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The cross-cultural validation of the English version of RhinAsthma patient's perspective (RAPP)

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ABSTRACT

Objective: No validated instrument is currently available in English for use in daily practice to assess Health Related Quality of Life (HRQoL) in asthma and comorbid allergic rhinitis (AR). The aim of this study was to validate and assess the psychometric characteristics of an English language version of RhinAsthma Patient Perspective (RAPP).

Methods: The study was performed in the Philippines. The RAPP was translated into English. Adult patients, diagnosed with asthma and AR, were recruited. Clinical and functional data were collected on two occasion with a 4-week interval between visits. At both visits patients completed the following questionnaires: RAPP, Short Form Health Survey-12 (SF-12), asthma control test (ACT), and rhinitis symptom Visual Analog Scale (VAS). Scale dimensions, internal consistency and convergent validity, reliability, discriminant ability, responsiveness, and minimal important difference (MID) were evaluated.

Results: About 150 patients (mean age 39.3 years) completed the study. Exploratory and confirmatory factor analysis identified a uni-dimensional structure of the questionnaire. Internal consistency was satisfactory (0.87 at visit 1; 0.89 at visit 2). The tool showed good discriminant and convergent validity at both visits ($p < 0.01$). High reliability was confirmed by an ICC of 0.97 and a CCC of 0.95. Responsiveness was shown by a significant association with VAS ($r = 0.34$, $p < 0.01$) and ACT ($r = -0.35$, $p < 0.01$). The MID value was 2.

Conclusions: The English version of RAPP was shown to have good psychometric properties and is a valid tool for assessing asthma and AR HRQoL in clinical practice.

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Introduction

Asthma and allergic rhinitis (AR) are chronic respiratory disorders whose prevalence and high morbidity rates result in a significant personal and socio-economic burden [1–3]. Increasing evidence of the link between AR and asthma comes from epidemiologic studies undertaken in various countries: up to 40% of patients with AR also suffer from asthma, and up to 80% of patients with asthma have nasal symptoms [4–8]. Health Related Quality of Life (HRQoL) is widely recognized as an important clinical outcome in respiratory allergy, allowing a fuller evaluation of the disease and going beyond the assessment of clinical and functional parameters. The concept is to measure the impact of an illness and its treatment on a patient, as perceived by the patient themselves [1,9] and to integrate this with the objective assessment of the disease. Since the 1990s

various disease specific tools have been validated for rhinitis (Rhinoconjunctivitis Quality of Life Questionnaire, Mini Rhinoconjunctivitis Quality of Life Questionnaire [10] and asthma (Asthma Quality of Life Questionnaire, Mini-Asthma Quality of Life Questionnaire, Living with Asthma Questionnaire, St George's Respiratory Questionnaire, Marks Asthma Quality of Life Questionnaire [11–12]). These tools consider AR and asthma as distinct disorders, while RHINASTHMA [13] can be used to evaluate HRQoL in patients suffering from respiratory allergy, irrespective of the specific disease. Thanks to the widespread use of these questionnaires, HRQoL, has been extensively evaluated as an outcome in clinical research [1,3,14] and various studies have confirmed that patients with respiratory allergy experience a reduction in the physical, emotional and social dimensions of daily life [15].

The need to assess the patient's perspective in clinical practice is increasingly recognized [16,17]. Routine assessment of HRQoL facilitates disease monitoring and management [18,19], has a positive effect on patient-clinician communication [18], encourages patient's involvement in their health care [20] and improves patient outcomes [21].

Specific guidance for clinicians to properly evaluate the patient's perspective in practice have been developed by the National Quality Forum [22] and the International Society for Quality of Life Research [23].

However, a standardized evaluation of HRQoL is rarely integrated into routine care [24]. The availability of simple, psychometrically sound HRQoL tools [23] should help to implement HRQoL assessment in daily practice.

The RhinAsthma Patient Perspective (RAPP), a self-administered 8-item tool, has been validated in Italian for this purpose [25,26]. Patients are asked to indicate the extent to which they have been affected by each problem listed during the last 2 weeks by a 5-point Likert-type scale (not at all = 1; little = 2; fairly = 3; much = 4; very much = 5). The questionnaire is simple to complete and the score can be easily calculated by summing the single answers (range 8–40), with higher scores indicate worse HRQoL. A cutoff point of 15 demonstrated the best sensitivity and specificity in identifying an optimal HRQoL. The validation procedure confirmed that RAPP satisfies all the psychometric requirements for successful implementation in clinical practice [3,27]. However, its cross cultural validation for the measurement of HRQoL in different languages needed to be performed [28]. This process is more complex than a simple translation to the target language since it must take into account idioms, discrepancies between written and spoken language, cultural context and lifestyle [29,30]. As part of a multinational project ongoing in Spain, France, Portugal and Poland, aim of this study, developed in the Philippines, was the trans-cultural adaption and validation of the RAPP in English. English is spoken today on all five continents as a result of colonial expansion but also because it has been adopted as general means of communication. Philippine English traditionally follows American English spelling and grammar, and it is used in higher education, religious affairs, print and broadcast media, and business [31].

