Translation, cross-cultural adaptation, and validation of the Portuguese version of the Rotterdam Elderly Pain Observation Scale (REPOS).

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Short Title: The Portuguese version of REPOS

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ABSTRACT

***Introduction*:** This study reports on the translation, cultural adaptation, and validation of a Portuguese version of the Rotterdam Elderly Pain Observation Scale (REPOS), a Dutch scale to assess pain in patients who cannot communicate, with or without dementia.

***Methods*:** This is a multicenter study in pain and neurological units involving Brazil (clinical phase) and The Netherlands (training phase). We performed a retrospective cross-sectional, two-staged analysis, translating and culturally adapting the REPOS to a Portuguese version (REPOS-P) and evaluating its psychometric properties. Eight health professionals were trained to observe patients with low back pain. REPOS consists of 10 behavioral items scored as present or absent after a two-minute observation. REPOS score of ≥ 3 in combination with Numerical Rating Scale (NRS) of ≥ 4 indicated pain. The Content Validity Index (CVI) in all items and instructions showed CVI values at their maximum. According to the higher correlation coefficient found between NRS and REPOS-P, it may be suggested that there was an adequate convergent validity.

***Results*:** The REPOS-P was administered to 80 patients with a mean age of 60 years (SD 11.5). The Cronbach's alpha coefficient showed a moderate internal consistency of REPOS-P (α=0.62), compatible with the original study of REPOS. All health professionals reached high levels of inter-rater agreement within a median of 10 weeks of training, assuring reproducibility. The Cohen's kappa was 0.96 (SD 0.03), and the intraclass correlation coefficient was 0.98 (SD 0.02), showing high reliability of REPOS-P scores between the trainer (researcher) and the trainees (healthcare professionals). Pearson correlation coefficient was 0.95 (95% C.I. 0.94 - 0.97), showing a significant correlation between the total scores of REPOS-P and NRS.

Conclusion: The Portuguese version of REPOS was a valuable scale for assessing elderly patients with low back pain by different healthcare professionals. Short application time, ease of use, clear instructions and the brief training required for application were essential characteristics of REPOS-P.

INTRODUCTION

Aging can be defined as a progressive process, with morphological, functional, biochemical, and psychological changes that determine the loss of the individual's ability to adapt to the environment, causing greater vulnerability [1] [2] [3].

The rising prevalence of cognitive impairment (CI) is an increasing challenge with aging. Populations of Latin America and the Caribbean are aging more rapidly [4]. For these countries, the CI prevalence estimates are between 1.9% and 12.5% [4] [5]. In Brazil, the mean prevalence rate of dementia is 7.1%, higher than the global prevalence of 5.8%, mainly in 65 and over. [6] [7]. In this context, it is important to note that longevity is accompanied not only by an increased risk of diseases related to aging, but many older people present pain as a symptom.

Due to pain, many elderly experience functional limitations and disabilities that may affect their independence and quality of life [8]. Commonly, the elderly are not inclined to report pain to their physician or caretaker as they are convinced that pain is part of aging [8] [9]. As a result, pain management is often inadequate [9] [10]. If a person suffers from speech limitations due to aphasia or dementia, the problem becomes even more significant. During possible painful interventions or circumstances, different behavioral reactions are difficult to be interpreted by caretakers or health professionals. In this setting, pain observation can be helpful for the assessment of pain in these people. The Rotterdam Elderly Pain Observation Scale (REPOS) was developed and validated by van Herk et al. (2009) for the assessment of pain in nursing home residents with communication difficulties [10] [11] [12]. It has been validated for chronic and daily pain in non-communicative adults and cognitively impaired elderly, who are unable to express pain by self-report, hospital patients, and for non-communicative palliative care patients [12][13][14][15][16][17].

Although an English version is available, the REPOS has not been validated for Portuguese-speaking elderly with speech limitations, so we adopted the translation and adaptation into Portuguese. Portuguese is the fourth most spoken language after Chinese, Spanish, and English [18]. Currently, more than 261 million people speak Portuguese in 5 continents, but indicators suggest that by 2050, Portuguese will have 380 million speakers, making it the third most spoken language in the world [18]. It is essential to consider that experience and culture create the relationship between pain and ethnicity [19,20]. Each culture and social group has its complex expressions and language of pain. However, pain and pain control are inner and subjective experiences of the person in pain [21]. The common of expressing pain by the elderly in many cultures include paralinguistic expressions (moaning, groaning), language and facial expressions (grimace, arching of the eyebrows), antalgic positions in cases of severe pain (panic attacks) [19][21][20].

