

# Development and validation of the Arabic allergic rhinitis quality of life questionnaire

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## ABSTRACT

**الأهداف:** تطوير أداة باللغة العربية لقياس جودة حياة المرضى المصابين بحساسية الأنف (AAQQ).

**الطريقة:** تم إجراء الدراسة في عيادات الأنف، والأذن، والحنجرة – مستشفى الجامعة الأردنية لمدة عامين من فبراير 2006 حتى يونيو 2007. تم تطوير الأداة بعد مقابلة ومناقشة 90 مريض بحساسية الأنف و تم التقصي من صحة الدراسة على 140 مريض. كما قمنا بتقدير الخصائص القياسية الأساسية لاستخدام AAQQ في الدراسات السريرية، والتجارب السريرية، و دراسة المسح الشامل.

**النتائج:** حقق معامل ارتباط مقياس جودة حياة المرضى المصابين بحساسية الأنف (AAQQ) درجات مماثلة 0.93، كما أن الأداة ذات صحة وثبات ودقة عالية. نتائج المقارنة المقطعية وطويلة الأمد ما بين الأداة والمقاييس السريرية لمرضى حساسية الأنف AAQQ كانت جيدة وحسب المتوقع ومثابه لما تم تحقيقه في الأدب والمقاييس المشابهة. أن معامل الاستجابة لحساسية الأنف مرتفعة (1.04) ومرتفعة بشكل أكثر مما سجل في أدوات مشابهة.

**خاتمة:** نتائج دراسة الصحة والدقة والثبات برهنت على فاعلية الأداة لقياس جودة حياة المرضى المصابين بحساسية الأنف. الأداة مهمة لمراقبة حالة المرضى الصحية ويمكن استخدامها في الدراسات السريرية والمقطعية. يجمع مقياس جودة حياة المرضى المصابين بحساسية الأنف AAQQ ميزة قصره واحتوائه على أهم العناصر.

**Objectives:** To develop and validate an Arabic allergic rhinitis quality of life questionnaire (AAQQ).

**Methods:** The study was conducted at the Ear, Nose, and Throat Clinic at the University of Jordan Hospital, Amman, Jordan, from February 2006 to June 2007. A questionnaire was developed from data obtained from 90 patients, and the validation study was conducted on 140 patients. The study was a 5-week observational study. We evaluated the measurement properties necessary for use of the AAQQ in clinical practice, clinical trials, and cross-sectional surveys.

**Results:** The intraclass correlation coefficient for the repeated AAQQ measurements was excellent (0.93), indicating a very high reliability and repeatability of the instrument. Cross-sectional correlations and longitudinal construct validity between the AAQQ and the other measures of health status was close to the priori predictions, and similar to those obtained in the literature for similar scales. The responsiveness index for the AAQQ was high (1.04), and higher than that reported for similar instruments.

**Conclusion:** The results from the validation study provide evidence that the AAQQ has strong discriminative and evaluative measurement properties, and can be used in patient monitoring, cross-sectional surveys, and clinical trials. The AAQQ has the combined advantage of being short, and contains the most important items and domains.

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Allergic rhinitis (AR) is a very common chronic condition, affecting 10-25% of adults,<sup>1</sup> and the prevalence is increasing.<sup>2</sup> Although sometimes viewed as an insignificant disease, AR may significantly impact a patient's quality of life (QOL),<sup>3</sup> by causing fatigue, headache, cognitive impairment, affecting psychological

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well-being, and causing other systemic symptoms.<sup>4</sup> Health-related quality of life has become an imperative outcome in clinical trials and disease management programs for a variety of conditions, including AR. Most clinical trials on AR utilize QOL as a primary endpoint. To date, there is no disease specific QOL instrument for use in Arabic speaking AR patients. Although the translation of the generic QOL instruments is available,<sup>5</sup> research has shown that both disease specific and generic quality of life instrument have to be used in patients with AR as they are measuring different constructs.<sup>6,7</sup> The Arabic language is considered the first language for more than 250 million people, and is spoken by more than 300 million people worldwide. Several instruments are currently available to measure QOL in AR, however, we did not intend to translate these. We preferred to develop a new instrument rather than to translate an existing one, since the health related QOL aspects of Arabic AR patients may be different from other populations due to possible genetic, social beliefs, and cultural differences. Therefore, they might be more or less affected by some of the problems associated with AR (such as, limitation of social activities, and embarrassment). In the present study, we aim to develop and validate a disease-specific, QOL questionnaire, the Arabic Allergic Rhinitis Quality of Life Questionnaire (AAQQ). We have used a recognized procedure for questionnaire specification, item selection, and scaling.<sup>8-10</sup>

