

Research article Ερευνητική εργασία

Translation and validation of the greek Psoriatic Arthritis Quality of Life Scale

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Psoriatic arthritis (PsA) is a chronic inflammatory disease that has a significant impact on patients' quality of life (QoL). The Psoriatic Arthritis Quality of Life (PsAQoL) Scale was developed in the UK to be specific to PsA patients and adopts the needs-based model of QoL. As a disease-specific measure, the PsAQoL is superior to generic measures of QoL in terms of relevance and sensitivity. The measure, which has been adapted into 50 languages, has not previously been available for use with Greek PsA patients. The aim of the study was to produce a Greek version of the PsAQoL that was suitable for native Greek speakers and that had comparable psychometric properties to the original UK version. The adaptation of the Greek PsAQoL consisted of three stages; translation, assessment of face and content validity and analysis of its psychometric properties. The translation stage adopted the dual panel methodology –a bilingual panel followed by a lay panel– to ensure conceptual equivalence of the scale to the original version. Cognitive debriefing interviews were conducted to determine the applicability and relevance of the adapted scale to patients. Finally, a postal validation survey was conducted to assess the psychometric properties of the draft measure, using the Nottingham Health Profile (NHP) as a comparator instrument. Non-parametric statistical analyses were performed to establish the reliability and construct validity of the PsAQoL. The translation panels produced a language version that sounded natural to native Greek speakers. Interviews revealed that patients found the measure comprehensible and appropriate. Only minor grammatical changes were made to the measure following these interviews. The Greek PsAQoL demonstrated good internal consistency (Cronbach's $\alpha=0.88$) and excellent test-retest reliability ($r=0.98$). As expected, the measure correlated moderately highly with the Physical Mobility and Pain sections of the NHP and correlated moderately with other sections, indicating convergent validity. Known group validity was established by the ability of the measure to distinguish between patients who differed according to their perceived general health and disease severity. No significant differences in PsAQoL scores were observed between males and females or older and younger patients. The Greek PsAQoL was well-received by patients and demonstrated sound psychometric properties. It forms part of a growing body of disease-specific measures that are available in Greece. It is recommended for use in routine clinical practice, international clinical trials and research studies as a valid and reliable measure of QoL in PsA patients.

Key words: Psoriatic arthritis, quality of life, PsAQoL, disease-specific, psychometric test.

Introduction

Psoriatic arthritis (PsA) is an inflammatory rheumatic disease that is associated with the chronic skin condition psoriasis. Patients with PsA are usually affected with psoriasis before there are signs of arthritis.¹ Psoriasis is characterised by raised patches of inflamed skin that can be itchy or sore. PsA causes pain, swelling and stiffness in the joints and tendons in the body. The disease presents itself equally in males and females and, although it can develop at any age, it is most likely to affect adults between the ages of 45 and 64 years.² An epidemiological study in North West Greece found the prevalence of PsA to be 56.6 cases per 100,000 adults, half of that reported in research from Northern Europe.²

PsA is associated with poor physical and psychosocial functioning.^{3,4} Lower employment rates for PsA patients compared to the general population have also been reported,⁵ with the disease imposing an inevitable burden on quality of life (QoL).⁶ In order to gain a complete picture of the impact of a health condition on the patient it is necessary to determine a patient's QoL.⁷ The Psoriatic Arthritis Quality of Life (PsAQoL) scale was developed in the UK as a PsA-specific measure of QoL that adopted the needs-based model.⁸ The model postulates that QoL is low when an individual is unable to satisfy certain human needs.⁹ The content of the instrument was derived from in-depth qualitative interviews with PsA patients exploring the ways in which the illness prevented need fulfilment.

As a disease-specific measure of QoL, all items in the PsAQoL are relevant to these patients, thus maximising the scale's relevance and sensitivity. This is contrary to generic measures, such as the SF-36 and NHP, which show weak scaling properties and lack responsiveness.^{10,11} It is commonly believed that only generic measures can be used to make comparisons of outcomes between different diseases. However, it is possible to co-calibrate scores generated from different disease-specific measures.¹² This quality of needs-based measures makes them particularly valuable for comparative-effectiveness research.¹²

The PsAQoL has been adapted into 50 languages, for use in North and South America (10); Asia (14); Europe (24); Australia (1) and Africa (1). However, prior to this study the instrument had not been adapted for use in Greece. The aim of this study was to pro-

duce a Greek version of the PsAQoL that demonstrated psychometric properties equivalent to those of the original instrument.⁸ This was necessary to confirm its suitability for use in international clinical trials and research.

