Development and validation of the French ASQoL questionnaire

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Abstract

Objective

Ankylosing spondylitis (AS) is a chronic condition with significant impact on quality of life. The objective was to cross-culturally adapt into French and validate the ASQoL, an 18-item disease-specific self-report questionnaire.

Methods

Cross-cultural adaptation according to published guidelines used forward and backward translations, with an emphasis on expert committee informed decision making. A sample of active AS French patients answered the questionnaire twice, two weeks apart. A transition question helped identify those with no or some change over time.

Results

Cross-cultural adaptation resulted in rewording outcome categories from yes/no into true/false to better suit the French context. In 139 patients (mean age 40.9 years, 54.6% males) with active disease (mean BASDAI 4.8), the mean ASQoL score was 10.0. A 2-parameter Rasch model confirmed unidimensionality (chi-square fit p=0.86) with good item discrimination. Internal consistency was high (Cronbach's alpha 0.9). Convergent validity was ascertained by high correlation of ASQoL score with disease activity measures (r=0.57 to 0.79). Test-retest reproducibility was satisfactory (ICC 0.89). Responsiveness was moderate (SRM 0.44) in patients improving and good (SRM 0.68) in patients worsening over the period.

Conclusion

These results show equivalence in content and validity of the cross-culturally adapted ASQoL for French speaking settings.

Key words

Ankylosing spondylitis, Rasch model, cultural adaptation

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Introduction

Ankylosing spondylitis (AS) is a chronic inflammatory disease that generally begins in early age, affecting mainly entheses, the lumbar spine, the sacroiliac joints and to a smaller extent the peripheral joints and is responsible for pain, morning stiffness and functional disability.

The AS prevalence is not clearly defined, depending, among others, on the studied population, the used criteria and the survey methodology. For the prevalence of the whole group of spondylarthropathies (SpA), several surveys have reported similar results of 0.2–0.5% in the general population (1, 2). The recent French EPIRHUM survey evidenced a prevalence rate of 0.08% [0.03;0.15] for AS and of 0.30% [0.17;0.46] for SpA (3) very close to that of rheumatoid arthritis (0.31% [0.18;0.48]) (4).

Patterns of disease progression are variable, but at least one third of AS patients carry a heavy burden of disease that leads to severe disability (5). The consequences of AS are similar to those seen in rheumatoid arthritis, with difficulty at work, social problems, and associated high direct and indirect costs for society (6, 7). For AS patients, overall quality of life is decreased and mortality is increased (8-10).

The impact of AS and spondylarthropathies on quality of life is significant and has been investigated using several generic instruments, like the SF-36, SF-12, the Nottingham Health Profile (NHP) and the Patient Generated Index (PGI) (11-13). However, this type of instruments has limited ability to detect changes over time, although some might be acceptable at a group level (14). The advantage of disease-specific instrument is to focus on consequences of signs and symptoms in daily life, thus to be more appropriate to the condition at stake, and to have the potential to better detect changes over time, either from natural evolution, or from drug or treatment effect. The ASQoL has been recently developed using an approach grounded on a needs-based model, where items were generated based on expectations from patients according to their current needs (15). It is a fixed-response questionnaire that asks endorsement (yes/no) of 18 items related to symptoms, functioning and disease-related distress. This self-report questionnaire has been developed jointly in Dutch and English settings and languages, is valid and responsive to change (16).

The importance of these quality of life measures is now recognised as being an integrated part of the patient-reported outcomes that matter in chronic conditions (17). They are aimed to capture current quality of life in its multidimensional aspects, to detect changes over time, whether from natural disease progression or by medical or surgical interventions, and to predict future changes (18). To be useful in clinical trials, such instruments need to be available at the international level. This implies to have cultural equivalence of all versions in different languages and culture, which goes far beyond a simple translation.

Our study had two objectives: to develop a French version of ASQoL following guidelines for cross-cultural adaptation of health-related quality of life measures (19, 20) and to assess its scaling and other metric properties, *i.e.* validity, reproducibility and sensitivity to change, in French speaking AS patients.

