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VALIDATION STUDIES

Translation, cross-cultural adaptation and validation of the Osteoarthritis Quality of Life (OAQoL) questionnaire for use in Portugal

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Abstract

Osteoarthritis (OA) is the most prevalent rheumatic disease and is a leading cause of decreased quality of life (QoL). The OA Quality of Life questionnaire (OAQoL) is an OA-specific patient-reported outcome measures. The aim of this study was to translate and validate the original UK English version of the Osteoarthritis Quality of Life (OAQoL) questionnaire into European Portuguese. The translation of the questionnaire was carried out according to a dual panel methodology (bilingual panel followed by lay panel). This was followed by cognitive debriefing interviews (CDIs) with OA patients to assess comprehension and relevance of the translated questionnaire. Finally, a validation survey was conducted to assess its psychometric properties. The Portuguese OAQoL, a comparator scale (the Nottingham Health Profile—NHP) as well as questions relating to demographic and disease information were administered to OA patients. A sub-sample of patients also completed the Portuguese OAQoL two weeks later, to assess test–retest reliability. The internal consistency, construct validity and known group validity (according to perceived OA severity) of the scale was also assessed. Both the bilingual and lay panels consisted of five individuals and no major difficulties relating to the translation process were identified. A total of ten patients with OA participated in the CDIs. The mean time to complete the questionnaire was 5 min. These interviews revealed that the Portuguese version of the OAQoL was clear, relevant and easy to complete. Finally, 53 OA patients (44 females; mean age of 67.6 years) completed the validation survey. Cronbach's alpha coefficient was 0.87, demonstrating high internal consistency. Test–retest reliability, assessed by Spearman's rank correlation coefficient, was 0.86. Moderate correlations were found with the majority of the NHP sections, providing evidence of construct validity. Significant differences in OAQoL scores were found between patients who differed according to their perceived OA severity, providing evidence of known group validity. The Portuguese version of the OAQoL is a valid and reliable questionnaire that can be used to assess QoL in OA, both in clinical practice and for research purposes.

Keywords Quality of life · Osteoarthritis · Patient-reported outcome measures · Degenerative arthritis · Osteoarthritis Quality of Life questionnaire · OAQoL

Introduction

Osteoarthritis (OA) is the most prevalent rheumatic disease and is a leading cause of disability and decreased quality of life (QoL) in the elderly population [1–4]. OA has a major impact on health systems [5] and its prevalence is estimated to grow during the following decades due to increased life expectancy of the general population [6, 7]. In Portugal, the estimated total prevalence of OA according to body location is 12.4% for the knee, 8.7% for the hand and 2.9% for hip [8]. In the same population, OA was associated with decreased

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QoL, disability and early exit from work, accounting for very high societal costs [9]. Despite significant efforts from the scientific community, no disease-modifying OA drug is available so far. Thus, all therapeutic interventions (non-pharmacological, pharmacological and surgical) in OA aim at reducing pain, avoiding / improving disability and improving patients' QoL [10, 11]. To date, most patient-reported outcome measures (PROMs) concerning OA assess Health-Related Quality of Life (HRQL). These include assessments of pain and physical function which, despite their clinical usefulness, do not directly address QoL [12–14]. Other PROMs that are applied to OA patients, including the EuroQol 5D and the 36-item Short Form Health Survey (SF-36), address HRQL but are not specific to OA [15, 16]. The Osteoarthritis Quality of Life questionnaire (OAQoL), developed in the United Kingdom (UK), is a unidimensional OA-specific PROM designed to provide an overall assessment of the impact of the disease and its treatment on individuals' ability to meet their needs [17]. The OAQoL consists of 22 dichotomous items with total scores ranging from 0 to 22 (high scores indicate poor QoL) and has been adapted and validated for use in Germany, Hungary, Italy, Spain and Turkey [18]. It has demonstrated excellent psychometric properties in all language versions and can be applied to OA of multiple locations (upper limbs, lower limbs and polyosteoarthritis) [17]. Thus, it is of utmost importance to have this questionnaire available for use with Portuguese patients. The aim of this study is to describe the translation and validation of the OAQoL questionnaire, allowing its use with Portuguese OA patients.