### **Methods. Principles of questionnaire development.**

According to Juniper et al,<sup>9,10</sup> the following criteria must be met for the development of an AR QOL questionnaire: 1. Both physical and emotional function should be included, 2. Items must reflect areas of function, which are most important to patients with rhinoconjunctivitis, 3. Summary scores must be amenable to statistical analysis, 4. The questionnaire should be reliable (reproducible) when the clinical state is stable, 5. The questionnaire should be responsive to clinically important changes, even if those changes are small, 6. The questionnaire should be valid (namely, actually measures rhinoconjunctivitis-specific impairments to QOL), 7. Short and easily understood by patients.

**Questionnaire development.** A list of 70 items of health related QOL impairment of patients with allergic rhinitis was developed. We used a range of resources to generate this list, which included focus group discussions with patients and physicians, and a review of the literature. Patients were asked to write down all the problems and symptoms they suffer from, as a result of their AR. The 70 items were divided into 7 domains:<sup>9</sup> allergic nose symptoms, allergic eye symptoms, non-allergic symptoms, practical problems, sleep problems,

emotional problems, and activity limitations problems. For each of these 70 items, 90 subjects affected by AR were asked: "How much are you bothered by the following?" They responded on a 7-point scale from "not bothered" to "extremely bothered." The items scoring highest (out of the 70 items, and not per domain) were then used to construct the QOL questionnaire (see results).

**Pre-testing of the AAQQ.** To examine face validity, the AAQQ was administered to 20 patients. They were asked to identify any concerns they had on the meaning of the questions or instructions, and were asked to tell us, in their own words, what they understood on the meaning of each question.

**Subjects for validation study.** One hundred and forty adults, 18 years of age or older, diagnosed with AR, and with current AR symptoms were enrolled in the study. Symptoms score was required to be one or more on the nasal symptoms domain of the AAQQ (0 = not bothered, 6 = extremely bothered). Subjects were recruited consecutively at the Ear, Nose, and Throat Clinic at the University of Jordan Hospital, Amman, Jordan, from February 2006 to June 2007. All subjects were required to be previously diagnosed with AR, and able to read and speak Arabic. Patients were excluded if they have any illness other than AR, that had an impact on health-related QOL. All patients signed an informed consent. The study was approved by the University of Jordan ethical committee.

**Questionnaire validation.** In the validation study, we evaluated the measurement properties necessary for use of the AAQQ in clinical practice, clinical trials, and cross-sectional surveys.<sup>11</sup>

**Validation study design.** This study was a 5-week observational study. Subjects were assessed at baseline (visit 0), and after one week (visit 1), and 5 weeks (visit 2). At baseline, the diagnosis of AR was confirmed by a consultant physician, demographic information was collected, and the patients were given a diary to record their AR symptoms. Patients were instructed to start recording their AR symptoms one week before each of the 2 follow up visits. The AAQQ, a visual analogue scale measuring perceived bother due to AR (VAS-AR), a visual analogue scale measuring general health (VAS-generic) related QOL, and the Rand (Short Form Health Survey) SF-36 were briefly explained to the patient, and then self completed at weeks one and 5 during clinic visits. A global rating of change questionnaire was completed at the last visit (see below).