Materials and methods

Questionnaire translation

The original Italian version was independently translated into English by two Filipinos that are native

English speakers. The cross-cultural adaptation was undertaken following international guidelines and involved 2 forward and 2 backward translations [32,33]. The two backward translations were confirmed to be conceptually equivalent to the original Italian version.

Subjects and study design

This study was approved by the Institutional Scientific and Ethical Review Board of St. Luke's Medical Center (CT-16169) and the University of Genoa's Ethics Committee (PR 333REG2016). It was conducted according to the Declaration of Helsinki (as amended in Edinburgh in 2000) and the general principles of Good Clinical Practice.

All Adult Filipinos, diagnosed with asthma and AR, attending the Otorhinolaryngology – Allergy Clinic of the St. Luke's Medical Center – Quezon City for a scheduled visit during the study period (March to November 2017) were asked to be enrolled into the study. A convenient data sampling method was used to recruit a total of 150 patients [34]. Patients had to meet the following inclusion criteria: age ≥ 18 , rhinitis and asthma diagnosed according to GINA and ARIA guidelines, comprehension of spoken and written English language and willingness to participate in the study (signature of informed consent).

Exclusion criteria were; occurrence of upper respiratory diseases, rhinosinusitis or otitis media, impaired cognitive functions, visual-auditory deficits and clinical conditions incompatible with completing the questionnaires.

Informed consent was obtained from all parents before study entry. Patients were assessed twice, with a 4-week interval between the visits. Socio-demographic and clinical data, current medications/treatment and last available spirometry data were collected from patients during the first visit. At both visits, patients were invited by the physician to fill in a paper-and-pencil version of the RAPP [25] along with the following self-completed questionnaires:

- Short Form Heath Survey-12 (SF-12) [35], a generic validated instrument developed from the Short Form 36 (SF-36) questionnaire to assess health status. It is composed of 12 questions and provides physical (PCS) and mental health (MCS) component scores, higher values indicating better health status.
- Asthma control test (ACT) [36] which is used to assess the level of asthma control. This validated

questionnaire consists of five items regarding the presence, in the preceding four weeks, of limitations at work or school due to asthma, the presence of diurnal and nocturnal symptoms, and the use of rescue medications. One item records the subjective perception of the level of asthma control. Patients assigned scores of 1–5 to each item, results are then graded according to the following scheme: uncontrolled asthma, scores 5–19; well controlled asthma, scores 20–24; total disease control, score of 25.

- rhinitis symptoms have been assessed by mean of a validated Visual Analog Scale (VAS) [37], in which the patients are asked to indicate the global discomfort caused by their AR during the previous week. Scores ranged from ‘not at all bothersome’ (0 mm) to ‘intolerable bothersome’ (100 mm).

On the second visit, patients were asked to rate whether their health condition has improved or deteriorated over time by mean of seven point global rating scale (GRS) [38] ranging from –3 (‘large deterioration’), to 3 (‘large improvement’) with 0 meaning ‘no change’.

Validation and statistical analysis

The statistical validation explored the descriptive statistics and the following psychometric issues:

1. Scale’s dimension was evaluated by exploratory and confirmatory factor analysis [39,40].
2. Internal consistency was determined by calculating Cronbach’s correlation coefficient [41] on the whole test. The criteria used to evaluate the factor solutions were the following: explained variance and number of residuals greater than |0.10|, Root-mean-square error of approximation (RMSEA), comparative fit index (CFI) and Standardized Root Mean Squared Residual (SRMR). RMSEA values equal to or less than 0.08 were considered to be satisfactory. Values greater than 0.09 were considered satisfactory for the CFI. Finally, SRMR values less than 0.10 were considered acceptable, and those below 0.05 as adequate [42]. Good correlation was assumed if the coefficients were 0.70 or higher [41]. Higher scores are recommended for use in the single patient [42].
3. Reliability was determined from patients in the stable group using two measures: Intra-class coefficient (ICC) and Lin’s concordance correlation coefficient (CCC) [43,44]. Coefficients of 0.70 or higher were taken as indicating a good

correlation. Higher scores are recommended for use in the single patient [41].

