Original Article

Validation of a Hindi Translation of Mini Asthma Quality of Life Questionnaire in North Indian Patients with Bronchial Asthma

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ABSTRACT

Background and Objective. There is little information on validated health-related quality of life (HRQoL) instruments for use in Indian patients with bronchial asthma. We attempted to validate the Hindi translation of Juniper's mini asthma quality of life questionnaire (MiniAQLQ) in north Indian patients with bronchial asthma.

Methods. Hindi translation of MiniAQLQ, and abbreviated World Health Organization quality of life questionnaire (WHOQOL-Bref), were administered to 30 patients with bronchial asthma twice at a six-week interval. Clinical and physiological data were also recorded. Psychometric properties (acceptability, validity, reliability and responsiveness) of MiniAQLQ were assessed after calculating four domain (physical, psychological, social relationships and environment), and a total score.

Results. Most questionnaires were returned without missing responses. MiniAQLQ had good convergent and discriminant validity, but moderate content and construct validity. All components (except emotional function domain) met standards for internal consistency (Cronbach's alpha coefficient >0.70), but intra-class correlation coefficients were variable. Change in MiniAQLQ scores between two assessments correlated poorly with corresponding changes in lung function. The effect sizes ranged from 0.02 to 0.34 in 11 patients whose forced expiratory volume in the first second (FEV_1) changed by >200mL and >12% from baseline, and were considered small.

Conclusion. The Hindi translation of MiniAQLQ is a moderately good discriminative and a relatively poor evaluative instrument to assess health related quality of life (HRQoL) in north Indian patients with bronchial asthma.
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Key words: Bronchial asthma, Cross-cultural adaptation, Quality of life, Questionnaires, Reliability, Validity.

INTRODUCTION

In modern medicine the traditional way of assessing change among patients has been to focus on laboratory or clinical tests. While these give important information about the disease, in chronic and progressive diseases in particular, it is impossible to separate the disease from the individual's personal and social context. One way of capturing the personal and social context of patients is to use health related quality of life (HRQoL) measures. These are accepted outcome measures in clinical research but rarely used in routine clinical practice.

Bronchial asthma is a common disorder managed by clinicians. Our own estimates in a recently concluded multicentre asthma prevalence study[1] point to a prevalence of bronchial asthma of about 3% in the adult general population. The disorder leads to significant morbidity, adverse socio-economic effect, and emotional strain. Adults with asthma are distressed by the symptoms, and are limited in their day-to-day work and participation in other activities with friends. Since goal of therapy in asthma is not to cure the disease, but rather control it to an extent that it allows normal day-to-day functioning of the patient, HRQoL measures may be more appropriate in assessing treatment response rather than clinical assessment and/or physiological testing. Although several generic HRQoL instruments are available for use in a wide variety of clinical settings, they have a limited utility in asthmatics due to a limited responsiveness (ability to detect small changes).[2,3] Disease-specific instruments may be more responsive to the effects of health care, since they focus on aspects of HRQoL that are relevant to those patients. Disease-

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specific instruments relate more closely to clinical symptoms and, as a consequence, may be more acceptable for the clinicians. Asthma quality of life questionnaire (AQLQ) is a commonly used tool for this purpose in patients suffering from bronchial asthma. The AQLQ has been developed in standard and abbreviated versions; both have been previously shown to have good performance characteristics in patients with bronchial asthma.[4,5] The original AQLQ instrument has 32 equally weighted items, each being scored on a continuous seven-point Likert scale. Four domain scores and a total score can be generated.[5] The mini asthma quality of life questionnaire (MiniAQLQ) is a shorter and simpler version that can be used with greater efficiency in the routine clinical setting, group patient monitoring and large surveys.[4] It has only 15 items with a two-week recall, and weighting, scoring and analysis of MiniAQLQ are similar to AQLQ in all respects. A higher score indicates better HRQoL.

Before using any HRQoL tool in a different population, it is necessary to verify that the tool indeed performs as adequately in the new population as it did in the native population from which it was developed. The AQLQ, and its various modifications, have been translated into several languages and shown to perform well for different populations.[6] The AQLQ in its original UK English version has already been validated in Indian patients with asthma.[7] A Hindi translation is available and was earlier used without prior validation in a study on Asian asthmatics in UK.[8] However, this Hindi translation has not been formally validated in Indian population. In this study, we attempted to validate the Hindi translation of MiniAQLQ in patients of bronchial asthma at our institution.