**Instruments. RAND SF-36-Arabic.** This generic health profile provides summary scores in 2 domains, such as physical health, and mental health. Scores range in this instrument from 0-100, with higher scores reflecting better health. The SF-36 has been validated for use in patients with rhinitis.<sup>12</sup> The Arabic version

was also previously translated and validated.<sup>5</sup> Cross-sectional correlation (Pearson correlation coefficient) between the different domains of a standard AR QOL questionnaire and the physical domain of the SF-36 was 0.19-0.44, while the correlation with the mental domain was 0.25-0.58.<sup>12</sup> Longitudinal correlation was 0.06-0.2 with physical domain, and 0.18-0.33 with the mental domain of the SF-36.<sup>13</sup> The physical domain is expected to have its highest correlation with the activity limitation domain of the AAQQ, and the mental domain of the SF-36 is expected to have its highest correlation with the emotional problems domain of the AAQQ. The global rating of change questionnaire asks patients regarding changes in their rhinitis QOL since their previous clinic visit.<sup>14</sup> The questionnaire has a 15 point scale (7 very much better, 0 - no change, and -7 - very much worse). Those who scores -1, 0, or 1 are considered stable.

**Allergic rhinitis symptom diary.** For one week before each follow up clinic visit, patients completed a diary of their symptoms.<sup>15</sup> Each evening they scored the severity (0 = nil, 6 = severe and continuous) of sneezing, stuffy nose, runny nose, itchy nose, post nasal drip, and eye symptoms. Cross-sectional correlation between the different domains of a standard AR QOL questionnaire and symptom diary was 0.45-0.7, and the longitudinal correlation was 0.49-0.72.<sup>13</sup> The symptom diary is expected to have its highest correlation with the nasal symptom domain of the AAQQ.

**Visual analogue scales (generic and disease specific).** Subjects completed a generic VAS (VAS-generic) to describe their QOL, and also completed a disease specific VAS (VAS-AR) to describe how much their quality of life was affected by AR. The VAS is a horizontal line of 100 mm ranging from 0 (worst imaginable quality of life) to 100 (perfect quality of life). The VAS-generic was previously investigated, and found to be valid as a single item indicator of QOL with cross-sectional correlation coefficient between 0.3 and 0.7 with multi-items instruments.<sup>16</sup> The VAS-AR was previously used in the development of the Pediatric Allergic Disease Quality of Life Questionnaire.<sup>17</sup>

**Internal consistency (internal validity).** The statistical test that was used to represent and evaluate internal consistency for ordinal responses was Cronbach's alpha ( $\alpha$ ). It was expected that there should be excellent internal consistency ( $\alpha \geq 0.9$ ), with good internal consistency for each individual domain ( $\alpha \geq 0.7$ ).

**Testing the measurement properties. General approach.** An instrument that is required to distinguish between people at a single point in time (for use in surveys and impairment assessment) must have good discriminative properties, which are reliability and cross-

sectional construct validity.<sup>11</sup> A health status instrument that is required to measure change over time (for use in clinical trials and clinical practice) must have good evaluative properties, which are responsiveness and longitudinal construct validity.<sup>11</sup> The AAQQ was tested for both discriminative and evaluative properties.

**Discriminative properties.** The estimate of reliability requires defining a group of patients whose rhinoconjunctivitis did not change between the 2 follow up visits. Patients were included in the reliability analysis if they scored -1, 0, or 1 on the global rating of change questionnaire completed at week 5 (visit 2).<sup>13</sup> Test-retest reliability was estimated as the within-subject standard deviation, and related to the overall standard deviation as an intraclass correlation coefficient.

Cross-sectional construct validity was evaluated by correlating AAQQ scores with the scores from the other measures of health status (RAND SF-36, AR symptoms diary, and VAS). Before the analysis, we made priori predictions concerning the level of correlation that should be expected between the AAQQ, and these other health status measures, if the AAQQ is truly measuring AR specific quality of life. These priori predictions were based on clinical experience and on previous findings (see instruments above). In general, we expected a moderate correlation with generic instruments (RAND SF-36 and VAS-generic), and a high correlation with disease specific instruments (symptom diary and VAS-AR).

**Evaluative properties.** Responsiveness of the AAQQ was examined in 3 ways. First, we determined the ability of the questionnaire to detect within - subject changes in patients whose clinical status changed between visits one and 2 by using a paired t test. Patients who either improved or deteriorated by a score of 2 or greater on the global rating completed at week 5 (visit 2) were included. Second, we examined the ability of the questionnaire to distinguish between patients who remained stable between visits one and 2, and those who changed by using an unpaired t test. Thirdly, the responsiveness index (mean change/standard deviation of change was calculated).<sup>13</sup> The responsiveness index was interpreted as trivial ( $<0.2$ ), small (0.2-0.5), moderate (0.5-0.8), or large ( $>0.8$ ).<sup>18</sup>

Longitudinal construct validity was evaluated by correlating change in each domain of the AAQQ with change in the other measures of health status (RAND SF-36, AR symptoms diary, and VAS). Like the cross-sectional correlations, priori predictions were made for the expected longitudinal correlations (see outcome measures above). In general, the change in AAQQ-overall and the change in AAQQ-nasal symptoms is expected to be highly correlated with the change in symptoms

diary and the change in VAS-AR. Other correlations are expected to be minor to moderate correlations.

