

## Greek adaptation and validation of the Ankylosing Spondylitis Quality of Life (ASQoL) measure

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### Abstract

**Background:** Ankylosing Spondylitis (AS) is a chronic rheumatic disease that has a significant impact on patient's quality of life (QoL). The Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire is a disease-specific patient-reported outcome measure for assessing QoL in AS. While the ASQoL has been adapted for use in 46 countries worldwide, a Greek language version of the measure has not been available and was required for an international clinical trial.

**Aim:** The aim was to develop and assess the psychometric properties of a Greek language version of the ASQoL.

**Methods:** The adaptation of the ASQoL into Greek involved three procedures: translation, assessment of face and content validity, and formal validation. The measure was translated into Greek using two translation panels. Cognitive debriefing interviews were employed to determine face and content validity. Finally, the translation's psychometric properties were examined by administering it on two occasions, with a 14-day interval. The Nottingham Health Profile (NHP) was used as a comparator measure.

**Results:** The ASQoL proved straightforward to translate into Greek and interviewees found it relevant, comprehensible and easy to complete. The measure had good internal consistency ( $\alpha = 0.92$ ) and test-retest reliability ( $r = 0.98$ ). Predicted correlations with the NHP provided evidence of the convergent validity of the two measures. Construct validity was confirmed by the measure's ability to distinguish groups of AS patients varying by perceived disease severity and general health.

**Conclusions:** The Greek ASQoL has been shown to be well-accepted, reliable and valid and can be recommended for use in clinical studies and routine clinical practice in AS. *Hippokratia* 2015; 19 (2):119-124.

**Keywords:** Ankylosing spondylitis, adaptation, ASQoL, quality of life, questionnaire, validity

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### Introduction

Ankylosing Spondylitis (AS) is a common rheumatic disease with significant impact on the lives of patients. It is a progressive and debilitating disease that involves chronic inflammation of the spine, affecting skeletal and extra-skeletal tissues<sup>1</sup>. Patients experience pain, morning stiffness and disability which are likely to increase with duration of disease<sup>2</sup>. These functional impairments have been associated with lower levels of mood and motivation and reduced ability to cope with day-to-day activities<sup>3</sup>, leading to both social and work-related problems<sup>4-7</sup>. In a sample of 612 patients with AS in the United Kingdom, the level of employment was approximately 14% lower than that of the national average for people of working age<sup>6</sup>. A Turkish study found that 32% of AS patients had quit their jobs as a result of their illness<sup>4</sup>.

The prevalence of AS varies by ethnicity and geography. Population studies have reported prevalence of between 0.5% and 1.6% and it is more commonly found in men than women<sup>8,1</sup>. The prevalence of AS was reported

to be 0.19% in western Norway between 1999 and 2002<sup>9</sup>. In Ancona, Italy, de Angelis et al (2007) reported a prevalence of 0.37%<sup>10</sup>. A higher rate (0.49%) was reported in Izmir, Turkey<sup>11</sup>. In Northwest Greece one study found AS prevalence to be 0.03%<sup>12</sup>. In contrast, in central Greece the rate was reported to be 0.29%<sup>13</sup>.

The Ankylosing Spondylitis Quality of Life questionnaire (ASQoL) is a disease-specific patient-reported outcome measure (PROM) that assesses the impact of AS on quality of life (QoL). It has 18 items, each with a dichotomous "yes/no" response option scored "1" and "0" respectively. Total scores range from 0-18, with a higher score indicating poor QoL. The ASQoL was developed by combining the statistical and diagnostic power of the Rasch model with the theoretical strengths of the needs-based QoL model. This model postulates that life gains its quality from the ability of the individual to satisfy his or her needs<sup>14</sup>. QoL is high when needs are fulfilled and low when few needs are satisfied. The model is well

established and has been applied successfully in the development of a large number of disease-specific QoL instruments, several of which have become established as the preferred outcome instrument for clinical trials and research<sup>15-17</sup>. The ASQoL was developed in parallel in the United Kingdom and the Netherlands and the needs included in the scale were derived from qualitative interviews conducted with AS patients in both countries. Application of the Rasch model ensured that the instrument was unidimensional and that it had excellent psychometric properties (specifically; reproducibility and construct validity). The ASQoL is the most frequently used disease-specific measure in AS studies<sup>18</sup> and has been adapted for use in 46 countries worldwide. Language adaptations have been produced for Europe (23); the Middle East (2); America (9); Australasia (1); Asia (9) and Africa (2).

The aim of the study was to produce a reliable and valid adaptation of the ASQoL for Greece for use in international clinical trials and for routine clinical use.

### Methodology

The language adaptation of the ASQoL for Greece involved three stages; translation, assessment of face and content validity and establishment of reliability and construct validity.