PATIENTS AND METHODS

Study Population

The study was conducted on 30 patients previously diagnosed to have bronchial asthma who were under regular follow up at the Chest Clinic of the Postgraduate Institute of Medical Education and Research, Chandigarh. Subjects were included if they were life-time non-smokers, understood Hindi well, and were willing to be available for regular follow-up. Patients with co-existing medical conditions that could potentially impair level of activity or worsen quality of life (such as cardiovascular or arthritic disorders), as well as those experiencing a disease exacerbation or worsening of symptoms in the preceding four weeks, were excluded. The study protocol was approved by our Hospital Ethics Committee, and informed consent was obtained from all the participants prior to enrolment.

Data Collection

All patients underwent detailed symptom enquiry, physical examination and lung function testing at initial evaluation. Spirometry was performed on a rolling seal spirometer (Spiroflow, P.K. Morgan Ltd, Kent, UK), and patients' observed values were compared to predicted values previously derived at our centre.[9] All this data were used to categorise level of asthma control in each patient using the scheme proposed as part of the recent Global Initiative for Asthma (GINA) guidelines.[10] Each patient was followed up six weeks after the first assessment, and again underwent a similar clinical and physiological evaluation. The HRQoL was assessed at both visits using the Hindi translation of MiniAQLQ.

At each visit, patients were asked to fill out questionnaires related to the MiniAQLQ. The 15 items of this instrument are divided into four domains: (*1*) symptoms (five items), (*2*) activity limitation (four items), (*3*) emotional function (three items) and (*4*) environmental stimuli (three items). In addition, patients also completed the 26-item abbreviated World Health Organization quality of life (WHOQOL-Bref) questionnaire in Hindi. The Hindi version of WHOQOL was developed in as a self-administered 100-item generic HRQoL instrument, with simultaneous development of the WHOQOL-Bref for use in busy clinics and in large studies.[11] The WHOQOL-Bref yields four domain scores: physical, psychological, social relationships and environment. Patients were requested to complete both MiniAQLQ and WHOQOL-Bref questionnaires themselves without any assistance, as honestly and as completely as they could. It was stressed that there were no right or wrong answers. Missing data was recorded as such. Data from each of these were entered into a computer database specifically designed for this purpose. Domain and total scores were calculated for either instrument for each patient as per guidelines proposed by their respective developers.

Statistical Methods

Psychometric properties (acceptability, validity, reliability and responsiveness) of the Hindi translation of MiniAQLQ were assessed through several methods. Acceptability of the MiniAQLQ instrument was assessed by the proportion of missing responses in the questionnaire forms returned by the patient at first visit. Validity implies that a HRQoL instrument indeed measures what it is supposed to measure; this was verified in several different ways. Construct validity of MiniAQLQ was assessed by noting the correlation between component and total MiniAQLQ scores, and other objective measures of disease control (impairment in pulmonary function, level of asthma control), as well as through correlation between MiniAQLQ and WHOQOL-Bref

scores, at the initial assessment. Convergent validity was assessed by noting the correlation between each item in MiniAQLQ and its domain score, and the correlation between a MiniAQLQ domain score and a related domain score of WHOQOL-Bref (e.g., activity limitation and emotional function domains of MiniAQLQ with physical health and psychological domains of WHOQOL-Bref, respectively). Discriminant validity was assessed by evaluating how poor the correlation was between each item and scores of other domains, as well as by noting poor correlation between a MiniAQLQ domain score and an unrelated domain score of WHOQOL-Bref. Spearman's rho correlation coefficients were used for all of the above, and a coefficient exceeding 0.4 was taken as a measure of good correlation.[12] Reliability is the degree to which an HRQoL measure is free from random error, and takes into account both internal consistency and reproducibility. Internal consistency (correlation of individual items within a component with each other) was evaluated using Cronbach's alpha on data from the baseline administration, and was considered acceptable for group comparisons if the coefficient exceeded 0.70.[12,13] Test-retest reproducibility was assessed on patients who had stable disease between the two clinic visits; this subset was defined as patients whose forced expiratory volume in the first second (FEV_1) estimates on the two visits fell within 12% and 200mL of each other. The random-effects intra-class correlation coefficient, which is considered a good indicator for reproducibility as it accounts for a possible systematic difference of replicated measurements, was used to calculate the test-retest reproducibility of two administrations of MiniAQLQ. Responsiveness of an instrument indicates how well the measure can detect clinically meaningful changes. This was assessed by measurement of effect size in the subgroup of patients whose disease was not stable between the first two visits.[14] Effect size is defined as mean score change between the two assessments, divided by the standard deviation of the baseline score. Although there are no absolute standards for effect size, it has been suggested that values of 0.2, 0.5, 0.8 may represent small, medium, and large effect sizes, respectively.[15] In addition, a correlation between change in MiniAQLQ score and change in FEV_1(% predicted) and peak expiratory flow (PEF) (% predicted) was also evaluated.