This study aimed to translate and culturally adapt REPOS into Portuguese (REPOS-P) and to validate it in adult and elderly patients with low back pain.

MATERIALS AND METHODS

This study was conducted at the university hospital of our institution, after a 6-month training at the Erasmus Medical Center (EMC), Rotterdam, The Netherlands.

Patients and setting

All patients were admitted to pain and neurological ambulatory care facilities of the university hospital of our institution. Inclusion criteria were adult patients (over 18 years old), not sedated or under mechanical ventilation, both able to and unable to

express pain by self-report. Exclusion criteria were patients with neuropathic diseases and chronic alcoholism.

The study extracted demographic and medical data from medical records and files. The pain diagnosis was classified by the WHO International Classification of Diseases (ICD-10, 2016). Pain medication was stratified according to the WHO analgesic ladder.

Each patient or a responsible relative signed an informed consent after explaining the study aims and procedures. The institutional ethical board approved the study of our hospital.

Instruments

The REPOS is a pain measurement tool for people who cannot communicate. It consists of 10 behaviors (relating to facial expression, motor behavior, and vocalization), which are scored to be absent (= 0) or present (=1) after a two-minute observation period, with a total score ranging from 0 to 10. A total score of three or higher indicates pain. Because other emotions (shame or anger) might influence the strength of the REPOS score, it is always used in combination with the Numerical Rating Scale (NRS) through the assessment of observers (NRS_{obs}). The NRS is a validated instrument rating pain on a scale ranging from 0 = no pain to 10 = worst pain. Scores of four and higher indicate substantial pain indicates the need for treatment. The self-reporting of pain may use the NRS, the gold standard, and proxy reporting [10] [11]. NRS_{obs} represent the health professional opinion of the patients' pain, taking the circumstances into account [10] [11] [22].

The original validation study of REPOS revealed a significant difference between pain and rest conditions. REPOS largely correlated with another pain assessment

instrument, the Pain Assessment in Advanced Dementia (PAINAD) (r = 0.75) [22] [23] [24]. A pilot implementation studied 15 nurses employed at eight wards in a nursing home which completed 52 REPOS observations on 24 residents in six months [15].

Procedures

The research procedure consisted of two phases: (I) translation and adaptation of the English version of the REPOS into Portuguese and (II) a pilot implementation of the new REPOS-P.

Translation and cross-cultural adaptation

Translation and cross-cultural adaptation of the REPOS were conducted according to the recommendations of Beaton et al. (2000), i.e., three qualified independent translators, which allowed the identification of different interpretations and resulted in a consensual version of the REPOS-P [25,26] [27] [28]. This consensual version was back-translated into English by three different qualified translators unfamiliar with REPOS and not involved with the first translation into Portuguese. A comparison between the back-translated version of REPOS-P and the original English version identified and adjusted discrepancies in translation, resulting in the second version of REPOS-P. These discrepancies and word modifications provided by the multidisciplinary pain experts did not affect the meaning of the words.

A multidisciplinary committee of 10 specialists experts on pain was informed about the purpose of the study and asked to compare the back-translated English version with the original version, taking the concepts of semantic equivalence of the instrument into account. **Table 1** gives an overview of the profession of the pain specialists and their years of experience. They were invited to make point modifications and

corrections and stimulated to provide suggestions to obtain a clear and functional version of REPOS-P [25,26] [27] [28]. The experts were specialists in pain and related aspects of pain, with an average of 21.6 years (SD = 10.8) of experience in their profession.

Insert **Table 1** about here

The final version of the scale was presented to the experts again with the request to examine each item of REPOS-P on the clarity of the new items, rating them as "unclear", "mostly clear", "clear" or "very clear". Content validity was assessed using the Content Validity Index (CVI). According to experts, the cutoff point adopted for the CVI was 0.78 [29] [30].