Material and methods

Translation of the PsAQoL scale

The dual-panel methodology¹³ was adopted for the translation of the PsAQoL into Greek. This process involves conducting two independent panels – a bilingual panel followed by a lay panel. The bilingual panel consisted of Greek professionals who were fluent in English and was attended by one of the PsAQoL developers. The purpose of this panel was to produce an initial Greek translation of the measure that was equivalent conceptually to the UK English original. This version was taken forward to a lay panel, consisting of monolingual Greek speakers of average educational attainment. Alternative translations could be taken to the lay panel for consideration. The lay panel could select from the alternatives or even suggest new words providing that the meaning was maintained. The comprehensiveness of items and whether they were of natural phrasing in the target language was assessed in the lay panel. Both panels were led by the same Greek researcher.

Psychometric assessment

Patients

Patients were invited to take part in the CDIs and postal validation survey if they were; aged 18 years or above, able to understand and complete the questionnaires and able to give written informed consent. An exclusion criterion was the presence of major comorbidity judged by the clinical team to be a significant influence on the patients' QoL. Participants were recruited through opportunity sampling by their clinician from one of the following locations:

- Rheumatology Clinic, Outpatient Department, St Paul General Hospital, Thessaloniki
- Outpatient Psoriasis Department, "Hospital of Skin and Venereal diseases", Aristotelian University Clinic, Thessaloniki
- Private Practice, Thessaloniki.

Ethics committee approval was obtained from St. Paul's Scientific Council.

Assessment of face and content validity

Face and content validity of the measure was assessed using cognitive debriefing interviews (CDIs) conducted with PsA patients.

The purpose of the CDIs was to assess the comprehension, ease of completion, relevance and comprehensiveness of the questionnaire. The interviews followed a face-to-face, semi-structured approach. Patients completed the questionnaire in the presence of an interviewer who observed and queried any difficulties in responding to the items. Patients were also asked to provide feedback on the questionnaire items, instructions and response format.

Postal validation survey

Finally, a postal validation survey was conducted to establish the psychometric properties of the Greek PsAQoL adaptation. The original UK version of the PsAQoL demonstrated excellent internal consistency ($\alpha=0.91$), test-retest reliability (0.89), convergent and known group validity.⁸ The measure has 20 items with a dichotomous "True/Not true" response option. The total number of "True" responses is summed to give the total score. The lowest and highest potential scores for the PsAQoL are 0 and 20 respectively, with a higher score indicating poorer quality of life.

At the first administration of the PsAQoL (Time 1), the Greek version of the Nottingham Health Profile¹⁴ was included in the postal survey as a comparator instrument. The NHP assesses health status in six sections; energy level, physical mobility, pain, sleep, emotional reactions and social isolation. It includes 38 statements with dichotomous "Yes/No" response options. Scores for the NHP are calculated as a percentage of the items affirmed in each section. All six sections of the instrument have a minimum potential score of 0 and a maximum of 100, with high scores indicating worse health status. The Greek NHP demonstrates test-retest reliability coefficients above the minimum acceptable level of 0.70 and is sensitive to differences in patients' perceived disease severity.¹⁴ Participants who completed and returned the PsAQoL and NHP at Time 1 were then sent the Greek PsAQoL approximately 14 days later (Time 2). Participants were allocated an ID number to ensure anonymity and to allow matching of respondents' data between administrations.