We estimated the minimal important change in the AAQQ overall score from the data obtained from those who had a change of 2 or 3 in the global rating of change questionnaire between visits one and 2.<sup>14</sup> The average change in the AAQQ score in these patients was considered as the minimal important change.

**Statistics.** Correlation was examined using Pearson correlation coefficient. Correlations were considered low ( $r < 0.20$ ), moderate ( $0.20 \leq r < 0.50$ ), or high ( $r \geq 0.50$ ) according to the recommendations of Cohen.<sup>18</sup> Paired t test was used for within subject changes, and independent t test was used for between groups comparison. All data analysis was carried out using the Statistical Package for Social Sciences software package version 15 (SPSS Inc., Chicago, IL., USA).

**Results. Questionnaire development.** Ninety subjects with AR participated in the questionnaire development phase. We divided the 70 items generated into 7 domains. The items scoring highest (based on subjects bother response) were then used to construct the QOL questionnaire. In order to meet the third specification mentioned in the method above, that summary scores must be amenable to statistical analysis, it was essential to ensure that each of the 7 domains of the questionnaire should have 2 or more items.<sup>13</sup> Therefore, we continued adding the highest scoring items until every domain composed of at least 2 items. Using this approach, we developed the questionnaire with the lowest possible number of items.

It should be noted that the procedure mentioned above led to some domains having more items than the others. Initially, the instrument was composed of 23 items, however, 3 items had correlations ( $r$ ) of more than 0.9, and therefore, they were considered synonyms and combined into one item. We combined itchy ear with itchy throat, itchy eye with watery eye, and the ability to carry out usual activities at home, with the ability to carry out usual activities at work. As a result of this combining procedure the allergic eye domain was reduced to one item (initially it was 2 items), and therefore, this one item was added to another domain, and we renamed the remaining 6 domains.

The final version of the instrument is composed of 20 items (see Appendix 1): 1. Nasal symptoms: sneezing, runny nose, stuffy nose, itchy nose and postnasal drip, 2. Non-nasal symptoms: itchy ear or throat, itchy or watery eye, headache, thirst, fatigue 3. Practical problems: inconvenience of carrying tissues, need to rub nose/eyes, inconvenience of using tissues frequently

4. Sleep problems: difficulty sleeping, wake up during the night, 5. Activity limitation: the ability to carry out usual activities at home or work, the ability to carry out social activities, 6. Emotional problems: depression, irritability, embarrassment.

In the AAQQ, patients are asked to recall their experiences during the previous week, and to respond to each item on a 7-point scale (0 = no impairment or not bothered; 6 = maximum impairment or extremely bothered). The average score for each domain and the average total score range is 0-6. The questionnaire can be completed in less than 5 minutes.

**Pre-testing of the AAQQ.** After pretesting the AAQQ, a few minor word changes were needed, but not sufficient to necessitate any further testing. Content validity was assured through the methodology used, which is similar to the method used in several published studies, and through consulting an ENT specialist on his opinion reading the instrument and its items. The specialist confirmed the importance of all the items used.

**Questionnaire validation.** During the study period, 150 eligible patients were asked to participate in the study, 140 patients completed visit one and 121 patients completed visit 2. Demographic and clinical characteristics of those patients who have completed visit one are shown in Table 1. Sixty patients (43%) of those who participated in the validation study were males.

**Internal consistency (internal validity).** The Cronbach  $\alpha$  coefficient for the AAQQ was 0.92, indicating excellent agreement between the individual items in the instrument. The Cronbach  $\alpha$  coefficients for the following individual domains were: nasal symptoms (0.71), non-nasal symptoms (0.77), practical problems (0.83), sleep problems (0.80), activity limitation (0.84), and emotional problems (0.77).