Validation of REPOS-P

A pilot implementation study tested the validity of the final version of REPOS-P. The principal researcher (JSM), a qualified REPOS trainer (Observer #1), trained eight healthcare professionals (physician, dentist, biomedical, psychologist, physiotherapist, nurse, and caregiver) to perform the REPOS-P observation. They were all female, with a mean age of 32 years (SD 11.6) and an average of 21.6 years (SD 10.8) of experience in their profession. The training program consisted of a theoretical (five hours plus training with video exercises) and a practical part. In the preparatory training, a CD-ROM provided by the Erasmus Medical Center, Rotterdam, The Netherlands, offered several examples of all REPOS items [22]. In the practical part, each trainee observed at least ten patients daily with the qualified trainer and scored the REPOS-P items

independently. These observations were used to calculate the interrater agreement (kappa and intraclass correlation coefficient).

Statistical analyses

Cohen's kappa was calculated per item, and the intraclass correlation coefficient (ICC) was calculated on the total score of the instrument, both to assess the reliability of REPOS-P between the trainer and the trainees [31] [32]. A Cohen's kappa of 0.65 was considered evidence of good interrater reliability [30] [31]. Cronbach's alpha coefficient for the internal consistency of REPOS should preferably be > 0.7 [29] [31] [32]. The Pearson product-moment correlation coefficient was used to establish the relationship between REPOS-total scores and NRS-proxy scores [22] [31]. The data analysis was implemented in R-cran software (version 3.2.2 and the Psych and Irr packages).

RESULTS

Translation and cross-cultural adaptation

The proportions of answers "clear" and "very clear" and the calculated CVI results according to the responses of the expert's committee about the clarity of the information and items of REPOS-P are presented in Table 2.

Insert **Table 2** about here

The main discrepancies between the original and the back-translated English versions included: (a) "Good posture" versus "Suitable posture" (postura adequada); (b) "moving body " versus "psychomotor agitation" (agitação psicomotora); (c) "Moaning /

groaning" versus "Moaning / wailing" (gemidos / lamentações); (d) "Change in posture" versus "Change of position" (mudança de posição); and (e) "Eyes (almost) squeezed" versus "Eyes squeezed" (olhos comprimidos).

Table 2 shows that almost all of the items and instructions of REPOS-P presented CVI values at their maximum (100 %; 1.0).

Validation of REPOS-P

The study evaluated 80 subjects from the neurology or pain outpatient clinics. Their mean age was 60 (SD 11.5; age range 29 to 80), and 66.3 % were female. table 3 shows the distribution of patients according to demographic and clinical characteristics.

Insert **Table 3** about here

The majority of patients were diagnosed with the musculoskeletal system and connective tissue diseases (47.5%), followed by neoplasm (13.8%), and injury, poisoning, and sure others (12.5%). Pain treatment with opioids was provided for 43.8% of patients.

The observations were conducted during a possible painful moment such as physical examination, locomotion such as walking (52.5%), rest, medical interview, and arterial pressure measurement (47.5%).

Table 4 shows the results of the interobserver agreement according to the observation of healthcare professionals (trainees - observer 2 to 9), and the principal observer (trainer - observer 1).

Insert **Table 4** about here

The mean kappa was 0.96 (SD 0.03), and the mean ICC was 0.98 (SD 0.02). The item "tense face" was the most observed, while "breath-holding/faltering respiration" was the least observed.

The Cronbach's alpha coefficient for the internal consistency of REPOS-P was α=0.62. The correlation between REPOS-P and the NRS proxy obtained by the Pearson correlation coefficient was 0.95 ($CI_{95\%}$=0.94-0.97).

The final version of REPOS-P

The final version of the REPOS-P form is available in Figures 1, 2, and 3. Figures 1 to 3 show the original REPOS template incorporating the translation to Portuguese.

Insert **Figure 1** about here

Insert **Figure 2** about here

Insert **Figure 3** about here

DISCUSSION

This study reports on the translation, cultural adaptation, and validation of a Portuguese version of REPOS and the first study to offer in Portuguese a scale to assess pain in patients who cannot communicate, with or without dementia. This scale has proved helpful in routine care in hospitals due to the short administration time, ease of use, and clear instructions. REPOS-P may provide an essential tool for Portuguese-speaking countries.

