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ORIGINAL ARTICLE

Translation and cultural adaptation of the Screener and Opioid Assessment for Patients with Pain Revised into Brazilian Portuguese

Tradução e adaptação cultural do *Screener and Opioid Assessment for Patient with Pain Revised* para o português do Brasil

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ABSTRACT

BACKGROUND AND OBJECTIVES: The control of chronic pain using opioids is routine in palliative care. Abusive use has led to the death of many users in developed countries, a phenomenon that has been called the opioid crisis or epidemic, causing the resurgence of opioid phobia, which is worrying in countries like Brazil where pain is undertreated. The approval of the National Palliative Care Policy leads us to believe that there will be an increase in the prescription and use of opioids. To assist health teams in addressing misuse and opioid phobia, we have the SOAPP-R (Screener and Opioid Assessment for Patients with Pain Revised), which measures the risk of developing aberrant behavior related to opioid use. This tool can contribute to studies on the prevalence of misuse, give clinicians greater confidence in prescribing, and guide a more appropriate approach to patients. The objective of this study was translated and adapt the SOAPP-R into Brazilian Portuguese, without validating it.

METHODS: A prospective longitudinal methodological study, of the type of validation of health assessment instruments, with a non-probabilistic sample, following the Beaton method.

RESULTS: After the initial translation and back-translation, the consensual version was submitted to a committee of experts. There was disagreement regarding semantic equivalence in two questions, which were corrected and validated. The pre-final version was applied to 24 patients using opioids.

CONCLUSION: The pre-final version obtained can be used for validation studies due to the low rate of disagreement and the absence of suggestions for new wording.

KEYWORDS: Analgesics. Opioids, Pain.Primary health care. Palliative care. Public health.

RESUMO

JUSTIFICATIVA E OBJETIVOS: O controle da dor crônica com o uso de opioides é rotina dos cuidados paliativos. O uso abusivo tem levado à morte muitos usuários em países desenvolvidos, fenômeno que tem sido chamado de crise ou epidemia dos opioides, provocando o ressurgimento da opiofobia, temeroso que ocorra em países como o Brasil onde a dor é subtratada. A aprovação da Política Nacional de Cuidados Paliativos faz-nos crer que ocorra aumento na prescrição e uso dos opioides. Para auxiliar as equipes de saúde para enfrentar o mau uso e a opiofobia, temos o SOAPP-R (Screener and Opioid Assessment for Patient with Pain Revised), que mede o risco de desenvolvimento de comportamento aberrante relacionado ao uso dos opioides. Essa ferramenta pode contribuir para realização de estudos sobre prevalência do mau uso, dar ao clínico maior segurança na prescrição e direcionar uma abordagem mais adequada aos pacientes. O objetivo deste estudo foi traduzir e adaptar o SOAPP-R para o português do Brasil.

MÉTODOS: Estudo longitudinal prospectivo, do tipo metodológico, de validação de instrumentos de avaliação em saúde, de amostra não-probabilística, seguindo o método de Beaton.

RESULTADOS: Após a tradução inicial e retro tradução, a versão consensual foi submetida a um comitê de juízes. Houve discordância em relação à equivalência semântica em duas questões, sendo corrigidas e validadas. A versão pré-final foi aplicada em 24 pacientes em uso de opioides.

CONCLUSÃO: A versão pré-final obtida pode ser utilizada para estudos de validação pelo baixo índice de discordância e ausência de sugestões para novas redações.

DESCRITORES: Analgésicos. Atenção primária à saúde. Cuidados paliativos. Dor. Opioides. Saúde Pública.

HIGHLIGHTS

- The recreational use of opioids has been increasing in developed countries, to the detriment of therapeutic use, leading to what appears to be a resurgence of opioophobia as a consequence of the opioid use disorder (OUD) crisis. This has a negative impact on Brazil, which still has problems with the availability of this class of drugs
- SOAPP-R It is a tool that has been used in the United States to identify people at risk of developing OUD and had not been translated into Portuguese before
- After a translation and back-translation process, an evaluation by a committee of judges, and a series of pre-testings on a sample of 24 cancer patients using opioids, the tool was found to be suitable for validation studies