**Reliability.** Fifty-four patients remained stable between clinic visits and contributed data to the reliability analysis. The intraclass correlation coefficient for the repeated AAQQ measurements was excellent (0.93) indicating a very high reliability of the instrument. The reliability was also excellent for the individual domains; for the nasal symptoms (0.91), non-nasal symptoms (0.86), practical problems (0.89), sleep problems (0.83), activity limitation (0.78), and emotional problems (0.89).

**Cross-sectional construct validity.** Cross-sectional validity was assessed by comparing the total and domain scores in the AAQQ with the scores from the other measures of health status (Table 2). Cross-sectional correlations between the AAQQ and the other measures of health status were in accordance with the

\*The full text including Appendix is available in PDF format on the Saudi Medical Journal website ([www.smj.org.sa](http://www.smj.org.sa))

priori predictions, and similar to those obtained in the literature for similar scales (see outcome measures). We obtained moderate correlations between AAQQ-overall and SF-36 and with VAS-generic, and high correlation with symptom diary and VAS-AR. As it would be expected, the nasal symptoms domain was most highly correlated with the symptoms diary, the emotional

problems domain was most highly correlated with SF-36 mental scale, and the activity limitation domain was most highly correlated with SF-36 physical scale.

**Responsiveness and minimal important difference.**

Sixty-seven patients experienced changes of 2 or greater on the global rating of change completed at visit 2 and, thus, contributed data to the responsiveness analysis (the unstable group). In these patients the AAQQ was able to detect the within subject changes both in overall score and in each domain with a high degree of significance (paired t-test,  $p < 0.001$ ) (Table 3). Similarly, the AAQQ was able to detect the difference between the stable and unstable group (independent t-test,  $p = 0.005$ ) (Table 3). The responsiveness index for the AAQQ was very high (1.04), and higher than that reported for similar instruments.

We estimated the minimal important change from the data obtained from those who had a change of 2 or 3 in the global rating of change questionnaire between visits one and 2. The average overall change in these patients was 1.1 (standard deviation=1, n=56).

**Table 1** - Demographic characteristics (N=140).

Characteristics	mean ± SD
Age	32.95 ± 12.10
AAQQ	3.21 ± 1.08
Allergic rhinitis symptoms diary	3.92 ± 0.97
SF-36 Physical domain	53.21 ± 24.94
SF-36 Mental domain	48.61 ± 22.10
VAS-generic	64.43 ± 18.59
VAS-allergic rhinitis	57.2 ± 19

SD - standard deviation, AAQQ - Arabic allergic rhinitis quality of life questionnaire, SF - Short Form Health Survey, VAS - visual analogue scale,

**Table 2** - Cross-sectional construct validity (Pearson correlation coefficients) (n=140, visit one)

Instruments and domains	Symptoms diary	VAS-Allergic rhinitis	VAS-generic	SF-36 Physical	SF-36 Mental
<i>AAQQ</i>					
Overall	0.631 <sup>†</sup>	0.638 <sup>†</sup>	-0.375 <sup>†</sup>	-0.462 <sup>†</sup>	-0.506 <sup>†</sup>
Nasal symptoms	0.635 <sup>†</sup>	0.537 <sup>†</sup>	-0.269*	-0.284*	-0.321 <sup>†</sup>
Non-nasal symptoms	0.457 <sup>†</sup>	0.380 <sup>†</sup>	-0.380 <sup>†</sup>	-0.331*	-0.409 <sup>†</sup>
Practical problems	0.517 <sup>†</sup>	0.469 <sup>†</sup>	-0.271*	-0.283*	-0.274*
Sleep problems	0.476 <sup>†</sup>	0.583 <sup>†</sup>	-0.366 <sup>†</sup>	-0.369 <sup>†</sup>	-0.404 <sup>†</sup>
Activity limitation	0.381 <sup>†</sup>	0.524 <sup>†</sup>	-0.350 <sup>†</sup>	-0.534 <sup>†</sup>	-0.485 <sup>†</sup>
Emotional problems	0.409 <sup>†</sup>	0.544 <sup>†</sup>	-0.348 <sup>†</sup>	-0.481 <sup>†</sup>	-0.565 <sup>†</sup>