4. Construct validity was evaluated using two components: convergent validity and discriminant validity. For convergent validity, Spearman’s correlation was used to examine the closeness of association between SF-12 and RAPP. A range of 0.4–0.8 confirmed convergent validity [45]. Discriminant validity was assessed by comparing patients according to level of asthma control and rhinitis severity (ANOVA model).
5. Responsiveness was evaluated by analyzing the correlation between changes in VAS & ACT and RAPP scores (Spearman correlation coefficient).
6. Clinical significance was assessed by determining minimal important difference (MID), as determined by receiver operating characteristics (ROC) curve method. The entire cohort for one dichotomization point (i.e. ‘no change’ versus ‘any improvement or deterioration’) was adopted [38]. The value that maximizes sensitivity, specificity, and the number of individuals correctly classified will be chosen [38].
7. ANOVA model and Spearman’s correlation coefficient were used to evaluate possible effects of education, age and smoking habits on patients’ response.

IBM SPSS Statistics was used to perform the statistical analysis (version 24, Armonk, NY) while confirmatory factor analysis was performed using Mplus 7.0 (Muthén & Muthén, Los Angeles, CA).

Results

One hundred and fifty patients were included in the study (estimated screening failure= 10%); the majority were female (74%), the mean age was 39.3 years (range 18–85 years). Regarding education, 49.3% possessed a degree and 44% a high school diploma of the remaining 2% had a secondary school and 4.7% primary school diploma 13.7% of the patients were students, 55.5% were employed, 22.6% were unemployed and 8.2% were retired. The majority of the patients (60.5%) suffered from persistent asthma. ACT scores at the first visit indicated that 2.7% were totally controlled, 38% were well controlled, and the remaining 59.3% were uncontrolled. The mean value of AR and asthma quality of life was 18 (V1 18.7 ± 6.4 ; V2 $M = 16.6 \pm 5.5$). The distribution of answers for the first and second visits are presented in Figure 1.

1. Scale dimensions: revealed a uni-dimensional structure that absorbed 45.7% of the total variance

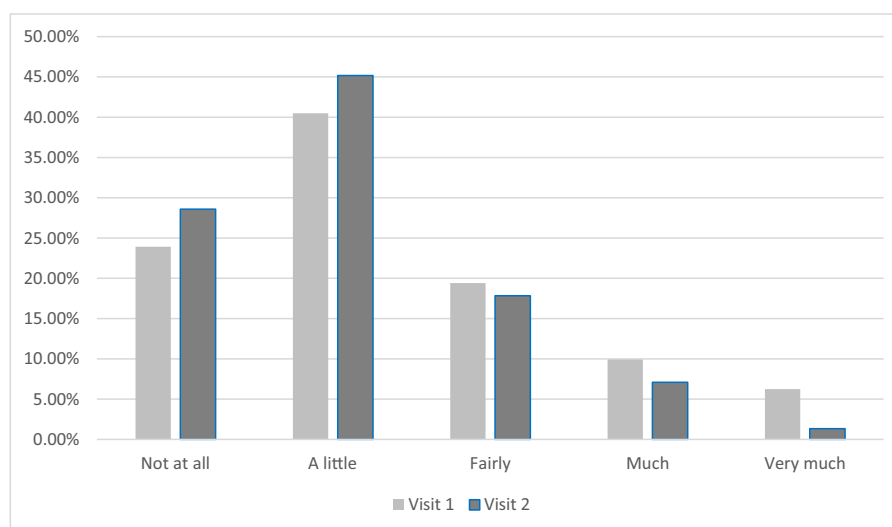


Figure 1. Frequency distribution of RAPP answers at Visit 1 and at Visit 2.

Notes: RAPP: RhinAsthma Patient Perspective.

and only 4 residuals greater than $|0.10|$ at first visit and 51.3% of the total variance and only 2 residuals greater than $|0.10|$ at the second visit. The confirmatory factor analysis identified the uni-dimensional structure: all the indexes were all satisfactory both at first (RMSEA 0.08, SRMR 0.06, CFI 0.90) and second visits (RMSEA 0.08, SRMR 0.05, CFI 0.91).

- Internal consistency: Cronbach alpha values of 0.87 were obtained at first visit and 0.89 at the second, both satisfactory.
- Reliability, assessed in 62 patients reporting a stable health status ($GRS = 0$), providing an ICC of 0.97 and a CCC = 0.95.
- Construct validity. Convergent validity: correlations between RAPP scores and the Physical Component Score of SF-12 were significant both at first ($r = -0.42$, $p < 0.01$) and second visit ($r = -0.40$, $p < 0.01$). Significant correlations were found between RAPP and the Mental Component Score of SF-12 both at Visit 1 ($r = -0.58$, $p < 0.01$) and at Visit 2 ($r = -0.37$, $p < 0.01$). Discriminant validity: RAPP results, presented in Table 1, show that the tool is able to discriminate between patients based on asthma control level and rhinitis severity ($p < 0.05$ for all the analyses).
- Responsiveness: the assessment of 88 patients reporting an improvement or deterioration in health status, shows that RAPP was significantly associated with VAS ($r = 0.34$, $p < 0.01$) and ACT ($r = -0.35$, $p < 0.01$).
- MID: A 2 point difference or change in RAPP maximizes sensitivity, specificity, and the number of individuals correctly classified (Table 2).