Methods

The translation and validation of the OAQoL questionnaire was carried out in three stages. First, the dual panel methodology [19] was applied to produce the Portuguese translation of the questionnaire and to achieve conceptual equivalence of the translated items to the original. This process involves a bilingual panel to provide the initial translation into the target language, which is then presented to a lay panel to assess the comprehension of the language used. Following translation, cognitive debriefing interviews (CDI) took place to assess if the questionnaire is relevant, acceptable and appropriate to respondents. The final stage of the process involves a validation survey to assess the psychometric properties of the questionnaire, to ensure the new language version is reliable and valid.

The translation and validation of the OAQoL questionnaire into European Portuguese followed the current international recommendations [20–22]. All stages were carried out in Portugal, under the supervision of the study coordinators. This study was conducted according to the Declaration of Helsinki and the International Guidelines for Ethical Review of Epidemiological Studies and was approved by the local ethics committee on the 18th of January 2017. Prior to inclusion in the study, patients participating in the CDI and validation survey stages provided written informed consent.

Translation

The translation process was conducted at Centro Hospitalar do Baixo Vouga, in Aveiro, Portugal. The dual panel methodology was applied [19] and consisted of two different steps: a bilingual panel followed by a lay panel.

The purpose of the bilingual panel was to provide an initial translation of the questionnaire. This consisted of individuals who are native Portuguese speakers and fluent in English, but who did not have experience of OA. The translation versions for each item were proposed by panel members, which were discussed by the group until agreement on the best wording was reached. When consensus could not be reached, more than one version of an item was allowed to be taken forward for consideration by the lay panel.

The purpose of the lay panel was to check that the translated questionnaire can be easily understood at an appropriate level for individuals from different educational and socioeconomic backgrounds. These individuals were monolingual Portuguese speakers, of a lower than average educational level, but who did not have experience of OA. The panel members checked for comprehension, acceptability and 'naturalness' of the language used. Whenever alternative translations of items were available, the panel was asked to choose the most appropriate.

The panels worked as a team to reach consensus on appropriate translations for the instructions and items in the questionnaire. As far as possible, a mix of genders and ages were recruited for the panels. The meetings were attended by the Portuguese study coordinators and by the original instrument developers, whose role was to explain the precise conceptual meaning of the items to panel members.

After consideration by the lay panel, a final version of the translation is formulated, which is then validated in the following stages. Of note, slight changes in the wording are still possible after this stage.

Cognitive debriefing interviews (CDI)

The translated version of the OAQoL questionnaire was applied to ten patients recruited from a rheumatology outpatient clinic in Lisbon, Portugal. Inclusion criteria for this stage were: fulfilling the American College of Rheumatology criteria for the diagnosis of knee, hip and/or hand OA [23–25]. Patients with foot OA (OA of first metatarsophalangeal joint, talar and subtalar joints) were diagnosed according to the treating rheumatologist and the clinical history,

physical examination and X-ray images were reviewed by the study researchers. Exclusion criteria were: inability to provide a written informed consent; illiteracy; other comorbidities capable of influencing QoL (judged by the clinician); concomitant inflammatory rheumatic diseases (i.e., rheumatoid arthritis, spondylarthrosis, gout); presence of failed joint arthroplasty for OA or arthroplasty in the previous 6 months.

The goal of these interviews was to test the face and content validity of the translated OAQoL questionnaire.

CDIs began with the researcher explaining to the patient the purpose of the interview and assuring full confidentiality of the collected data. Patients filled in demographic and clinical information and were asked to complete the questionnaire in the presence of the researcher. During this period, any questions, hesitations or comments towards individual items in the questionnaire were observed and recorded by the interviewer. After completion, patients were asked if the questionnaire was relevant, easy to understand and acceptable, and if there were any ambiguous or inappropriate questions. Then, they were asked about the items where pauses, questions or comments took place and if any aspect of their disease had been missed out. A report on the ten CDIs was produced which summarized all relevant information, including the time taken by the patient to complete the scale.

Validation survey

A survey pack consisting of the Portuguese OAQoL questionnaire was administered to patients on two occasions, approximately two weeks apart. Patients were also asked to complete a comparator questionnaire, the Nottingham Health Profile (NHP), at the first administration. The NHP is a generic health status questionnaire (scores 0–100) that assesses pain, energy level, mobility, sleep, social isolation and emotional reaction [26]. A higher score on each of these sections indicates greater perceived distress in physical, emotional and social domains. Convenience sampling was used to recruit patients using the same inclusion and exclusion criteria as for the CDIs. Apart from the completion of OAQoL, patients also provided relevant demographic and clinical information, including patient-perceived OA severity (mild/moderate/quite severe/very severe).