VAS - visual analogue scale, SF - Short Form Health Survey, AAQQ - Arabic allergic rhinitis quality of life questionnaire, \* $p = 0.0005$ , <sup>†</sup> $p = 0.00005$

**Table 3** - Responsiveness-mean change in score between visit one and visit 2.

Domain	Stable patients mean (SD) n=54*	Patients who changed mean (SD) n=67	Difference, p-value <sup>‡</sup>
Overall	-0.34 (0.57)	-1.25 (1.20) <sup>†</sup>	0.00005
Nasal symptoms	-0.32 (0.66)	-1.14 (1.24) <sup>†</sup>	0.00005
Non-nasal symptoms	-0.24 (1.1)	-0.85 (1.35) <sup>†</sup>	0.008
Practical problems	-0.57 (0.97)	-1.39 (1.51) <sup>†</sup>	0.00005
Sleep problems	-0.27 (1.30)	-1.39 (1.53) <sup>†</sup>	0.00005
Activity limitation	-0.22 (1.23)	-0.96 (1.65) <sup>†</sup>	0.007
Emotional problems	-0.40 (0.94)	-1.10 (1.44) <sup>†</sup>	0.002

SD - standard deviation, \*stable is defined as a change of -1 to 1 on the global rating of change questionnaire between visits one and 2, <sup>†</sup> $p = 0.0005$  paired t-test for within subject changes, <sup>‡</sup>independent t test for the difference between stable and stable patients

**Table 4** - Longitudinal construct validity (Pearson correlation coefficients) (n=121).

Instruments and domains	$\Delta$ Symptoms diary	$\Delta$ VAS-Allergic rhinitis	$\Delta$ VAS-generic	$\Delta$ SF-36 Physical	$\Delta$ SF-36 Mental
<i>AAQQ</i>					
$\Delta$ Overall	0.510 <sup>†</sup>	0.790 <sup>†</sup>	-0.426 <sup>†</sup>	-0.465 <sup>†</sup>	-0.511 <sup>†</sup>
$\Delta$ Nasal symptoms	0.647 <sup>†</sup>	0.699 <sup>†</sup>	-0.408*	-0.434 <sup>†</sup>	-0.397 <sup>†</sup>
$\Delta$ Non-nasal symptoms	0.219*	0.469 <sup>†</sup>	-0.351 <sup>†</sup>	-0.357 <sup>†</sup>	-0.360 <sup>†</sup>
$\Delta$ Practical problems	0.505 <sup>†</sup>	0.586 <sup>†</sup>	-0.464*	-0.472 <sup>†</sup>	-0.443 <sup>†</sup>
$\Delta$ Sleep problems	0.340 <sup>†</sup>	0.532 <sup>†</sup>	-0.221*	-0.358 <sup>†</sup>	-0.220*
$\Delta$ Activity limitation	0.321 <sup>†</sup>	0.502 <sup>†</sup>	-0.329 <sup>†</sup>	-0.393 <sup>†</sup>	-0.425 <sup>†</sup>
$\Delta$ Emotional problems	0.333 <sup>†</sup>	0.536 <sup>†</sup>	-0.363 <sup>†</sup>	-0.379 <sup>†</sup>	-0.398 <sup>†</sup>

$\Delta$  - change, VAS - visual analogue scale, SF - Short Form Health Survey, AAQQ - Arabic allergic rhinitis quality of life questionnaire, \* $p=0.0005$ , <sup>†</sup> $p=0.00005$

**Longitudinal construct validity.** Correlations between change in AAQQ scores between visits one and 2, and change in other measures of health status were close to the priori predictions (Table 4).

**Discussion.** Almost all clinical trials on AR utilize QOL as a primary endpoint. The QOL instruments can also be vital in cross-sectional studies and routine patient monitoring. To date, there is no disease specific QOL instrument for use in Arabic speaking AR patients. In the present study, we have developed and validated a disease-specific QOL questionnaire, the AAQQ. We have used a recognized procedure for questionnaire specification, item selection, and scaling.<sup>8-10</sup> The procedure we used in the questionnaire development ensured that we will have the minimum number of, and the most important items in the final instrument. This is important considering the very limited clinic time, and the need to complete the instrument in the shortest time possible. The developed instrument can be self completed in less than 5 minutes by most patients. It should be recognized, however, that the more we reduce the number of items in a questionnaire, the more likely it is that individual patient problems will be omitted, and the instrument may lose content validity.