Non-parametric tests were used for all group comparisons in view of a non-normal distribution of several variables of interest.

RESULTS

The symptom duration ranged from 1-30 years; there were 11 males (Table 1). In all, 13 patients lived in Chandigarh and others were residents of Punjab (n=8), Haryana (n=8) or Uttar Pradesh (n=1). Asthma was well controlled in nine (30%), partly controlled in 15 (50%) and poorly controlled in six (20%) patients. All patients with poorly controlled disease were women (Table 1). Most patients returned their MiniAQLQ questionnaires fully completed at the initial assessment. There was only one missing response each for item 9 (concerned about having asthma) and item 15 (limitation of work related activities).

Table 1. Profile of 30 patients of bronchial asthma included in the study

Variables	Men (n=11)	Women (n=19)
Age in years (median, range)	28 (17–66)	38 (18–53)
Duration of symptoms in years (median, range)	6 (1–30)	5 (1–25)
FEV_1% predicted (median, range)	88 (53–115)	86 (27–127)
PEF% predicted (median, range)	89 (57–116)	62 (23–140)
Control of asthma [No. (%)]		
Well controlled	5 (45.5%)	4 (21.1%)
Partly controlled	6 (54.5%)	9 (47.4%)
Poorly controlled	0	6 (20.0%)

FEV_1=Forced expiratory volume in the first second; PEF=Peak expiratory flow

Content validity of MiniAQLQ was only moderate. A broad spectrum of domain and total scores was recorded at both visits. However, individual domain scores did not span the entire range of possible scores, either at initial or at follow-up assessment (Table 2). Individual responses to each item were quite variable at first assessment. However, the two worst choices (scored as 1 and 2) were marked by very few respondents. In fact, option '1' was not chosen by any patient for 10 of the 15 items (Figure 1). There was also a significant 'ceiling effect' for item 5 (afraid of not having asthma medication available), as 18 of the 30 respondents marked the best option (none of the time) (Figure 1). Overall change in scores between the two assessments were small and insignificant (Table 2). Between the two clinic visits, 19 patients had remained stable, while eight had improved and three had deteriorated.

Construct validity of MiniAQLQ was also moderate. Activity limitation and emotional function domain scores (but not symptom or environmental stimuli domain scores), as well as total MiniAQLQ scores, were significantly lower for patients with progressively poor control of asthma at initial assessment (Table 3). Total MiniAQLQ score correlated significantly with response to WHOQOL-Bref item 1 (overall rating of quality of life) but not with response to WHOQOL-Bref item 2 (health satisfaction) (Table 2). None of the MiniAQLQ domain scores correlated well with either of these two items (Table 2). Symptom and activity limitation domain scores, as well as total MiniAQLQ scores did not correlate with pulmonary function test results (Table 2). The emotional function domain score did not correlate with WHOQOL-Bref psychological or social relationship domain score, but the activity limitation domain score correlated significantly with WHOQOL-Bref physical domain score (Table 2).