Patients and methods

Study instrument

ASQoL is a self-administered questionnaire consisting of 18 items related to the specific AS quality of life (15). Its completion requires two minutes. Each statement on the ASQoL is given a score of "1" where the item is endorsed, indicating poor quality of life, or of "0" for good quality of life. All item scores are summed to give a total score or index. Scores can range from 0 (good quality of life) to 18 (poor quality of life). Cases with more than three missing responses (*i.e.* more than 20%) can not be allocated a total score. For cases with one to three missing responses, the total score is calculated as followed: T = 18*x/18-m where "T" is the total score, "x" is the total score for the items endorsed and "m" is the number of missing items.

Development of the French ASQoL version

The procedure followed published recommendations (19, 20) and cumulated experience of this group (21). The original English ASQoL was translated into French separately by two translators (one English native speaker, one French native speaker). They were aware of the objectives underlying the material to be translated to obtain a better idiomatic and conceptual translation rather than simple literal equivalence.

The translations were then submitted to a bilingual expert committee (two epidemiologists, four rheumatologists, one linguist, one AS patient and two translators) to reach a consensus French version. This version was back-translated into English by two translators into their mother tongue, unaware of the topic.

All the translations were lastly compared, with discussion on each item and on adaptation of the answer modalities, until agreement was reached for each item.

A pre-test was administered to a few French speaking patients of a self-help group of AS to assess the readability and the comprehensibility of the formatted questionnaire.

Patient sample

The patients were consecutive outcome AS patients participating into the international ISSAS study aimed at describing potential candidates to TNF-blocker drugs with regards to the rheumatologist point of view (22). In France, the study was conducted in 17 rheumatology departments, between June and October 2003. To enrol in the study, patients had to have a diagnosis of AS confirmed by a certified rheumatologist (23). Patients already treated with TNF blocker drugs were not included in the study.

French AS patients were administered the French ASQoL. The following data were also collected: demographic and social data, date of disease onset, current and previous treatment, surgery history, extra-articular manifestations, clinical and biological activity variables, *i.e.* Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) (24), Bath Ankylosing Spondylitis Functional Index (BASFI) (25), Bath Ankylosing Spondylitis Patient Global Score (BASG) (26), lumbar pain visual analog scale (VAS) (0-10), patient's global disease activity VAS (0-10), number of swollen joints, number of tender enthesis, spinal mobility measures, and recent acute phase reactants serum level.

To assess reproducibility, patients received a second French ASQoL questionnaire to be completed two weeks after the first one, and to be sent back by mail. This latter contained an independent transition question asking on possible changes in their quality of life, pain (VAS) and global disease activity (VAS) between the two ASQoL administrations, on a 7-level Likert scale (low, moderate or major worsening/improvement or no change) (27).

The sample size requirement was set at 150 for construct validity with binary response modality (factor analysis) and 60 for test-retest reproducibility [ANOVA].

Statistical analysis

Construct validity & scaling properties: Construct validity (*i.e.* dimensionality of the instrument) and the scale metric of the French ASQoL administered to the entire study sample of AS patients was explored based on item-response theory using Rasch model analysis. The difficulty of an item is defined by its location on the continuum of the latent trait measured (quality of life): the easier to achieve a good quality of life (ability), the more likely it will be endorsed. The discrimination of an item can be characterised along the logit curve of probability of answering yes to this item, *i.e.* the trace of item: the steeper the slope, the higher probability to discriminate between high and low quality of life individuals. The assumption of unidimensionality of the ASQOL instrument was assessed by overall model chi-square fit statistics. Item difficulty was estimated by item location on an interval-level scale and item chi-square fit. Item discrimination was examined by estimates of the slopes of the trace of items. These properties were assessed consecutively in a 1-parameter (difficulty) (28) and a 2-parameter (difficulty and discrimination) (29) logistic model.

Internal consistency: Internal consistency was assessed using Cronbach's alpha coefficient (30). This statistic indicates the degree of relatedness between items. A value of 0.70 or above is considered as reflecting adequate internal consistency.