#### Translation

The translation procedure was designed to produce a Greek version of the measure that would be meaningful and natural for Greek speakers. The procedure focused on conceptual rather than literal translation of the items and used two independent panels. The first consisted of Greek (bilingual) professionals who were fluent in English. One of the developers of the ASQoL attended this meeting to explain the conceptual meaning of the items. The panel worked as a group and came to a consensus about the most appropriate translation for the items and instructions. This translation was then considered by a second panel. This consisted of Greek speakers who were considered to be typical of the target population (while not having AS). The panel, which worked only in Greek, was asked to comment on the acceptability of the Greek items and instructions.

#### Assessment of face and content validity

Cognitive debriefing interviews were conducted with AS patients to determine the relevance and comprehensiveness of the Greek questionnaire and to see whether they found it easy to understand and complete. Patients were identified by their physician at one of the following:

- Rheumatoid Arthritis outpatient clinic, Hippokratiko General Hospital, Thessaloniki
- Out-patient clinic of Endocrinology, Hippokratiko General Hospital, Thessaloniki
- Anthropometric laboratory (Endocrinology-Diabetic), Aristotle University of Thessaloniki
- Private practice

Interviewees completed the ASQoL in the presence of an interviewer, who noted any obvious difficulties. They

were then invited to comment on the items, instructions and response format. Respondents were also asked to rate the severity of their symptoms as mild, moderate, quite severe or very severe and their general health as very good, good, fair or poor.

#### Postal validation survey

The internal consistency, reproducibility (test-retest reliability), convergent and known-group validity of the Greek ASQoL were examined by administering the ASQoL at clinic on two occasions, with two weeks between administrations. Participants were recruited from the same three hospitals and private medical offices described above. Patients were selected based on the follow eligibility criteria:

#### Inclusion criteria

- Confirmed AS diagnosis.
- Aged 18 years and above.
- Ability to understand and complete questionnaires independently (as judged by the clinical team).
- Ability to provide written informed consent.

#### Exclusion criteria

- Presence of major co-morbidity judged by the clinical team to be a significant influence on subject's QoL and therefore likely to influence their answers on a PRO.
- Judged by the clinical team to be incapable of participating in the study (e.g. if the patient has cognitive difficulties that limit ability to read and respond to questionnaires).

Participants also completed the Nottingham Health Profile questionnaire (NHP) on the first occasion as a comparator scale<sup>19</sup>. The NHP assesses perceived distress, a construct related to QoL. It consists of 38 items covering six sections: energy level, pain, emotional reactions, sleep, social isolation and physical mobility. Scores on each section are expressed as a percentage of items affirmed, varying from 0 to 100. A zero score indicates that the patient has no perceived distress in that section. Data were analysed using the Statistical Package for the Social Sciences (SPSS) version 19.0 software (SPSS Inc., Chicago IL, USA).

Non-parametric assessments were employed throughout due to the ordinal nature of the data. Spearman rank correlation coefficients were used to test the strength of associations and Kruskal-Wallis one-way analysis of variance to compare known groups.

### Results

#### Translation of the ASQoL

The first panel consisted of two male and four female Greek (bilingual) professionals who were fluent in English. The mean age of the panel was 30.33 [standard deviation (SD) 12.2] years, ranging from 18 to 47 years. The panel had very few difficulties producing translations of the items and instructions. The only item that required extended discussion was '*It's impossible to sleep*',

for which two translations were produced by the panel: '*I cannot sleep*' and '*I have trouble sleeping*'. Both options were sent to the second panel for consideration.

The second panel comprised three male and three female Greek participants believed to be typical of the target population. The mean age of the panel was 45.7 (SD 17.5) years and ranged from 23 to 67 years. The panel considered the translations produced by the first bilingual panel without reference to the original English questionnaire. Consensus on all items was reached. For the item '*It's impossible to sleep*' the lay panel decided to select the option that was simpler and closer to everyday language, with the meaning 'trouble sleeping'. Minor alterations were also made to three other items to make them more acceptable to future respondents and to better reflect their original meaning.

#### *Assessment of face and content validity*

Cognitive debriefing interviews were conducted with six male and four female AS patients. Their mean age was 43.2 (SD 12.2) years, ranging from 24 to 61 years. The time taken to complete the questionnaire varied from 3 to 6 with a mean of 3.7 minutes. All items and instructions were considered appropriate and no particular item stood out as being awkwardly worded or difficult to understand. Interviewees considered the content of the questionnaire to be appropriate. Consequently, no changes were necessary as a result of the debriefing exercise.

#### *Postal validation survey*

Ninety-two AS patients completed and returned the questionnaire package on the first occasion. Of these, 87 (94.6%) returned the second administration package. Table 1 shows details of the sample and their ratings of health status. The mean age of the sample was 49.6 (SD 11.5) years with ages ranging from 27 to 75.