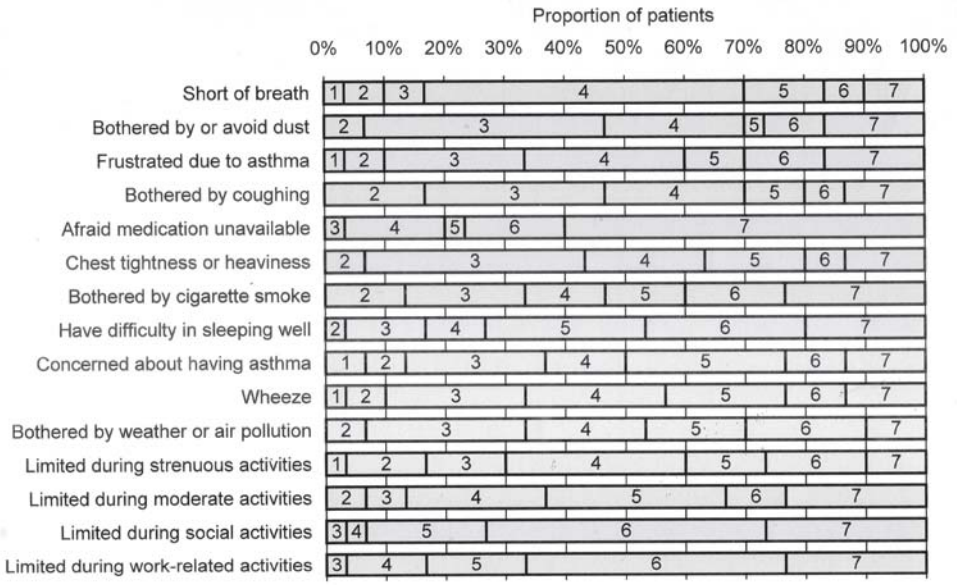

Figure 1. Distribution of responses to various items of MiniAQLQ. Figures in each box represent the response category to questionnaire items. Responses to individual items are scaled from 1 to 7, with '1' representing the worst and '7' representing the best condition.

All individual items of MiniAQLQ were significantly correlated with their corresponding domain scores ($p<0.01$), implying good convergent validity, with 13 of 15 items having Spearman's rho coefficient exceeding 0.60, and 8 of 15 items having Spearman's rho coefficient exceeding 0.75 (Table 4). Correlations of individual items with non-corresponding domain scores were in general much poorer than those with corresponding domain scores, indicating reasonable discriminant validity.

Cronbach's alpha coefficient had high values exceeding 0.70 for all, except the emotional function, domains, suggesting good internal consistency (Table 2). For the 19 patients having stable disease between the two assessments, the intra-class correlation coefficients for individual questions were highly variable, and ranged from 0.158 to 0.729. These values exceeded 0.60 for only four questions.

Table 2. Parameters related to scoring and performance of mini asthma quality of life questionnaire

	Symptoms	Activity Limitation	Emotional Function	Environmental Stimuli	Total
Number of questions	5	4	3	3	**15**
Theoretical range of scores	1.0–7.0	1.0–7.0	1.0–7.0	1.0–7.0	**1.0–7.0**
First visit data					
Mean observed score (±SD)	4.4±1.1	5.2±1.0	4.9±1.1	4.5±1.4	**4.8±0.9**
Range of observed scores	2.0–7.0	3.5–7.0	2.7–7.0	2.3–7.0	**3.5–6.9**
Correlations					
FEV_1% predicted	-0.097	0.266			**0.155**
PEF% predicted	0.136	0.237			**0.208**
WHOQOL-Bref item 1	0.253	0.336	0.261	0.250	**0.429**
WHOQOL-Bref item 2	-0.067	0.314	0.109	0.308	**0.203**
WHOQOL-Bref Physical score	0.156	0.660			
WHOQOL-Bref Psychological score			0.358		
WHOQOL-Bref Social relationship score			0.072		
Second visit data					
Mean observed score (±SD)	4.9±1.0	5.4±1.1	5.3±1.2	4.7±1.3	**5.0±0.9**
Range of observed scores	3.2–7.0	2.2–7.0	3.0–7.0	2.7–7.0	**3.7–6.9**
Summary performance characteristics					
Cronbach's alpha coefficient	0.775	0.737	0.508	0.756	–
Intra-class correlation coefficient	0.312	0.425	0.656	0.685	**0.683**
Effect size	0.137	0.337	0.022	0.079	**0.127**

FEV_1=Forced expiratory volume in first second; PEF=Peak expiratory flow; SD=Standard deviation, WHOQOL-Bref=Abbreviated World Health Organization quality of life questionnaire

Table 3. Baseline lung function and mini asthma quality of life questionnaire scores based on level of asthma control