Convergent validity: The hypothesis of a relationship of ASQoL score with clinical measures of disease activity and pain (BASDAI, BASFI, BAS-G, lumbar pain VAS and patient's global disease activity assessment) was assessed by Spearman's correlation coefficients.

Discriminant validity was assessed by Student *t*-test according to the willingness of the rheumatologists to treat with TNF-blockers drugs (TNF blocker candidate yes/no).

Reproducibility: Test-restest reliability was assessed using the intraclass correlation coefficient (ICC), in patients reporting no change over time to the transition question at the second measurement time.

The reproducibility of a questionnaire is considered to be good when the correlation coefficient between questionnaire scores is between 0.6 and 0.8 and excellent when the coefficient is over 0.8 (31). French ASQoL reproducibility was evaluated in comparison with pain VAS and patient's global assessment VAS reproducibility.

Sensitivity to change. Sensitivity to change was assessed in patients reporting any low, moderate or major worsening or improvement to the transition question at the second measurement time. The standardised response mean (SRM), *i.e.* the mean difference in score over time divided by the standard deviation of the score difference, was calculated. A SRM is considered low <0.4, moderate up to 0.6, good up to 0.8 and excellent over 0.8.

Statistical analyses were conducted using SAS® 8.2 for psychometric analyses and Parscale® for Rasch analyses (32).

Results

Patients

All the 139 French AS patients included in the international ISSAS study com-

pleted the French ASQoL questionnaire. Their mean age was 40.9±13.7 years, and 76 were male (54.6%). Mean disease duration was 13.1±11.3 years. They presented with a mean of 0.7±1.7 number of swollen joints, of 5.7±5.8 number of tender enthesis and 53.3% had elevated CRP. Their main disease activity measures are summarized in Table I.

French ASQoL version

The French ASQoL version is presented in Fig. 1. The cross-cultural translation was difficult for the three following items leading to French specific wordings: "I struggle to do jobs around the house" was translated into "*Ça me demande des efforts pour faire ce qu'il y a à faire à la maison";* "I have to keep stopping what I am doing to rest" was translated into "*Il faut tout le temps que j'interrompe ce que je suis en train de faire pour me reposer"* and "I often get frustrated" was translated into "*Je me sens souvent frustré(e) de ne pas faire ce que je veux"*.

The cross-cultural translation led also to an answer modalities modification, from a "yes / no" modality into a "true / false" modality, which was felt better adapted to the settlement of the formatted questionnaire and which avoided any misunderstanding for the items with negative sentence (*i.e*. items 5, 6 and 11).

The results of the French ASQoL obtained in the study sample covered the complete 0-18 range (mean ± SD: 10.0±5.3), showing a good capacity of the instrument to elicit a range of responses across the scale.

Pre-testing of the questionnaire was conducted with a few patients members of a self-help group of AS. All items were probed for correct understanding. There was no ambiguity or misunderstanding, and the questionnaire was found easy to fill in overall.

Validity of the French ASQoL

Construct validity & scaling properties: The Rasch analysis found a 2-parameter model to better fit the data than a 1-parameter model, supporting the hypothesis of different slope parameters between items. The unidimensionality hypothesis was not rejected, as shown by a good adequation of the model to the data (overall chi-square fit statistic: 75.46; p=0.86). Only two items were of low (although not significantly) adequation with the full scale: item 7

Table I: Correlations between the 18-item ASQoL score and the disease activity clinical measures (Spearman rank correlation coefficient) (n=139).

Disease activity clinical measures	mean ± SD	r
BASDAI (0-10)	4.8 ± 2.2	0.79
BASFI (0-10)	3.4 ± 2.9	0.69
BAS-G (0-10)	5.4 ± 2.5	0.76
Lumbar pain at night VAS (0-10)	4.3 ± 2.8	0.57
Lumbar pain global VAS (0-10)	4.6 ± 2.6	0.63
Patient's global disease activity VAS (0-10)	5.1 ± 2.6	0.65

Instructions : Vous trouverez ci-dessous des affirmations formulées par des personnes atteintes de spondylarthrite ankylosante. Lisez attentivement chacune de ces affirmations et cochez « vrai » si elle s'applique à vous et « faux » dans le cas contraire.
Cochez **une seule** réponse, celle qui s'applique le mieux **au moment** où vous répondez.

