measure and document the degree of infiltration, in addition to supporting the implementation of interventions,<sup>(5,6,9,10)</sup> as infiltration may lead to more serious consequences such as tissue necrosis, when irritating and/or vesicant solutions are infused.<sup>(6,7,8,17)</sup>

The use of a scale enables early identification of the first signs and symptoms of infiltration, and a quick approach to the initiation of treatment and prevention of damage. The first intervention when identifying any degree of infiltration must be immediate removal of the catheter.<sup>(2,5,6,17)</sup>

The evaluation of the venous catheter insertion site and adjacent areas should not be confined to the catheter utilization period, but should be extended for at least 96 hours after its removal, because the signs and/or symptoms may appear within three weeks, and may require surgical intervention or assessment/treatment by the wound team.<sup>(5,18)</sup> It is important, as well, to evaluate catheter patency with 0.9% saline solution before the administration of medications, to identify possible signs of infiltration and prevent inadvertent infusion of medicinal products into the tissues. In case of doubt about the presence or absence of infiltration, the removal

of the catheter and its replacement by another in a distant region is recommended, preferably in the opposite limb.

The evaluation of the psychometric properties of the scale for construct validity of the study showed that the clinical criteria of the scale measured what one wanted to measure. The internal consistency, determined by a Cronbach's alpha of 0.85, indicated that the scale was valid and reliable for assessing the degree of infiltration, but studies in other realities are needed, since this is the first study in the Portuguese scenario.

The main components exploratory factor analysis found that the scale consisted of a single factor, and was one-dimensional, with high loadings, particularly for the item "edema". The increase of edema was the sign most identified by nurses at the catheter insertion site or in the surrounding areas during all infiltration assessments, and was supported by the literature.<sup>(19)</sup>

The use of the *Portuguese Infiltration Scale* in the clinical setting found inconsistency in the analysis and interpretation of the degree of infiltration. As described below, only the presence of clinical criteria to characterize infiltration generated ambiguity and doubt on the record of the degree of infiltration when "Edema" was not associated with one or more clinical criteria, as in the presence of "Pele p alida" only, or "Frio ao toque", or "Com ou sem dor", which may be present both in Grade One as well as Grade Two, and the degrees of infiltration differ depending on the extent of edema (< 2.5 cm, between 2.5 - 15 cm). The same applies to the criteria "Pele p alida, transl ucida" and "Edema extenso > 15cm em qualquer dire ao", which, when not associated with other clinical criteria, can be interpreted as Grade Three or Four; or the criterion "Frio ao toque" alone can characterize Grade One, Two, or Three. However, the clinical criterion of Grade Four, "Infiltra ao de qualquer quantidade de produtos derivados do sangue, irritantes, ou vesicantes", is unique to this level and does not depend on the extent of edema, and other signs and symptoms to be categorized on the scale.

Thus, the *Escala Portuguesa de Infiltra ao* (Chart 2), with the inclusion of the words "*podendo asso-*

*ciar-se a*", was proposed for Grades 2, 3 and 4. It could support the interpretation of the degree of infiltration, considering that the identification of edema at the insertion site or in the surrounding areas is an important condition to characterize the infiltration in these Grades. There is an exception for the clinical criteria "Infiltra ao de qualquer quantidade de produtos derivados do sangue, irritantes, ou vesicantes" in Grade 4, which alone determined this degree of infiltration, but can be associated to one or more clinical criteria.

**Chart 2.** Portuguese scale Infiltration

Grau	Cr�terios cl�nicos
0	Sem sintomas
1	- Pele p�alida - Edema <2,5cm em qualquer dire�ao - Frio ao toque - Com ou sem dor
2	Edema entre 2,5 e 15cm em qualquer dire�ao podendo associar-se a: - Pele p�alida - Frio ao toque - Com ou sem dor
3	Edema extenso >15cm em qualquer dire�ao, podendo associar-se a: - Pele p�alida, transl�ucida - Frio ao toque - Dor leve a moderada - Poss�vel diminui�ao da sensibilidade
4	Infiltra�ao de qualquer quantidade de produtos derivados do sangue, irritantes ou vesicantes podendo associar-se a: Ou Edema extenso >15cm em qualquer dire�ao podendo associar-se a: - Pele p�alida, transl�ucida - Pele tensa, com perda de flu�idos - Pele descorada, com hematoma e edema - Edema depress�vel dos tecidos - Comprometimento circulat�rio - Dor moderada a severa

## Conclusion

The scale adapted to the Portuguese culture presented linguistic equivalence to that published by the *Infusion Nurses Society*; it proved to be valid and reliable, with good internal consistency to assess infiltration in the clinical setting. The inclusion of the expression "*podendo associar-se a*" has made it a self-explanatory scale, as it facilitates the assessment process and allows for greater discriminative capacity in the assessment of the degree of infiltration.

The results with the use of the scale in clinical context allowed for the finding of a 60% prevalence of infiltration by patient, which would not have been possible to identify without such a scale. The

systematic evaluation of infiltration with the use of this scale can support nurses' decision-making and the implementation of preventive measures.

It is suggested that studies should be conducted to validate the *Portuguese Infiltration Scale* in other clinical settings, with larger samples and inter-observer evaluators, since the Grade Three and Four infiltrates were not identified in this study.

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## Collaborations

Braga LM, Parreira PMSD, Salgueiro-Oliveira AS and Henriques MAP contributed to the project design, literature review, analysis and interpretation of data and writing of the article. Arreguy-Sena C contributed to the project design, data analysis and writing of the article. All authors approved the final version to be published.

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