The internal consistency, test-retest reliability, convergent and known-group validity of the PsAQoL were determined from the postal survey data. As the data

were at the ordinal level of measurement, non-parametric statistical analyses were performed. Internal consistency is a measure of the extent to which items in a scale are inter-related and is assessed by Cronbach's alpha coefficient. An alpha value below 0.7 indicates that the items do not work together to form a scale.¹⁵ Test-retest reliability and convergent validity were measured using Spearman's rank correlations. The former provides an estimate of the measure's reproducibility over time by correlating scores on the scale on two occasions. A minimum value of 0.85 is required.¹⁶ The latter assesses the level of association between scores on one scale and those on a comparator scale that measures a related construct. In this case, PsAQoL scores were correlated with scores on the NHP sections. A Mann-Whitney U test was used to assess known group validity. This tests the ability of the PsAQoL to distinguish between patients who differed according to their self-reported ratings of general health and PsA severity. The categories for general health were "very good/ good" and "fair/poor". PsA severity was grouped into "mild/moderate" versus "quite severe/very severe". Statistical analyses of the data were conducted using the Statistical Package for the Social Sciences (SPSS) version 19.0 software (SPSS Inc., Chicago IL, USA).

Results

Translation of the PsAQoL scale

The bilingual panel consisted of two males and three females aged between 25 and 57 years. The group produced the first Greek translation of the PsAQoL. Five of the items produced significant discussion but appropriate translations were produced that captured the intended concept. There was discussion in the bilingual panel concerning the response options, where "It is true" and "It is not true" was suggested before deciding on "I agree" and "I disagree".

The lay panel consisted of three males and three females aged from 21 to 62 years. The lay panel confirmed that the translations sounded natural in Greek and only minor changes were made to the questionnaire instructions. The lay panel amended the response options to "True" and "False" as it was considered this would work best with respondents.

Assessment of face and content validity

Ten patients participated in the CDIs, of whom 6 were female. Time taken to complete the questionnaire ranged from 5 to 8 minutes. Patients considered the in-

structions and all items to be clear, understandable and appropriately worded. Minor modifications were made to two of the items to correct grammatical errors.

Postal validation survey

Seventy-five patients completed the questionnaire package at Time 1. Sixty-one patients (81%) also completed the second administration of the PsAQoL. Data for those participants who did not return the questionnaire at Time 2 or who had missing responses were excluded from the statistical analyses. Table 1 presents demographic and disease information for this sample.

Patients' scores on the PsAQoL and NHP are shown in table 2. The median score for the Greek PsAQoL was 11.0 at both time points. No floor or ceiling effects (high number of patients scoring the minimum and maximum, respectively) were observed for the PsAQoL. For the NHP, respondents scored highest on the Energy level, Emotional reactions and Sleep sections.

Internal consistency

Cronbach's alpha coefficient for the PsAQoL was 0.88 at both administrations, indicating that the items are sufficiently inter-related.

Test-retest reliability (reproducibility)

The PsAQoL showed excellent test-retest reliability with a Spearman rank correlation coefficient of 0.98 ($p < 0.01$). This shows that the scale demonstrates low levels of random measurement error.

Convergent validity

Correlations between PsAQoL scores and those on the six NHP sections at Time 1 can be seen in table 3. PsAQoL scores correlated strongly with the Physical Mobility and Pain scales of the NHP, showing the importance of these factors on QoL. There were also moderately high correlations between the PsAQoL and the NHP Emotional reactions and Sleep scales, suggesting that multiple factors influence QoL in PsA.

Known group validity

Figure 1 shows patients who rated their general health as fair or poor scored higher on the PsAQoL (Mdn=15.0; IQR=14.0–16.0) than those who rated their general health as very good or good (Mdn=6.0; IQR=3.75–8.0). This indicates significantly worse QoL in patients rating their general health less favourably ($U=41.50$, $n=33$, $n=26$, $p < 0.01$, two-tailed). Also as expected, patients who evaluated their PsA severity

Table 1. Details of postal validation sample (n=61).

Age	Years	
Mean (SD)	46.0 (10.8)	
Median (IQR)	44.2 (37.3–56.8)	
Range	28.0–69.4	
Gender	n	(%)
Male	40	65.6
Female	21	34.4
Marital Status		
Married/Living as Married	33	54.1
Divorced	8	13.1
Widowed	3	4.9
Single	17	27.9
Work Status		
Full-time	7	11.5
Part-time	15	24.6
Homemaker	7	11.5
Retired	11	18.0
Unemployed	21	34.4
Patient-perceived general health		
Very good	5	8.2
Good	22	36.1
Fair	24	39.3
Poor	10	16.4
Patient-perceived PsA severity		
Mild	20	32.8
Moderate	17	27.9
Quite severe	18	29.5
Very severe	6	9.8

PsA: Psoriatic Arthritis

as quite or very severe scored higher on the PsAQoL (Mdn=15.5; IQR=15.0–16.0) than patients who regarded their PsA severity as mild or moderate (Mdn=6.0; IQR=4.0–9.0) (figure 2). There was a significant difference between the two groups for PsA severity ($U=32.00$, $n=35$, $n=24$, $p < 0.01$, two-tailed).