The developed instrument was found to have a high internal consistency indicating excellent agreement between the individual items in the tool. The excellent intraclass correlation coefficient for the repeated AAQQ measurements also indicates a very high reliability of the instrument.

The results from the cross-sectional construct validity evaluation of the AAQQ were in accordance to a priori hypothesis. We obtained high correlations with AR symptoms diary and VAS-AR, and moderate correlations with generic instruments. The high correlation between the symptom domain and the AR symptoms diary is in accordance with expectations. The high correlation between the AR symptoms diary and

the practical problems domain was also expected, since practical problems are a result of nasal symptoms. The moderate correlation between the different domains of the AAQQ (all domains except nasal symptoms and practical problems) and the AR symptoms diary provide evidence that the AAQQ is not only measuring only impairment related to symptoms, but also measuring health related QOL impairments. The instrument was also found to have excellent longitudinal construct validity.

We have also shown that the instrument is responsive to change, and able to discriminate between patients who remain stable and those who change overtime. Responsiveness to change was very high, and higher than that reported in the literature for similar instruments.

Based on an up-to-date literature review we have found that Juniper et al's<sup>9</sup> Rhinoconjunctivitis Quality of Life Questionnaire (RQOL), and Juniper et al's<sup>13</sup> Mini Rhinoconjunctivitis Quality of Life Questionnaire (RQOL-mini) are probably the most commonly used, and widely adapted instruments for use in patients with AR. The AAQQ is composed of 20 items and 6 domains, compared with 28 items and 7 domains in the RQOL, and 14 items and 5 domains in the RQOL-mini.

The RQOL have an additional separate eye symptoms domain as compared to the AAQQ. We do not believe that this additional domain would affect the validity of the AAQQ, since the method we used ensured that we included the most important items. On the other hand, the AAQQ has an item for measuring the 2 most important eye symptoms (itchy or watery eye) under the non-nasal symptoms domain that can give us an idea regarding the eye symptom problems. The RQOL-mini was developed to have a shorter questionnaire that requires less time to be filled, and therefore, be more suitable for use in the busy clinics. In the RQOL-mini the authors have omitted the emotional problems domain. We believe that this could compromise the usefulness of the RQOL-mini, as emotional problems

are of prime concern in patients with AR.<sup>4</sup> The authors have also combined the sleep problems domain with the activity domain. We believe that sleep problems should be measured independently, due to its significance in patients with AR. In many patients with AR, the severity of allergic symptoms tends to peak during the night, and in the early morning.<sup>19</sup> In accordance with this point, and possibly controversially, Juniper et al<sup>10</sup> discussed the importance of sleep problems in AR, and developed the nocturnal allergic rhinoconjunctivitis QOL questionnaire.

We identified that the minimal important difference of the AAQQ is equal to 1.1. This is the minimum change in QOL that can be considered clinically important. This is higher than the minimal important difference for RQOL which is 0.5, and higher than the minimal important difference for RQOL-mini which is 0.7. This difference is most probably due to the higher responsive of the AAQQ, which has a very high responsiveness index of 1.04 as compared to 0.76 for the RQOL, and 0.83 for the RQOL-mini. The higher responsiveness of the AAQQ is probably a result of including the minimum number of items that are considered the most important.

One of the limitations of the current study is that the questionnaire developed is different than the commonly used RQOL, which may make it difficult to make cross-cultural comparison. However, since AAQQ was developed from scratch in the Arabic speaking AR patients, it is expected that it will better reflect QOL in these patients than the RQOL. It is more important to measure QOL accurately than to conduct cross cultural comparison with a possibly less valid measure.

In conclusion, the results from the validation study provide evidence that the AAQQ has strong discriminative and evaluative measurement properties, and can be used in patient monitoring, cross-sectional surveys, and clinical trials. The AAQQ has the combined advantage of being short and also containing the most important items and domains at the same time when compared to the other available instruments. Future research should focus on utilizing the AAQQ in clinical trials and providing more evidence on the validity of the AAQQ.

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