Variable	Poorly Controlled (n=6)	Partly Controlled (n=15)	Well Controlled (n=9)	p Value
Pulmonary function				
FEV_1 (% predicted)	66.2 (43.2–74.0)	84.6 (66.0–96.9)	103.9 (96.0–110.7)	0.004
PEF (% predicted)	47.1 (42.6–60.0)	67.3 (55.3–81.4)	93.5 (85.5–98.2)	0.002
MiniAQLQ scores				
Symptoms	4.2 (3.6–5.2)	4.2 (3.4–5.2)	4.6 (4.0–5.4)	0.432
Activity limitation	3.9 (3.5–5.2)	5.0 (4.7–5.5)	6.0 (5.5–6.5)	0.007
Emotional function	3.8 (3.0–5.3)	4.7 (4.0–5.3)	6.0 (5.0–6.3)	0.037
Environmental stimuli	4.3 (4.0–5.0)	4.0 (3.0–5.7)	4.0 (3.7–6.3)	0.512
Total	**4.1 (4.0–4.6)**	**4.6 (4.1–5.0)**	**4.8 (4.5–6.1)**	**0.045**

FEV_1=Forced expiratory flow in the first second; PEF=Peak expiratory flow
All values are shown as median (interquartile range); p values derived from Kruskal-Wallis test

Table 4. Convergent validity of Hindi translation of mini asthma quality of life questionnaire

Questionnaire Items	Domains			
	Symptoms	Activity Limitation	Emotional Function	Environmental Stimuli
Shortness of breath	0.487			
Bothered by or avoid dust				0.789
Frustrated due to asthma			0.687	
Bothered by coughing	0.748			
Afraid medication unavailable			0.602	
Chest tightness or heaviness	0.844			
Bothered by cigarette smoke				0.833
Have difficulty in sleeping well	0.573			
Concerned about having asthma			0.846	
Wheeze	0.778			
Bothered by weather or air pollution				0.794
Limited during strenuous activities		0.760		
Limited during moderate activities		0.883		
Limited during social activities		0.669		
Limited during work-related activities		0.612		

All figures are Spearman's rho correlation coefficients between individual item scores and corresponding domain scores
$p<0.01$ for all questionnaire items

The intra-class correlation coefficients for the symptom, activity, impact and total scores were also low or moderate (Table 2).

Among the 11 patients whose condition had changed between the two visits, effect size was uniformly low for all domain, as well as total, scores (Table 2). The change in total MiniAQLQ score between the two visits correlated poorly with corresponding changes in FEV_1 or PEF (Spearman's rho 0.003 and 0.366 respectively).

DISCUSSION

For a chronic disease like bronchial asthma, it may be difficult to isolate the clinical aspects from patients' personal and social contexts. The HRQoL measures provide a way to assess these aspects, with an individual patient-centered perspective, within the overall frame of health care delivery. There has been a recent increase in recognising HRQoL as an important and independent outcome parameter, especially in chronic diseases. Measuring HRQoL may have an important role in describing health outcomes, guiding and assessing clinical management, predicting health outcomes, formulating clinical policy, and allocating health resources. While much data on the routine application of HRQoL assessment in asthmatics is available from the developing world, there is hardly any initiative on the issue in India.[7] Lack of awareness among clinicians, the limited availability of appropriate measures, complexity of validating and analysing of quality of life data, and difficulties in incorporation into routine clinical decision-making are some of the problems responsible for this.

The AQLQ is a scientifically validated disease-specific instrument that has been used to describe HRQoL among asthmatics all over the world for nearly a decade. Its simplicity, broad applicability (due to availability of several modified versions as well as many linguistic translations), and large clinical and research experience have made it one of the most widely used HRQoL measure in asthma management. Comparative data suggests the AQLQ might be the best among its peers in this regard.[16] Although the original English version was recently validated among patients with bronchial asthma in Delhi, these results are difficult to generalise till vernacular translations are evaluated in India.[7] This cross-cultural validation needs to be scientifically performed, and is essential before suggesting routine use of any such HRQoL measure in India. We have recently described the psychometric properties of the Hindi translation of St. George's Respiratory Questionnaire in a similar fashion among patients of chronic obstructive pulmonary disease.[17]

We choose the MiniAQLQ for this study. This 15-item instrument is an abbreviated version of the original 32-item AQLQ questionnaire. The Mini AQLQ has been shown to have good measurement properties, although these are perhaps not as strong as those of AQLQ.[4] Nonetheless, the MiniAQLQ is much shorter, and therefore, much more likely to be put to use at busy outpatient clinics or in population-based studies. Indeed we found that the questionnaire had excellent acceptability among patients with bronchial asthma included in this study.