Demographic findings

The Mann Whitney U tests revealed no difference in PsAQoL scores between males (Mdn=14.0; IQR=6.0–15.0) and females (Mdn=8.5; IQR=3.25–15.0), or between older (Mdn=11.0; IQR=4.0–16.0) and younger patients (Mdn=12.0; IQR=6.5–15.0). Therefore, PsAQoL scores did not significantly differ between patients grouped by gender ($U=311.5$, $n=39$, $n=20$, $p=0.21$, two-tailed) or age group ($U=427.5$, $n=30$, $n=29$, $p=0.91$, two-tailed).

Table 2. Descriptive scores for the PsAQoL and NHP sections.

	n	Median (IQR)	Mean (SD)	Range	(%) scoring minimum	(%) scoring maximum
PsAQoL (Time 1)	59	11.0 (6.0–15.0)	10.6 (5.4)	1.0–19.0	0.0	0.0
PsAQoL (Time 2)	60	11.0 (6.0–15.0)	10.5 (5.5)	1.0–19.0	0.0	0.0
<i>NHP</i>						
Energy level	61	66.7 (16.7–66.7)	51.4 (36.3)	0.0–100.0	24.6	21.3
Pain	61	37.5 (0.0–75.0)	36.7 (35.9)	0.0–87.5	41.0	0.0
Emotional Reactions	61	44.4 (11.1–72.2)	44.6 (35.0)	0.0–100.0	14.8	14.8
Sleep	61	40.0 (0.0–100.0)	44.6 (43.9)	0.0–100.0	41.0	29.5
Social Isolation	61	40.0 (0.0–80.0)	40.7 (36.3)	0.0–100.0	27.9	14.8
Physical Mobility	61	37.5 (0.0–62.5)	32.6 (27.0)	0.0–87.5	29.5	0.0

PsAQoL: Psoriatic Arthritis Quality of Life scale, NHP: Nottingham Health Profile
 Note: Participants with missing data were excluded from the analyses

Discussion

The Greek adaptation of the PsAQoL was successful. The measure reflected the same concepts as in the original UK version, was comprehensible and appropriate to patients and demonstrated excellent psychometric properties, comparable to those of the original UK PsAQoL.⁸ The new language version has excellent internal consistency, reproducibility and is able to detect meaningful differences in terms of general health status and perceived PsA severity.

The sensitivity and responsiveness of a measure is reduced with the presence of floor or ceiling effects. The absence of floor and ceiling effects for the Greek PsAQoL demonstrates that the measure is well targeted to the patients. This is in contrast to a significant proportion of patients scoring the minimum, and maximum in some cases, for the NHP sections. This means that the NHP is less able to discern

meaningful differences between subjects at either extreme of the measure.¹⁷

The dual panel translation methodology¹³ employed in the adaptation proved successful in overcoming potential difficulties related to English colloquialisms in the original measure. It also ensured that the final version would appeal to future Greek respondents. Research has shown that patients rate translations using the dual panel methodology as more satisfactory compared to forward-backward translations.¹⁸

The Greek PsAQoL adds to a growing body of disease-specific measures available for use in Greece

Table 3. Association between PsAQoL and NHP section scores (n=59).

	PsAQoL
Energy Scale	0.63*
Pain Scale	0.83*
Emotional Reactions	0.71*
Sleep Scale	0.71*
Social Isolation	0.46*
Physical Mobility	0.82*

*Correlation significant at p<0.01 (Spearman rank correlation coefficient)