1. Ma maladie me limite dans mes déplacements	❒ Vrai ❒ Faux
2. J'ai quelquefois envie de pleurer	❒ Vrai ❒ Faux
3. J'ai des difficultés pour m'habiller	❒ Vrai ❒ Faux
4. Il faut que je fasse des efforts pour faire ce qu'il y a à faire à la maison	❒ Vrai ❒ Faux
5. Je n'arrive pas à dormir	❒ Vrai ❒ Faux
6. Je ne peux pas participer à tout ce que font mes amis ou ma famille	❒ Vrai ❒ Faux
7. Je suis tout le temps fatigué(e)	❒ Vrai ❒ Faux
8. Il faut tout le temps que j'interrompe ce que je suis en train de faire pour me reposer	❒ Vrai ❒ Faux
9. J'ai des douleurs insupportables	❒ Vrai ❒ Faux
10. Il me faut longtemps pour me mettre en route le matin	❒ Vrai ❒ Faux
11. Je ne peux pas faire ce qu'il y a à faire à la maison	❒ Vrai ❒ Faux
12. Je suis facilement fatigué(e)	❒ Vrai ❒ Faux
13. Je me sens souvent frustré(e) de ne pas faire ce que je veux	❒ Vrai ❒ Faux
14. La douleur est toujours là	❒ Vrai ❒ Faux
15. J'ai l'impression de passer à coté de beaucoup de choses	❒ Vrai ❒ Faux
16. J'ai des difficultés pour me laver les cheveux	❒ Vrai ❒ Faux
17. Ma maladie me démoralise	❒ Vrai ❒ Faux
18. L'idée qu'on ne puisse pas compter sur moi me tracasse	❒ Vrai ❒ Faux

Fig. 1. French version of the ASQoL.

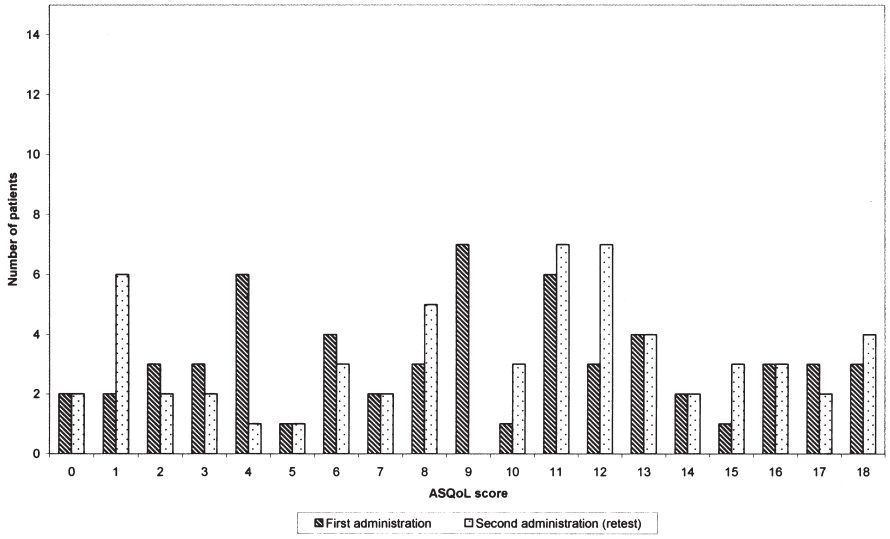

Fig. 2. Distribution of French ASQoL scores among 59 AS patients reporting no change at the two administration times (two-week interval).