Respondents' scores on the ASQoL and NHP are shown in Table 2. The mean score for the Greek ASQoL remained the same (9.1) across administrations. Respondents scored highest on the energy level, pain and physical mobility sections of the NHP.

**Table 1:** Details of postal validation sample consisting of 92 Ankylosing Spondylitis patients who completed and returned the questionnaire package.

Characteristics	Number (%)
<b>Gender</b>	
Male	63 (68.5)
Female	29 (31.5)
<b>Educational Level</b>	
Primary (5-10/11 years)	14 (15.2)
Secondary (11-15/16 years)	52 (56.5)
Higher education	26 (28.3)
<b>Marital Status</b>	
Divorced	13 (14.1)
Married	63 (68.5)
Single	12 (13.0)
Widowed	4 (4.3)
<b>Employment Status</b>	
Employed	43 (46.7)
Unemployed	17 (18.5)
Student	1 (1.1)
Retired	31 (33.7)
<b>Self-reported general health</b>	
Poor	22 (23.9)
Fair	38 (41.3)
Good	28 (30.4)
Very good	4 (4.3)
<b>Self-reported severity of AS</b>	
Mild	18 (19.6)
Moderate	32 (34.8)
Quite severe	29 (31.5)
Very severe	13 (14.1)

AS: Ankylosing Spondylitis.

#### *Internal reliability*

Cronbach's  $\alpha$  coefficient for the Greek ASQoL was 0.92 at both time points, indicating that the items were adequately inter-related on each occasion.

#### *Reproducibility*

Test-retest reliability was calculated for the 87 patients who provided fully completed questionnaires on both occasions. The Spearman rank correlation coefficient was 0.98 demonstrating that the Greek ASQoL generates a very low level of random measurement error. No patients changed in perceived severity or general health between the two assessments.

**Table 2:** Descriptive scores for the Ankylosing Spondylitis Quality of Life questionnaire (ASQoL) and the Nottingham health profile (NHP) sections.

	n	Mean	SD	Range	% scoring minimum	% scoring maximum
ASQoL (time 1)	92	9.1	5.7	0-18	2.2	2.2
ASQoL (time 2)	87	9.1	5.8	0-18	2.3	4.6
<b>NHP section scores</b>						
Energy level	92	60.9	38.8	0-100	22.8	37.0
Pain	92	46.7	35.8	0-100	19.6	12.0
Emotional reactions	92	37.7	25.6	0-88.9	13.0	1.1
Sleep	92	29.8	30.5	0-100	32.6	5.4
Social isolation	92	22.2	23.1	0-100	35.9	2.2
Physical mobility	92	42.8	27.7	0-100	8.7	5.4

n: number, SD: Standard deviation, ASQoL: Ankylosing Spondylitis Quality of Life questionnaire, NHP: Nottingham Health Profile

### Convergent validity

Table 3 shows the correlations between ASQoL scores and those on the NHP sections at Time 1. Relatively high correlations were found between the ASQoL and NHP Pain, Emotional reactions and Physical mobility sections. Sleep and, especially, Social isolation were less related to QoL, suggesting that Social aspects do not have a major influence on the impact of AS on QoL.

**Table 3:** Spearman rank correlation coefficients between Ankylosing Spondylitis Quality of Life questionnaire (ASQoL) and the Nottingham Health Profile (NHP) section scores (n =92).

	ASQoL
Energy level	0.69*
Pain	0.79*
Emotional reactions	0.75*
Sleep	0.57*
Social isolation	0.10
Physical mobility	0.84*

ASQoL: Ankylosing Spondylitis Quality of Life questionnaire

, \*: Correlation was significant at  $p < 0.01$ .

### Demographic findings

Women in the sample had higher scores on the ASQoL than men with a mean score of 11.6 (SD =5.8) compared to 8.0 (SD =5.3) ( $p < 0.01$ ). This mirrors previous studies that have found significantly higher scores in women for the ASQoL and other generic measures of Health-Related Quality of Life (HRQL)<sup>20-21</sup>.

### Known group validity

Patients who rated their perceived disease severity quite or very severe scored higher on the ASQoL (mean =14.5, SD =2.5) than those who rated their disease severity moderate (mean =6.3, SD =2.7) or mild (mean =1.7, SD =1.2) (Figure 1). Similarly, patients suffering from poor general health scored higher on the ASQoL (mean =15.1, SD =2.1) than those with fair (mean =10.2, SD =4.4) or good or very good general health (mean =3.7, SD =3.4; Figure 2). Both these findings demonstrate the ability of the ASQoL to distinguish between subgroups of patients expected to have differences in QoL.