In the first phase of this study, the translation process of the items and instructions presented a consensus back-translated version that confirmed good similarity and semantic equivalence between the original and REPOS-P. According to the experts' committee, REPOS-P was adequate and clear to the target population, which the CVI values for all items can reinforce.

The training was necessary for the reliable administration of the pain observation tool. The availability of an instruction chart increases interrater reliability while the decision tree helps evaluate the observation and decide if an intervention is necessary. For training in the Portuguese language, those interested can contact the corresponding author. For the English version of REPOS, there is an e-module REPOS available at www.comfortassessment.nl/reposscale/index.php [19] [15] [22].

In the second phase, eight observers were invited for reliability analysis of interrater measures, with the beneficial interest to validate an easy-to-use scale in clinical and hospital settings [24] [31] [32].

The observation of the patients reflected the expected conditions in elderly patients, i.e., musculoskeletal system and connective tissue diseases, and neoplasm, injury, or poisoning. The item tense face was the most observed, while breath-holding/faltering respiration was the item that appeared the least. The REPOS-P presented versatility of use in the studied population, despite the heterogeneous clinical settings and a wide age range of patients. Rhodee van Herk et al. (2009) evaluated 174 patients, mostly female, with a median age of 82 years (ranging from 73 to 87 years). The present study was equivalent concerning pain diagnoses, most patients with musculoskeletal disorders, but we had a more significant number of neoplasms, 13.8% versus 2% [15] [22].

The results of the interobserver agreement, according to the observation of healthcare professionals (trainees - observer 2 to 9) and the principal observer (trainer - observer 1), showed that the mean kappa and the mean ICC were adequate (Table 4). These results are in line with the original pilot implementation project of REPOS [15].

According to the high correlation coefficient found between NRS and REPOS-P, it may be suggested that there was an adequate convergent validity. The result in the REPOS study showed that the correlation between REPOS and NRS was small to medium [29] [30] [31]. The internal consistency of REPOS-P showed acceptable content reliability (α) of 0.62, being compatible with the original study of REPOS and indicating a moderate internal consistency [29] [30].

This study has some limitations, such as the small size of the sample and the number of trained professionals. Further studies should assess the psychometric properties of REPOS-P in representative samples of healthcare professionals observing patients with distinct health conditions, not only in low back pain.

CONCLUSIONS

REPOS-P showed adequate reliability and validity in the present study. Different health professionals can use it to assess pain in adults and the elderly with verbal communication problems.

STUDY APPROVAL STATEMENT

The Ethics Committee of the Clinical Hospital of the Ribeirão Preto Medical School, University of São Paulo, Brazil, approved this study, approval number 14114/2014. This study was conducted ethically under the Declaration of Helsinki.

CONSENT TO PARTICIPATE STATEMENT

All participants signed the written informed consent to participate in the study.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

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AUTHOR CONTRIBUTIONS

Conception and design of the study: Julieta Seixas-Moizes, Erica Negrini Lia, Eduardo Barbosa Coelho, Lauro Wichert-Ana. Data acquisition, analysis, and interpretation: Julieta Seixas-Moizes, Miriane Lucindo Zucoloto, Laís Almeida Leal Wichert-Ana, Tatiana Reis Icuma. Drafting and revising for critical intellectual content: Julieta Seixas-Moizes, Anneke Boerlage, Lucas Emmanuel Lopes e Santos, Fabíola Dach, Priscila Colavite Papassidero, Oscar Della Pasqua, Marianne Louise Wiesebron, Vera Lucia Lanchote, Dick Tibboel, Lauro Wichert-Ana. Final approval of manuscript: Julieta Seixas-Moizes, Anneke Boerlage, Oscar Della Pasqua, Dick Tibboel, Lauro Wichert-Ana. Accountability for accuracy or integrity of the work: Julieta Seixas-Moizes, Lauro Wichert-Ana.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study can be acquired from the corresponding author upon reasonable request.

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LEGEND TO FIGURES

Figure 1. The Portuguese Version (REPOS-P) of the Rotterdam Elderly Pain Observation Scale (REPOS), Page 1.

Figure 2. The Portuguese Version (REPOS-P) of the Rotterdam Elderly Pain Observation Scale (REPOS), Page 2.

Figure 3. The Portuguese Version (REPOS-P) of the Rotterdam Elderly Pain Observation Scale (REPOS), Page 3.