Statistical analysis

Non-parametric statistical tests were used for all statistical analyses due to the ordinal nature of the measures employed. All statistical tests were two-tailed with a p value < 0.05 indicating statistical significance.

Internal consistency of the translated OAQoL questionnaire was evaluated using Cronbach's alpha coefficient. Adequate internal consistency was defined as $\alpha > 0.7$. Reproducibility was assessed through test–retest reliability using Spearman's rank correlation coefficient. A minimum value of 0.85 is required to suggest the scale produces low random measurement error.

Convergent validity was assessed using Spearman's rank correlation coefficients to correlate scores obtained on the OAQoL with scores on the NHP sections. The level of correlation was based on predefined thresholds: "weak" 0.3–0.5, "moderate" 0.5–0.70 and "strong" > 0.8. Known group validity was assessed using Mann–Whitney U test to test for differences in OAQoL scores between groups of people that are considered likely to differ. Perceived OA severity was used in the current study for assessing known group validity.

Results

Demographic and clinical data from participants who took part in the CDIs and validation survey are shown in Table 1.

Translation

The bilingual panel consisted of five individuals (mean age = 41.2 years, range = 22–73 years). No major difficulties were experienced in the bilingual panel with an appropriate translation generated for all instructions and items. For the item 'I can't be as independent as I want', more than one translation was taken forward to the lay panel for consideration.

The lay panel also consisted of five individuals, (mean age = 48.2 years, range = 28–66 years). Individuals in the panel had a good understanding of the translated items and made some additional modifications to the wording of four items, without changing the meaning. The result was a more comprehensible and natural Portuguese translation of the questionnaire.

Cognitive debriefing interviews

Overall, ten patients [seven females; mean age of 68.7 years (range = 59–86)] were recruited to take part in the CDIs. On average, patients took 5 min to complete the questionnaire (range = 3–8 min). In general, all patients understood the instructions and were clear about the purpose of the interview. For a few of the items (mainly Q.4, Q.8 and Q.12), a small number of patients found it difficult to decide between "true" and "false" and suggested there should be a middle response option. Nevertheless, patients were still able to choose between the two options, so it was decided that no changes would be made. Overall, patients considered the questionnaire easy to understand, simple, quick to complete and did not find any items inappropriate or unacceptable.

Table 1 Demographic data for the cognitive debriefing interviews and validation surveys

	Cognitive debriefing interviews ($N=10$)	Validation survey ($N=53$)
Gender (female), *N* (%)	7 (70)	44 (83)
Age (in years), mean (±SD)	64.5 (62.5–77)	67.6 (±9.2)
Marital status, *N* (%)		
Married/living as married	5 (50)	33 (62)
Divorced	2 (20)	6 (11)
Widowed	1 (10)	7 (13)
Single	2 (20)	7 (13)
Work status, N (%)		
Full-time	4 (40)	13(25)
Part-time	0	3 (6)
Retired	6 (60)	31 (59)
Homeworker	0	5 (9)
Long-term sick leave	0	1 (2)
Perceived general health, *N* (%)		
Good	4 (40)	9 (17)
Fair	3 (30)	38 (72)
Poor	3 (30)	6 (11)
Perceived OA severity, *N* (%)		
Mild	0	4 (7)
Moderate	4 (40)	26 (49)
Quite severe	5 (50)	20 (38)
Very severe	1 (10)	3 (6)
OA duration (in years) mean (±SD)	–	8.1 (±7.8)
OA treatment *N* (%)	–	44 (83)

IQR interquartile range, *SD* standard deviation, *N* number, *OA* osteoarthritis

Validation surveys

A total of 53 patients (44 females) with OA participated in the validation study, with a mean age of 67.6 years (range = 42–85). Most of the patients were retired, married and rated their perceived general health as "fair". Concerning OA location, 21 patients had knee OA, 10 had hand OA, 8 had hip OA, 3 had foot OA and 11 had "multiple-site" OA (when there was more than one body location involved). The majority of patients were taking medication for OA and had a perceived OA severity as "moderate" or "quite severe". The average duration of OA was 8.1 (SD = 7.8) years.

All patients completed the OAQoL and NHP at the first administration and the OAQoL at the second administration (14 days after). The median OAQoL scores were 7 (IQR = 2–12) and 8 (IQR = 1.5–13) at each administration, respectively. Questionnaire descriptive statistics and correlation coefficients for the OAQoL and NHP are shown in Tables 2 and 3.