INTRODUCTION

Palliative care (PC) is undergoing a clear process of global and national expansion. In 2022, the number of teams operating in Brazil increased by 54.7%, totaling 234 services[1]. Its main focus is on quality of life, and symptom control is one of the pillars of its work[2]. Despite the perceived progress with the increase in the number of PC services, the supply is still insufficient, which contributes to Brazil ranking 79th in the world ranking of quality of death[3]. Among the most prevalent symptoms, pain stands out regardless of the disease being considered, being a source of great disturbance and suffering[4-6]. Epidemiological data show that the prevalence of pain in cancer patients can reach 54% in cases of advanced disease, and severe pain can reach a prevalence of around 30% of patients[7]. In patients who do not have cancer, chronic pain prevails between 35.3% and 52.6%[8]. Adequate large-scale pain control can be threatened by inequality in the availability of opioids[9] and by "opioid phobia": the fear of prescribing or using these drugs or even the fear of prosecution, which can lead to avoidable suffering for patients with life-threatening conditions[10]. This fear is based on the phenomenon that has been occurring in developed countries since the early 2000s, with more than 500,000 deaths in the US as a result of opioid misuse[11]. A similar situation has affected Europe, with records of 8317 deaths attributed to opioid use, and Australia, where 50% of 2070 deaths were attributed to this type of drug[12]. Table 1 shows these statistics in detail.

These facts have already reached the Brazilian media, which has frequently reported on this real problem, without, however, mentioning the barriers to access to opioids and pain control in the Brazilian population[14-16]. There is concern that news reports about the inappropriate use of opioids in other countries may stimulate opioid phobia in Brazil[10].

The creation of the National Palliative Care Policy[17] encourages the training of central and smaller care teams, which will certainly contribute to an increase in the prescription and use of opioids. There is also a risk of an increase in the misuse of opioids and the emergence of a situation similar to that in the countries already mentioned, or the opposite, widespread opiophobia. One of the ways that USA have developed to address this problem is to develop tools that identify people at risk of exhibiting aberrant behavior related to opioid use[18]. Among these tools is the Screener and Opioid Assessment for Patients with Pain Revised (SOAPP-R), a 24-question questionnaire that has demonstrated the best relationship between sensitivity, specificity, positive predictive value, and negative predictive value with a score of 18 out of a possible 96 points[19].

The translation and cultural adaption of this tool is of high importance so that it can be made available to Brazilian health professionals, especially those who are not pain specialists, as a way to assess patients with pain who need to receive opioids in terms of the risk of developing aberrant behavior. If the patient scores positively for this condition, they may receive a differentiated and appropriate approach.

The present study's objective was to translate and adapt the SOAPP-R tool into Brazilian Portuguese and subsequently submit it to validation processes for clinical use.

METHODS

Methodological, longitudinal, and prospective study for instrument validation, using Beaton's method[20] for translation and cross-cultural adaptation as a reference.

The translation and cultural adaptation process followed six methodological phases:

Phase 1 (Initial Translation): The original English scale was translated into Portuguese by two Brazilian translators with experience in medical translation, unfamiliar with the instrument, resulting in versions T1 and T2.

Phase 2 (Synthesis of Translation): Versions T1 and T2 were synthesized into a single version (T12) by consensus between the main researcher and a Brazilian collaborator who is a native Portuguese speaker with extensive knowledge of the English language.

Phase 3 (Back-translation): Version T12 was back-translated into English by two native English speakers with no prior knowledge of the tool, generating versions BT1 and BT2. These versions were consolidated into a final version (BT12) by a native English speaker collaborator.

Phase 4 (Judges Committee): The original version, T12 and BT12, was submitted to a committee of experts (a psychologist, a linguist, a palliative care physician, and the author of the study). The committee evaluated semantic, idiomatic, experiential, and conceptual equivalences. Agreement was quantified by the Content Validity Index (CVI), calculated by the proportion of judges who rated the item as "Adequate" or "Totally Adequate." The calculation formula used to assess the agreement rate achieved by the committee of judges can

Table 1. Increase in opioid consumption in different countries.

Country	Year	Unit used	Perceived increase
Canada	2014	Defined daily dose	3 times
Australia	2015	Oral morphine equivalent/1000 inhabitants	51%
Germany	2010	Prescriptions	1.22%
United Kingdom	2012	Defined daily dose/1000 inhabitants	Higher in the cancer population
Norway	2010	Number of opioid users	Increase from 8.6 to 13.3/1000 inhabitants
New Zealand	2012	Number of opioid-related deaths	33% increase

Source: Shipton et al.[13].

be expressed as follows[21]: The percentage of agreement is equal to the number of participants who agree with the item divided by the total number of participants; this quotient is multiplied by one hundred to be expressed as a percentage.

$$\frac{\%\ agreement\ =\ number\ of\ participants\ who\ agree}{total\ number\ of\ participants} X100 \quad (1)$$

Multiplication by a factor of 100 was omitted in this article so that the expression of results would be simplified, and values were expressed in decimal numbers. A CVI ≥ 0.75 was considered acceptable[22,23]. Disagreements were discussed via videoconference to reach a consensus.