RAPP scores showed no significant differences between smokers, former smokers and nonsmokers (ANOVA Fisher's test. Visit 1: $p = 0.35$; Visit 2: $p = 0.35$). No significant associations were found between age and RAPP scores (Spearman's correlation. Visit 1: $r = -0.05$; Visit 2, $r = -0.14$). However, a significant association between RAPP scores and level of education was found (ANOVA Fisher's test. Visit 1: $p < 0.01$; Visit 2: $p = 0.03$).

Figure 1 shows the frequency distribution of answers (first and second visits).

Discussion

Historically, HRQoL was evaluated as a research tool in patients with respiratory allergy, using specific questionnaires addressed to AR or asthma [10–12], or by the RHINASTHMA [13] that was developed as an instrument for patients with both conditions. It has been included as primary or secondary outcome in clinical trials or observational studies [9,10]. As such, HRQoL data was not directly made available to the clinicians, and therefore had no direct influence on the care of the individual patient [34]. The lack of questionnaires specifically developed and validated for routine assessment has limited the integration of HRQoL in clinical setting [35]. The RAPP, originally available in Italian, has been designed and tested for this purpose. It meets the requirements of the international societies for tools that may be used with the individual patient.

In the present study, following the procedure used for HRQoL tools [46,47] the English version of the RAPP was fully cross-culturally adapted for a native

Table 1. RAPP discriminant validity.

	RAPP score (mean)	
	Visit1	Visit2
ACT		
Totallycontrolled	16.7	11.6
Wellcontrolled	14.3	13.7
Uncontrolled	21.6	20.2
<i>p-value</i>	<0.001	<0.001
Rhinitis		
Intermittent	16.8	14.7
Persistent	19.9	17.9
<i>p-value</i>	0.003	0.001
Rhinitis severity		
Moderate	17	15.7
Severe	22.9	18.9
<i>p-value</i>	<0.001	0.003

Notes: RAPP: RhinAsthma Patient Perspective; ACT: Asthma Control Test.

Table 2. The MID of RAPP obtained with the ROC analysis with different cutoff.

Cutoff $\geq$	Sensitivity	1-Specificity
5	0.989	0.519
4	0.955	0.471
3	0.931	0.374
2*	0.912	0.267
1	0.906	0.169

Notes: *cutoff point chosen; MID: minimal important difference; RAPP: RhinAsthma Patient Perspective; ROC: Receiver Operating Characteristics.

English speaking Filipino population from the original Italian version by two forward and two backward translations. The intent of this process was to capture the connotative meaning of the original items while considering possible cultural aspects. As with any questionnaire, validation is an iterative process. The present study represents a useful starting point for further adaptations that would make the RAPP available to the 1.5 billion English speakers worldwide, —approximately 20% of the Earth's population. The use of the RAPP in other English-language countries, could require an intra-lingual validation aimed at verifying the suitability of the RAPP in terms of clarity and relevance of each item and cultural and linguistic specificity of the target country [36]. The results of validation analysis show that the English RAPP has satisfactory psychometric properties for the assessment of HRQoL in clinical practice. The uni-dimensional structure of the original version was confirmed. All the requested standards of internal consistency and reliability have been achieved. The English RAPP behaved as expected compared to existing validated health status measure, SF-12, and performed well as a tool for discriminating between patient groups according to level of control and disease severity. The high responsiveness to clinical change and the MID of the original version have been confirmed.

Some limitations of this study should be acknowledged. The generalizability of the results may be

limited because the patients were recruited in a single specialized center and the recruitment was non-randomized. Due to this the sample could include primarily the most severe groups of AR and asthma patients, with under-representation of the milder stages.

However, the RAPP adequately captures the concepts in the original Italian version of the questionnaires, thereby showing the conceptual, semantic and cultural equivalence of the cross cultural adaptation. The questionnaire is simple to use and to score. The cutoff MID makes it simple to understand the clinical significance of changes over time. The RAPP has proven to be a reliable, valid, and sensitive instrument to assess HRQoL in patients with respiratory allergy. These results indicate that the instrument is suitable for use in clinical setting with English speaking patients.

Conclusions

The English version of RAPP has good psychometric properties and provides a valid, standardized and reliable tool for assessing and monitoring asthma and AR HRQoL in clinical practice in one of the world's most widely spoken languages.

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