Contrary to OAQoL, the NHP showed high floor effects (percentage of patients scoring the minimum = 27.5%) as well as some ceiling effects (percentage of patients scoring the maximum = 11.3%), meaning that the NHP is not well-targeted to OA patients in this sample.

Cronbach's alpha coefficient was 0.87, indicating that the Portuguese OAQoL has high internal consistency. A test–retest correlation coefficient of 0.86 was found, suggesting the scale will produce low levels of random measurement error.

Moderate correlations were found between scores on the OAQoL and those on the NHP scales. As expected, OAQoL scores correlated most strongly with the energy ($r=0.74$) and physical mobility ($r=0.73$) scales. There were also moderate correlations between OAQoL scores and NHP emotional reactions ($r=0.69$), pain ($r=0.63$) and social isolation ($r=0.61$) scale scores. However, a weak association

Table 2 Validation surveys—NHP and OAQoL questionnaire descriptive statistics

	N	Median	IQR	Min–max	% Scoring minimum	% scoring maximum
OAQoL (time 1)	53	7	2–12	0–21	11.3	0
NHP (time 1)						
Energy level	53	33.3	0–66.7	0–100	39.6	22.6
Pain	53	62.5	37.5–100	0–100	5.7	26.4
Emotional reactions	53	22.2	11.1–55.6	0–100	18.9	1.9
Sleep	53	40	0–70	0–100	26.4	17
Social isolation	52	0	0–20	0–80	63.5	0
Physical mobility	53	50	25–62.5	0–87.5	9.4	0
OAQoL (time 2)	53	8	1.5–13	0–22	13.2	1.9

N number, *IQR* interquartile range, *NHP* Nottingam health profile, *OAQoL* osteoarthritis quality of life questionnaire

Table 3 Correlation coefficients between OAQoL and NHP section scores

	Correlation with OAQoL
NHP sections	
Energy	0.74
Pain	0.63
Emotional reactions	0.69
Sleep	0.43
Social isolation	0.61
Physical mobility	0.73
Overall	0.64

NHP Nottingam health profile. All correlations significant at the 0.01 level (two-tailed). Correlations were assessed using Spearman rank correlation coefficient

Table 4 Median OAQoL scores by age and perceived OA severity

	N	Median OAQoL scores (IQR)
Age		
Below median	26	3.5 (1–10)
Above median	27	10 (5–15)
p value	53	< 0.01
Perceived OA severity		
Mild/moderate	30	2.5 (1–7.3)
Quite/very severe	23	11 (7–14)
p value	53	< 0.001

IQR interquartile range, *N* number, *OAQoL* osteoarthritis quality of life questionnaire

was observed between OAQoL scores and the Sleep scale ($r = 0.43$).

Significant differences in OAQoL scores were found between patients grouped by perceived OA severity, as shown in Table 4. Patients who rated their OA severity as "quite severe" or "very severe" ($N = 23$) had significantly higher scores on the OAQoL than patients who rated their OA severity as "mild" or "moderate" ($N = 30$). These findings demonstrate the ability of the Portuguese OAQoL to detect meaningful differences.

An additional finding was that older patients (above median age) presented significantly worse QoL compared to younger patients (below median age). A Chi square test of independence was performed to assess the relation between age and perceived OA severity. A significant association was found between these variables (χ^2 (53) = 5.6, $p < 0.05$), with a greater proportion of younger patients rating their severity as 'mild/moderate' compared to older patients. As the validation sample was predominantly female, a comparison of scores related to gender was not performed.

Discussion

This article describes the translation and validation of the Portuguese version of the OAQoL questionnaire. Few difficulties were found during the translation process, providing further support for the dual panel methodology being highly appropriate for the adaptation of need-based measures. The dual panel methodology was effective in ensuring that the final questionnaire is well-understood by patients [27]. During this process, the adaptation of conceptual rather than linguistic equivalence of the items was of utmost importance. The success of this approach was demonstrated by the absence of inappropriate, irrelevant or missing questions during the cognitive debriefing interviews. These interviews also demonstrated that this disease-specific questionnaire is easy to administer and requires an average of 5 min to complete, which makes it feasible in routine clinical practice and for research purposes.