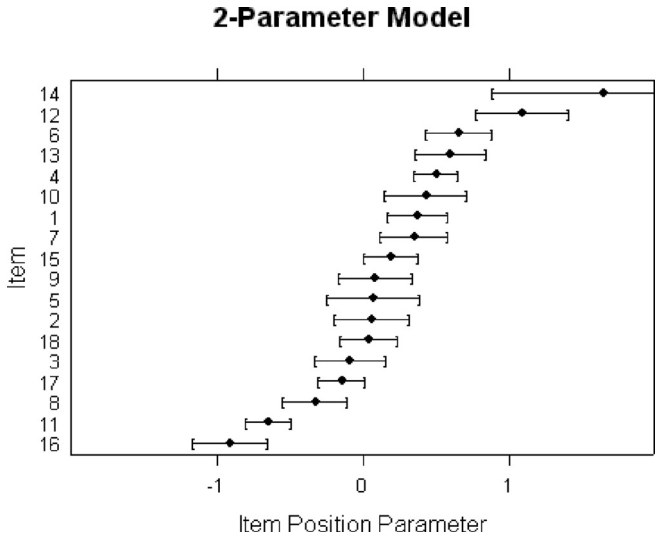

Fig. 3. Item difficulty (position) of each item in a 2-parameter model (Rasch analysis).

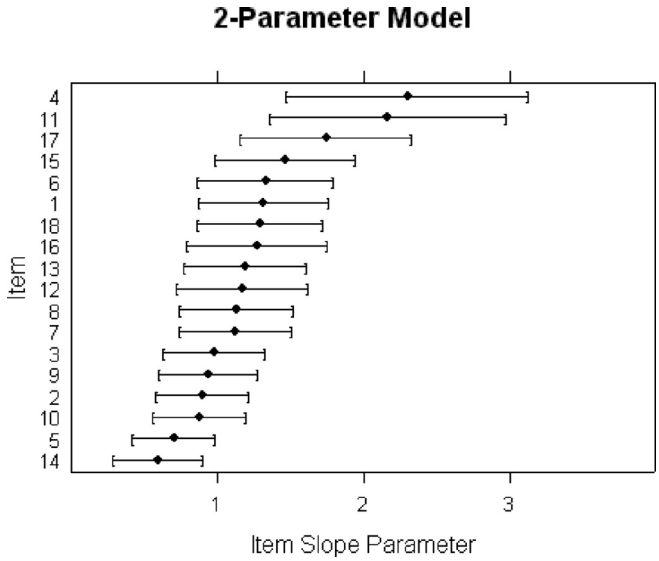

Fig. 4. Item discrimination (slope) of each item in a 2-parameter model (Rasch analysis).

(p=0.075) and item 9 (p=0.063). The item location (Fig. 3) showed some items clustering around similar location, indicating some overlap on the difficulty scale. The item discrimination (mean 1.25), represented in the slope of item trace (Fig. 4), was heterogeneous in a relatively narrow range (0.87-1.74), except for items 4 (2.30), 11 (2.16) and 14 (0.59).

Internal consistency: Cronbach's alpha coefficient had a highly satisfactory value of 0.90.

Convergent validity: Evidence of convergent validity was provided by assessing the levels of correlation between the French ASQoL and the comparator measures, *i.e.* BASDAI, BASFI, BAS-G, lumbar pain and patient's global assessment of the disease activity. Moderate to high correlation were found between French ASQoL and the comparator instruments, ranging from 0.57 to 0.79 (Table I).

Reproducibility: A second French ASQoL questionnaire was completed by 107 patients. The mean value of the second French ASQoL, administered 2 weeks after the first one, was 9.8±5.3. At the second administration time, mean patient's global disease activity assessment was 4.5±2.5. In 59 patients reporting no change in the transition question, the intra-class correlation coefficient for the test-retest reliability was 0.89 [0.82 - 0.93], indicating that the measure has an excellent reliability (Fig. 2).

Sensitivity to change: In 23 patients reporting an improvement (mean change 0.77, SD 1.74) in the transition question, the SRM was moderate (0.44) while it was good (0.68) in 25 patients reporting a worsening (mean change -2.79, SD 4.06).

Discussion

Although the quality of life assessment of an individual with a disease such as AS is considered as core component of health outcomes (33), the Assessment in SpondylArthritis international Society (ASAS) indicated that quality of life could not be included in the core domain in AS evaluation due to uncertainty over the best measurement approach (34). Since the publication

of the ASAS core set, two AS-specific quality of life questionnaires were proposed and validated, *i.e.* AS-AIMS2 (35) and ASQoL (15).