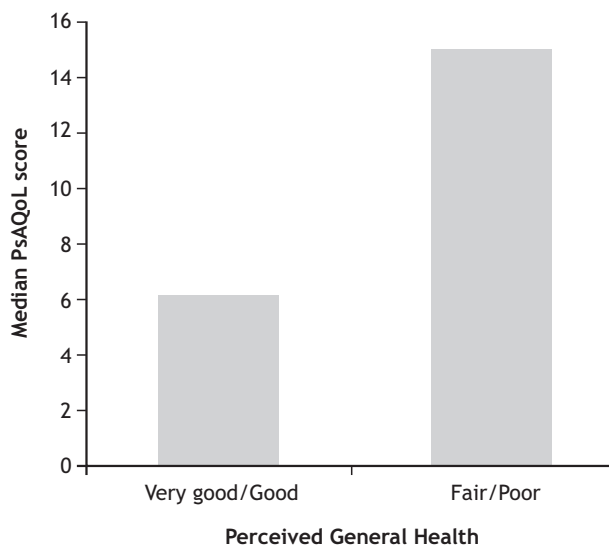


Figure 1. Median scores on the Psoriatic Arthritis Quality of Life (PsAQoL) scale by patient-perceived general health (n=59).*

*Association is significant at p<0.01 (Mann Whitney U test)

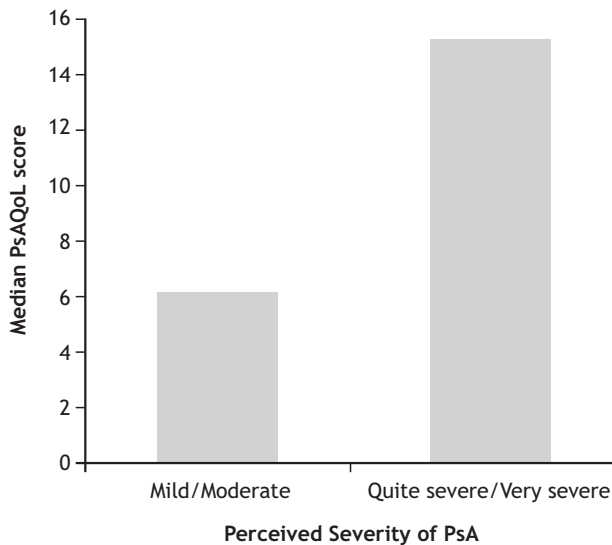


Figure 2. Median scores on the Psoriatic Arthritis Quality of Life (PsAQoL) scale by patient-perceived PsA severity (n=59).*

*Association is significant at $p < 0.01$ (Mann Whitney U test)

that adopt the needs-based model of QoL. This includes the ACQLI (Alzheimer's Carer's Quality of Life Instrument), QoL-AGHDA (Quality of Life Assessment of Growth Hormone Deficiency in Adults) and ASQoL (Ankylosing Spondylitis Quality of Life scale; for example, see Graham¹⁹). As these measures have the same underlying theoretical construct, research using the Rasch model would allow for comparisons of QoL across different diseases.¹² Because of the small sample size employed in the current study, Rasch analysis was unable to be performed. While this does not compromise the psychometric properties of the Greek PsAQoL, it should be noted that further research is required to perform co-calibration and also to determine the responsiveness of the measure.

The Greek PsAQoL will prove a valuable tool for use in international clinical trials including Greece, in routine clinical practice and research studies as a valid and reliable measure of QoL in PsA patients.

Μετάφραση και προσαρμογή της ελληνικής έκδοσης της Κλίμακας Εκτίμησης της Ποιότητας Ζωής στην ψωριασική αρθρίτιδα