The psychometric analysis, performed to validate the questionnaire, has shown that the Portuguese version of the OAQoL has high internal consistency, and that the scale is reproducible over time, as shown by excellent test–retest reliability. Furthermore, there were no missing responses on the adapted measure at either administration. Comparing with previous adaptations of the questionnaire [18], the Portuguese version of OAQoL presented slightly lower Cronbach´s alpha coefficient (0.87 vs 0.94 to 0.97) and test–retest reliability coefficients (0.86 vs 0.87–0.98), which can be explained by different disease characteristics in the Portuguese OA population and by the lower number of included participants in the present questionnaire adaptation. Despite these slight differences, internal consistency and test–retest reliability were high. Similarly to the German, Hungarian, Italian and Turkish version of OAQoL, the correlation between the NHP and OAQoL was moderate, demonstrating convergent validity. Overall, the psychometric properties of the Portuguese OAQoL did not differ significantly from previous adaptations of the questionnaire [18].

The correlations between OAQoL and different sections of the NHP indicate that multiple factors influence QoL. However, sleep problems do not seem to be a major influence on QoL in this sample. The absence of floor and ceiling effects shows that the new language version of the OAQoL is well-targeted to Portuguese OA patients.

Older patients and those who perceive their OA severity as "quite/very severe" reported worse QoL, showing that the Portuguese version of OAQoL assures a good discriminative power in terms of OA severity and age. Also, this study suggests that older patients perceive their OA as more severe. It is therefore very likely that perceived OA

severity contributed to the differences in OAQoL scores between age groups. Unfortunately, a comparison of scores according to gender was not performed, as the male gender sample was clearly underpowered. Nevertheless, the current sample is actually representative of the OA population in which the prevalence is higher in women [8, 28].

There are some limitations to the study. The size of the validation sample was relatively limited and the patients were recruited from a single centre. Furthermore, this was a tertiary rheumatology referral clinic that may not be representative of the whole Portuguese OA population. However, to minimise sampling bias, recruitment was performed by experienced researchers and obeyed predefined inclusion and exclusion criteria. It is important to note that the purpose of the validation exercise was to show that the measure was acceptable to patients, reproducible and valid, which was achieved. The study was not designed to generate epidemiological data about Portuguese patients. Future studies are required to determine such information and sensitivity to change.

Conclusion

A European Portuguese version of the OAQoL was successfully produced and validated for use with Portuguese OA patients. This new language version demonstrates excellent psychometric properties which should prove to be a valid and reliable measure of QoL in OA. Thus, the OAQoL can be used for evaluating patients, not only in routine clinical practice, but also in OA-related research projects in Portugal.

Author contributions João Lagoas Gomes actively participated in the translation panels, cognitive debriefing interviews, validation survey, data collection and analyses, as well as drafting and revising the manuscript and approved its final version. Ana Filipa Agueda actively participated in the translation panels, cognitive debriefing interviews, validation survey, data collection and analyses, as well as drafting and revising the manuscript and approved its final version. Alice Heaney coordinated the translation panels, performed data analysis, drafted and revised the manuscript and approved its final version. Cátia Duarte actively participated in the translation panels, revised the manuscript and approved its final version. Carina Lopes recruited participants, actively participated in the validation surveys, revised the manuscript and approved its final version. Tiago Costa recruited participants, actively participated in the validation surveys, revised the manuscript and approved its final version. José Marona recruited participants, actively participated in the validation surveys, revised the manuscript and approved its final version. Santiago Rodrigues-Manica recruited participants, actively participated in the validation surveys, revised the manuscript and approved its final version. Sara Maia performed data collection, study coordination, revised the manuscript and approved its final version. Manuela Costa actively recruited participants, revised the manuscript and approved its final version. Jaime C Branco recruited participants, revised the manuscript and approved its final version. Stephen P McKenna coordinated and overviewed the translation panels, performed data analysis, revised the manuscript and approved its final version. Anabela Barcelos actively participated in the translation panels, revised the manuscript and approved its final version. Fernando M. Pimentel-Santos actively participated and recruited participants to the cognitive debriefing interviews, validation survey, revised the manuscript and approved its final version.

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Compliance with ethical standards

Conflict of interest João Lagoas Gomes, Ana Filipa Águeda, Alice Heaney, Cátia Duarte, Carina Lopes, Tiago Costa, José Marona, Santiago Rodrigues-Manica, Sara Maia, Manuela Costa, Jaime C Branco, Stephen P McKenna, Anabela Barcelos and, Fernando M. Pimentel-Santos declare they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants in the cognitive debriefing interviews and in the validation survey.

Ethical standards All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. It was approved by the local ethics committee.

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