The AS-AIMS2 is an AS adaptation of the Arthritis Impact Measurement Scales 2 (AIMS2) initially developed for arthritis (36). The AIMS2 is an instrument developed on the basis of a functionalist, utilitarian approach, targeting the current perceived health status of patients. An additional dimension has been built consisting of 7 items oriented toward physical AS specific problems that patients may encounter in their daily life. This resulted in a 64-item self-report questionnaire with 13 dimensions (AS-AIMS2) validated in English and French (35).

ASQoL appears quick to fill-in and easy to use, has good reliability, is sensitive to change and varies as expected with patient-reported activity and severity of AS (15, 37). To be useful, this instrument needs to be available in different languages and culture. However, there is no gold standard methodology for performing cross-cultural adaptation of patient reported outcomes, although the growing need for international measures is well identified. A recent review identified 17 different sets of guidelines developed by identified groups, institutions or individual researchers (38). None of these sets can serve as a gold standard. Three main approaches were considered important: the one we adopted in this paper, the one used in a previous work to adapt the ASQoL into non-English languages (39) and the IQOLA approach (40). Authors concluded that a multistep approach is strongly recommended. Research is still needed to set minimal requirements for the linguistic validation of patient reported outcomes measures (41). The translation process we adopted followed one of these guidelines to preserve the content validity of the original questionnaire (19, 20). In particular, this process included translation and back-translation, committee review and a pre-test phase. During the process, the back-translation process has been put into question because of its abitility to mask some errors when back-translators identify (by guessing) mistake in the forward translation and spontaneously corrects (without mentioning) for the assumed original meaning (21). More attention should be paid to the forward translation during the process (42).

Since the initiation of our cross-cultural adaptation project, another French language version has been published using a different methodology (39). It would be interesting to formally compare the resulting versions of these two different processes.

A dichotomous "yes / no" response system for the ASQoL instrument was chosen for the original version, driven by practical issues related to language equivalence and ease of completion. However, in the French version, we had to change the response system into a "true / false" modality, mainly to avoid any misunderstanding for the items with negative sentence, without leading any loss in sensitivity. Also this true/false answer modality has the advantage of easy translation and completion. A check for complete cultural equivalence of this version in other French speaking countries should be further performed.

The Rasch analysis showed acceptable unidimensionality of the scale with some item location redundancy, *i.e.* assessing similar level of ability (QoL) and good discrimination of items along the scale. Overall, the metric of this scale looks reasonable, although a few items are probably redundant or introducing a lack of precision. However, this analysis has some limitations. The number of subjects is moderate, and although the binary (true / false) answer modalities allow its computation modelling, a larger number of subjects would be needed to confirm the findings. The limitations found for some items location or discrimination are those specific to this French version and cannot be extended to any other language version of the instrument without testing. Some techniques like differential item functioning analysis with Rasch model performed on several sets of data can be useful for the purpose of testing scale homogeneity across various language versions (43). Overall, however, it gives reasonable clue that the French ASQoL assesses a unidimensional concept, with appropriate discriminative items spread along a difficulty interval-level scale, and do not depart from the original version. These good qualities may also result directly from the development process of the instrument original version, which was conducted in parallel in the United Kingdom and in the Netherlands. This process permitted to remove items that were problematic in one or the other language version at each stage of the procedure, selecting the common determinator of both langages, and probably facilitated the translation into another language.

The sensitivity to change of the instrument, assessed on a short period of time in this study (two weeks) looks better for detecting worsening than improvement in this sample, but it needs to be interpreted with caution as only 23 patients indicated an improvement and 25 a worsening. It should probably be confirmed in situations where calibrated change is expected, *e.g.* the initiation of a DMARD (44). Whether a higher sensitivity to detect improvement would be observed in patients with more severe status at baseline deserves further investigation. These results could form the basis for minimal clinically important improvement calculation.

The French ASQoL version will serve as a valuable instrument for assessing impact of AS in French speaking patients, with a cultural equivalence with the original version permitting its use in the same fields.

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