Phase 5 (Pre-test): The pre-final version resulting from phase 4 (SOAPP-R-Br) was applied to a convenience sample of 24 cancer patients, aged 18 years or older and using opioids for at least 60 days, recruited from the hospital's radiotherapy department. After responding to the SOAPP-R-Br, patients completed a semantic validation questionnaire to assess the relevance, difficulty of comprehension, and clarity of the response options for each item[24].

Phase 6 (Final Version): After analyzing the pre-test results, the documentation of the entire process was reviewed and the final version of the instrument was generated.

Ethical issues

The project was approved by the Research Ethics Committee of the Amor de Barretos Hospital (Opinion 2,696,338). Permission to translate and use the questionnaire was granted by the copyright holder. All participants signed the Free and Informed Consent Term (FICT), and data confidentiality was ensured.

RESULTS

The methodological process, which began in May 2023 and was completed in February 2024, resulted in the final version of the SOAPP-R-Br.

Evaluation by the Committee of Judges

In the committee's analysis, 22 of the 24 items in the questionnaire achieved a CVI of 0.75 or higher and were considered adequate. In the semantic equivalence (SE) assessment carried out by the judges, the Totally Adequate (TA) option obtained a concordance index of 1.0 in 12 (50%) of the questions, 0.75 in 9 (37.5%) of the questions, 0.50 concordance in 1 (4.17%) of the questions, and 0.25 in 2 (8.33%) of the questions. In terms of idiomatic equivalence (IE), the TA option obtained a concordance of 1.0 in 12 (50%) of the questions, 0.75 in 10 (41.7%) of the questions, 0.50 in 1 (4.17%) of the questions, and 0.25 in 1 (4.17%) of the questions. In terms of experiential equivalence (EE), the TA option obtained a score of 1.0 in 9 (37.5%) of the questions, 0.75 in 11 (45.8%), 0.50 in 1 (4.17%), and 0.25 in 3 (12.5%). Regarding conceptual equivalence, the TA option obtained a score of 1.0 in 10 (41.7%) questions, 0.75 in 9 (37.5%), 0.50 in 3 (12.5%), and 0.25 in 2 (8.33%).

Two questions did not reach the minimum recommended CVI and were rewritten. They were:

Question 9: "*Com que frequência você tomou mais fármacos para dor do que lhe foi prescrito?*" ("How often have you taken more pain medication than was prescribed?").This item was classified as inadequate with a CVI of 0.75 in the "Semantic Equivalence" category. The term "*prescrito*" was considered too formal and rigid, and its replacement with "*orientado*" was suggested and incorporated into the new wording by consensus of the judges.

Question 17: "*Com que frequência outras pessoas lhe impediram de conseguir o que você merece?*" ("How often have other people prevented you from getting what you deserve?"). This item was classified as inadequate with an CVI of 0.75 in the category "Semantic Equivalence". The term "*merece*" was considered problematic because it carried a value judgment. It was suggested that it be replaced with the term "*deseja*," which was incorporated into the final version by consensus of the judges.

Pre-testing with patients

The pre-final version was applied to 24 patients. Table 2 shows the demographic and clinical data of the patient sample.

Analysis of the answers to the semantic validation questionnaire revealed that the items were generally well understood and clear. The overall average agreement was 70% for relevance, 98% for easy understanding (only 2% reported difficulty), and 100% for clarity of answer options. Table 3 summarizes patient agreement with the items evaluated.

Twelve questions, pertaining to the domains of Physician-Patient Relationship, Psychosocial Problems, Drug-Related

Table 2. Patient demographic data in the pre-test phase (semantic validation).

Sociodemographic data	n = 24	%
GENDER		
Female	14	58.3
Male	10	41.7
AGE		
Mean	54.9	Years
Standard deviation	15.4	Years

Table 2. Continued...