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Η ψωριασική αρθρίτιδα (ΨΑ) είναι χρόνια φλεγμονώδης νόσος που επηρεάζει σημαντικά την ποιότητα ζωής των ασθενών. Η κλίμακα εκτίμησης της ποιότητας ζωής ασθενών με ΨΑ αναπτύχθηκε στη Μεγάλη Βρετανία για τους αντίστοιχους πάσχοντες και υιοθετεί το μοντέλο της ποιότητας ζωής με βάση τις ανάγκες. Η κλίμακα αυτή PsAQoL είναι προσαρμοσμένη σε ένα νόσημα και είναι καλύτερη από τα εργαλεία γενικής χρήσης μέτρησης της ποιότητας ζωής όσον αφορά στην ειδικότητα και ευαισθησία. Το εργαλείο αυτό εκτίμησης της ποιότητας ζωής έχει προσαρμοστεί σε 50 γλώσσες, και μέχρι σήμερα δεν ήταν διαθέσιμο για χρήση σε Έλληνες ασθενείς πάσχοντες από ΨΑ. Σκοπός της εργασίας ήταν η παραγωγή ελληνικής έκδοσης της κλίμακας μέτρησης της ποιότητας ζωής ασθενών με ΨΑ με σκοπό τη χρήση της σε Έλληνες ασθενείς, η οποία να είναι ισοδύναμη με την αυθεντική κλίμακα που παρήχθη στη Μεγάλη Βρετανία. Η προσαρμογή της κλίμακας εκτίμησης της ποιότητας ζωής PsAQoL περιέλαβε τρία στάδια, της μετάφρασης, της εκτίμησης της εγκυρότητας του περιεχομένου και της ανάλυσης των ψυχομετρικών ιδιοτήτων της. Το μεταφραστικό στάδιο υιοθέτησε τη μεθοδολογία της διπλής ομάδας (μια δίγλωσση ομάδα και ομάδα ατόμων που δεν σχετίζονταν με τον χώρο της υγείας) για να εξασφαλισθεί η εννοιολογική ισοδυναμία της κλίμακας με την αρχική της έκδοση. Διεξήχθησαν

γνωστικές συνεντεύξεις για να προσδιοριστεί η εφαρμογή και η συνάφεια της κλίμακας σε ασθενείς με ΨΑ. Χρησιμοποιώντας το Nottingham Προφίλ Υγείας (NHP) ως μέσο σύγκρισης διεξήχθη ταχυδρομική έρευνα για να καθιερωθεί η αξιοπιστία και η εγκυρότητα της κλίμακας. Μη-παραμετρικές στατιστικές αναλύσεις πραγματοποιήθηκαν για να καθιερωθεί η αξιοπιστία και η δομική εγκυρότητα της κλίμακας PsAQoL. Οι ομάδες μετάφρασης παρήγαγαν μια γλωσσική έκδοση που ικανοποιούσε τους Έλληνες. Οι συνεντεύξεις έδειξαν ότι οι ασθενείς εκτίμησαν την κλίμακα ως εύληπτη και κατάλληλη. Μετά τις συνεντεύξεις έγιναν μόνο μικρές γλωσσικές αλλαγές στην κλίμακα. Η ελληνική έκδοση της κλίμακας PsAQoL έδειξε καλή εσωτερική συνοχή (Cronbach's $\alpha=0,88$) και καλή αξιοπιστία επαναληψιμότητας ($r=0,98$). Όπως αναμενόταν, το ερωτηματολόγιο έδειξε μέτρια συσχέτιση σε σχέση με τις ενότητες που αφορούσαν στη φυσική κινητικότητα και τον πόνο του NHP και μέτρια συσχέτιση με τις άλλες ενότητες, ευρήματα που συνηγορούν για την εγκυρότητά του. Η εγκυρότητα της κλίμακας εκτιμήθηκε από την ικανότητα του ερωτηματολογίου να διακρίνει τους ασθενείς ανάλογα με το πώς εκτιμούν τη γενική τους υγεία και τη σοβαρότητα της ασθένειάς τους. Δεν παρατηρήθηκαν διαφορές μεταξύ ανδρών και γυναικών ούτε μεταξύ ηλικιωμένων και νέων ασθενών. Η ελληνική κλίμακα PsAQoL έδειξε αξιόπιστες ψυχομετρικές ιδιότητες και ήταν αποδεκτή από τους ασθενείς. Εντάσσεται στον αυξανόμενο αριθμό ψυχομετρικών κλιμάκων που αφορούν σε συγκεκριμένα νοσήματα και είναι διαθέσιμες στην ελληνική γλώσσα. Οι ψυχομετρικές αυτές κλίμακες μπορούν να συνεκτιμηθούν με άλλες κλίμακες για την εκτίμηση της ποιότητας ζωής. Συνιστάται για χρήση στην καθημερινή κλινική πρακτική σε διεθνείς κλινικές μελέτες και στις συγκριτικές έρευνες αποτελεσματικότητας διαφόρων θεραπευτικών μεθόδων.

Λέξεις ευρητήριο: Ψωριασική αρθρίτιδα, ποιότητα ζωής, PsAQoL, νόσος, ψυχομετρική δοκιμασία.

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