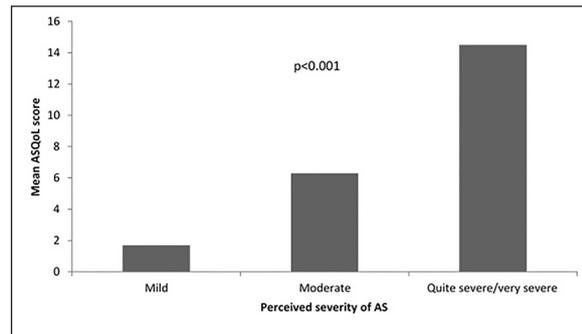
### Discussion

The results of this study indicate that the Greek adaptation of the ASQoL was successful. The measure was well accepted and completed by respondents and it showed good reproducibility and construct validity. The adaptation will make a valuable contribution to routine clinical practice and research studies in Greece.

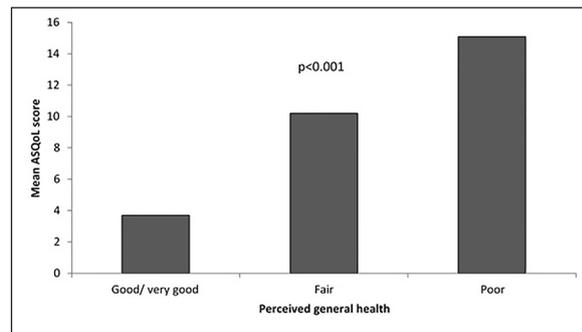
The ASQoL has been successfully adapted for use in 46 countries worldwide. As such, availability of the

new adaptation means that Greece can be included in multinational clinical trials in which a QoL endpoint is included.

The psychometric properties found in the present study were similar to those in the original UK study. Reproducibility of the Greek ASQoL (0.98) was comparable to that of the UK ASQoL (0.92), indicating that the measure has excellent test-retest reliability. Again, as



**Figure 1:** Mean scores on the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire by patient-reported severity group. Association tested using the Kruskal-Wallis one-way analysis of variance. A significant association at the 0.01 significance level was observed.



**Figure 2:** Mean scores on the Ankylosing Spondylitis Quality of Life (ASQoL) questionnaire by patient-reported general health group. Association tested using the Kruskal-Wallis one-way analysis of variance. A significant association at the 0.01 significance level was observed.

with the UK ASQoL, relatively high correlations were found between Greek ASQoL scores and those on the Emotional reactions, Pain and Physical mobility sections of the NHP. In both cases, Social isolation demonstrated the lowest correlation. Furthermore, both the UK and Greek measures were able to show significant differences between groups that differed in perceived general health status and AS severity.

In an evaluation of the existing guidelines concerning translation, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) task force<sup>22</sup> formulated a nine-step method to produce language versions of Patient Reported Outcomes (PROs). This method includes: preparation, forward translation, reconciliation, back translation, back translation review,

harmonisation, cognitive debriefing, review of cognitive debriefing results and finalisation, proofreading and final report. Thus, it involves a double-forward and a double-backward translation methodology.

The dual panel translation methodology<sup>23</sup> was employed for the adaptation of the Greek ASQoL. Two panels are conducted; a bilingual panel to provide the initial 'forward translation' and a lay panel within which items are assessed for comprehension and 'naturalness' of language. This methodology omits back translation. The primary purpose of back-translation is to provide a quality-control step. However, there is no evidence in the literature that back-translation is of value. In one study comparing the dual panel methodology with a forward-backward translation procedure the dual panel methodology led to more satisfactory translations as rated by patients<sup>24</sup>.

There is a major benefit in applying an AS-specific outcome measure such as the ASQoL. Such measures are able to include all important impacts of the disease and avoid asking irrelevant questions. This increases their responsiveness, increasing the chance of observing true improvements in QoL<sup>25-28</sup>.

It is commonly believed that generic outcome measures such as the SF-36 and NHP should also be used in order to allow comparisons to be made with the impact of others diseases. However, research using modern statistical models shows that such comparisons may be invalid<sup>29-31</sup>. Because of their lack of responsiveness and generally poor reproducibility, studies employing the generic measures require very large sample sizes and are unlikely to show differences between interventions.

Certain limitations apply to this study. The small sample size used was not able to test the unidimensionality of the ASQoL. Also, it was not possible to investigate the responsiveness of the new adaptation as no intervention was involved. This is an important property of any measure intended for use in longitudinal studies. However, the high reproducibility of the Greek ASQoL and consequent low levels of measurement error maximise its chances of detecting change in QoL over time. A further study, with a larger sample size would be required to test fully for the impact of demographic variables on ASQoL and to test the measure's sensitivity to clinical variables and ratings of perceived disease severity.

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#### Conflict of Interest

Authors report no conflict of interest. The study was part funded to produce a Greek adaptation of the ASQoL for use in a multinational clinical trial. No conflict of interest is reported.

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