Sociodemographic data	n = 24	%
Median	60	Years
Min-Max	22 - 76	Years
SKIN COLOR		
White	12	50.0
Brow	10	41.7
Black	2	8.3
MARITAL STATUS		
Single	8	33.3
Married	7	29.2
Common-law marriage	4	16.7
Divorced	3	12.5
Widower	1	4.2
Ignored	1	4.2
ORIGIN (STATE)		
São Paulo	10	41.7
Goiás	5	20.8
Minas Gerais	3	12.5
Mato Grosso do Sul	3	12.5
Ceará	1	4.2
Maranhão	1	4.2
Sergipe	1	4.2
RELIGION		
Catholic	13	54.2
Evangelical	7	29.2
Spiritualism	1	4.2
Ignored	2	4.2
Other	1	4.2
SCHOOLING		
Primary school 1	11	45.8
High school	6	25.0
Primary school 2	4	16.7
Complete graduation	1	4.2
No schooling	1	4.2
Ignored	1	4.2
FAMILY INCOME		
1 to 3 minimum wages	13	54.2
Ignored	6	25.0
3 to 10 minimum wages	4	16.7
> 10 minimum wages	1	4.2
PRIMARY SITE OF CANCER (ICD-10)		
Lung (C34)	5	20.8
Breast (C50)	4	16.7
Rectum (C20)	2	8.3
Anal canal (C21)	2	8.3
Soft tissue (C 49)	2	8.3
Unspecified metastases (C79)	2	8.3
OTHERS	7	29.2

Table 3. Proportion of responses to the semantic validation questionnaire applied to patients in the pre-test phase.

	Proportion > 70% answered "yes"	Proportion < 70% answered "yes"
a. Is this question relevant (important) to your situation?	**12(50%)**	**12(50%)**
b. Do you have difficulty understanding this question?	**0(0%)**	**24(100%)**
c. Are the answer options clear and consistent (as per each question)?	**24(100%)**	**0(0%)**

Behaviors, and History of Substance Abuse, showed agreement on relevance below 70%. Question 7 ("How often do you worry that people will judge you for taking pain drugs?") and question 20 ("How often have you been so out of control in an argument that someone got hurt?") had the lowest relevance rates (45.8% and 50%, respectively).

DISCUSSION

The expansion of palliative care in Brazil, driven by the National Palliative Care Policy (NPCP), is an achievement for public health, but also a catalyst for an imminent dilemma: how to balance the necessary access to opioids with the prevention of misuse? This study addressed this issue by adapting a risk screening tool, SOAPP-R, to the national context.

The rigorous process of cross-cultural adaptation ensured that SOAPP-R-Br would be more than a simple translation. The modifications to questions 9 and 17 are clear examples of the importance of conceptual and cultural adaptation. Replacing "*prescrito*" with "*orientado*" and "*merece*" with "*deseja*" aligns the instrument with the language and nuances of clinical practice and Brazilian culture, increasing the likelihood that patients' responses will accurately reflect their experiences.

The pre-test results, although limited by a small sample size (n=24), offered valuable insights. The high clarity and easy comprehension indicate that the instrument is linguistically accessible. The low perceived relevance of certain items may have multiple interpretations. It may reflect a psychological defense mechanism of patients when answering questions on sensitive topics (conflicts, drug use) or, alternatively, indicate that such problems were not prevalent in this specific sample. This observation does not invalidate the questions but reinforces the need for psychometric validation in a larger and more diverse sample, where the variability of responses will allow for a robust analysis of the factor structure and criterion validity of the instrument.

This study showed limitations, notably the size of the pre-test sample, which was below the 30-40 subjects recommended in the literature for cultural adaptation[16], and its restriction to cancer patients from a single center. The reduced sample size resulted from the need to adapt the research schedule (which is part of the doctoral thesis of one of the authors – L.F.R.) to logistical issues related to recruitment and inclusion within the stipulated time frame. However, as the main stage was the evaluation by experts and verification of understanding, the authors believe that these limitations do not compromise the validity of the agreement established here.

The availability of SOAPP-R-Br for clinical use, following the completion of its psychometric validation, will be an essential step toward the implementation of safe prescribing protocols. The tool will enable doctors to take a safer and more confident approach, identifying patients who require more cautious monitoring without depriving them of pain relief.

CONCLUSION

The process of translation, cross-cultural adaptation, and content validation of the SOAPP-R has been successfully completed, resulting in a version (SOAPP-R-Br) considered appropriate for Brazilian culture. The tool is now ready for the next phase of evaluation of its psychometric properties. Once validated, it will serve as an essential support for clinical practice, assisting in the safe and monitored prescription of opioids in a context of expanding palliative care in Brazil, contributing to relief of suffering and minimization of risks.

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AUTHORS' CONTRIBUTIONS

Luís Fernando Rodrigues: Funding Acquisition, Data Collection, Conceptualization, Resource Management, Project Management, Research, Methodology, Writing – Preparation of the Original, Writing - Review and Editing, Validation, Visualization

Marcos Aparecido Sarria Cabrera: Funding Acquisition, Conceptualization, Resource Management, Project Management, Research, Methodology, Writing - Preparation of the Original, Writing - Review and Editing, Supervision, Validation