Validity of the English version of MiniAQLQ has been described in a few previous studies.[4,18,19] In India, validity of the English version of AQLQ has also been described.[7] Content validity and construct validity of the Hindi version of MiniAQLQ in our study were only moderate, whereas the convergent and discriminate validity were good. Correlations of domain scores with FEV_1 % predicted were nearly as poor as those observed earlier with the English version of AQLQ in India.[7] In fact, poor correlation of HRQoL measures with spirometrically determined severity of airflow limitation has been earlier recorded by other investigators as well.[20-22] In fact, this has been advanced as one strong reason to suggest that HRQoL measures assess a different but important patient construct that needs to be evaluated separately in addition to the routine monitoring based on symptoms and pulmonary function testing.

Internal consistency was overall very good. The weakest domain in this regard was the emotional function domain, which is composed of few items. The longitudinal data was derived from information from two visits spaced six weeks apart. The test-retest reproducibility among patients remaining stable between the two assessments was only moderate, as suggested by high intra-class correlation coefficient values for less than 25% items, and moderately low values for domain scores. Among patients whose pulmonary function had significantly changed between the two visits, this change correlated weakly with MiniAQLQ scores. The effect size, which is a more rigorous measure of responsiveness, was also uniformly low for all domain scores. This might suggest that the Hindi version of MiniAQLQ is not a very good tool for short-term longitudinal assessment of HRQoL. We are not certain whether this relates to the somewhat short interval between the two assessments (which is perhaps too small to assess a measurable change in disease impact), the use of lung function (which may not have been an appropriate single measure to describe change in health status) to categorise clinical stability or lack of it, and/or to actual socio-cultural differences in perception between Indian and Western patients. The small number of patients studied, which is a limitation of this study, may have also contributed to some extent to the quality of our results.

The results from the present study appear somewhat different from those obtained earlier from a study[7] using the English version of AQLQ (with 32 questions) in 38 adult patients with bronchial asthma from Delhi. This study reported that AQLQ had sufficiently acceptable evaluative and discriminatory properties in the subjects assessed. As the study did not employ the entire battery of statistical procedures used by us for assessment of psychometric properties, we are unable to strictly compare the observations in these two studies. However, the previous study did show better reproducibility for symptoms, activity limitation, and emotional function domains. These, and other, differences between the two studies could be attributed to several factors such as differences in questionnaire structure (32 *vs* 15 items), differences in study population (educational, economic and/or cultural factors), and differences in methods to assess asthma control and clinical status. In addition, the linguistic translation itself may change the results, especially if it fails to reflect the socio-cultural matrix of the study population.

Our study is not without limitations. The most obvious is a small sample size, which is likely to have adversely affected the robustness of our statistical analysis, more so for group comparisons. As subjects were recruited at a tertiary academic centre, there may have been a referral bias that did not allow us to study subjects with relatively milder disease in sufficient numbers. This is also reflected in a somewhat skewed distribution of MiniAQLQ scores in our study population, with majority of subjects having scores beyond the mid-point of the possible spectrum of score range (Table 2). We also relied almost exclusively on pulmonary function changes as a surrogate for shifts in asthma control status. Use of additional tools to formally assess asthma control at both patient visits might have allowed better delineation of patients having a change in

clinical status from those remaining clinically stable. Finally, our observations regarding reproducibility and responsiveness may also prove imprecise, as the important precondition of a good instrument validity for such estimations was not strictly fulfilled.

Although it is perhaps best to develop an altogether new HRQoL instrument in Indian patients, adapting a measure developed in a different language and culture may be more time-saving and cost-effective than developing a new one. The precise level of correlation or statistical similarity that should be accepted as evidence of equivalence between an original and translated instrument is difficult to establish.[23] Overall, our results suggest a reasonably high degree of acceptability, validity, and internal consistency, and moderately low reproducibility, as well as conceptual equivalence, for the Hindi translation of MiniAQLQ. In general, discriminative measures help to differentiate patients with better and worse HRQoL, while evaluative tools have good responsiveness and help to quantify longitudinal changes in HRQoL subsequent to an intervention.[24] The Hindi translation of MiniAQLQ emerges as a moderately good discriminative and a relatively poor evaluative instrument for asthmatics. There certainly remain important limitations in applying this instrument, in clinical and/or research settings, for routine assessment of health status of Indian asthmatics. However, the use of Hindi translation of MiniAQLQ can still be encouraged in India till a more appropriate instrument is specifically developed in this country.

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