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RhinAsthma patient perspective: A Rasch validation study

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ABSTRACT

Objective: In daily practice, Health-Related Quality of Life (HRQoL) tools are useful for supplementing clinical data with the patient's perspective. To encourage their use by clinicians, the availability of tools that can quickly provide valid results is crucial. A new HRQoL tool has been proposed for patients with asthma and rhinitis: the RhinAsthma Patient Perspective—RAPP. The aim of this study was to evaluate the psychometric robustness of the RAPP using the Item Response Theory (IRT) approach, to evaluate the scalability of items and test whether or not patients use the items response scale correctly. **Methods:** 155 patients (53.5% women, mean age 39.1, range 16–76) were recruited during a multicenter study. RAPP metric properties were investigated using IRT models. Differential item functioning (DIF) was used for gender, age, and asthma control test (ACT). **Results:** The RAPP adequately fitted the Rating Scale model, demonstrating the equality of the rating scale structure for all items. All statistics on items were satisfactory. The RAPP had adequate internal reliability and showed good ability to discriminate among different groups of participants. DIF analysis indicated that there were no differential item functioning issues for gender. One item showed a DIF by age and four items by ACT. **Conclusions:** The psychometric evaluation performed using IRT models demonstrated that the RAPP met all the criteria to be considered a reliable and valid method of measurement. From a clinical perspective, this will allow physicians to confidently interpret scores as good indicators of Quality of Life of patients with asthma.

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Introduction

The need for routine collection of Health-Related Quality of Life (HRQoL) data and other Patient-Reported Outcomes (PROs) has recently been underlined [1–4]. PROs can be used in daily practice to supplement clinical data with the patient's perspective, facilitate disease monitoring, and improve patient engagement and share of decision-making [5,6].

A new HRQoL tool, the RhinAsthma Patient Perspective—RAPP [7], has recently been developed and validated for use in clinical settings for patients with asthma and allergic rhinitis. The RAPP has demonstrated adequate psychometric performance and clinical relevance. Moreover, it shows pragmatic characteristics that enhance uptake in routine care [8]: the questionnaire is self-administered, easy to complete, short, and simple to calculate and interpret the scores.

The psychometric properties of the RAPP questionnaire have only been tested using the classical test theory (CTT). Also, when estimating a sophisticated model such as confirmatory factor analysis, the main aim of the CTT approach is to determine the capability of the items

to measure a latent construct, and focus on correlations between items and their properties.

In addition to the classical validity perspective, the modern IRT approach presents several desirable features [9–13]. First, IRT models directly analyze the relationship between the item-level score (item difficulty) and the patient's level of Quality of Life (QoL; person ability), producing a joint measure of individuals and items. Secondly, IRT models produce a common metric scale starting from dichotomous or ordinal responses to a questionnaire. Moreover, they are suitable for testing whether or not the items' response scale has been correctly interpreted and used by patients, i.e. whether or not respondents are able to discriminate among each response scale's point of any instrument's item.

In order to prove the reliability and reinforce the validity of a short tool that can be used in daily clinical practice, the objective of the present study is to evaluate the psychometric adequacy of the RAPP using Rasch analysis, with Rasch being the current psychometric approach for conducting an in-depth analysis of the scaling properties of an assessment instrument.

Methods

Study design

Data were collected during a multicenter study that involved nine allergology and pulmonology centers in Italy. 155 participants, aged over 18 years and with a good knowledge of both spoken and written Italian language, were recruited because of their clinical diagnosis of concomitant asthma and rhinitis, according to Global Initiative for Asthma (GINA) and Allergic Rhinitis and its Impact on Asthma (ARIA) classifications.

The study was approved by the Ethics Committee of Azienda Ospedaliera Universitaria San Martino, Genoa (Protocol number 602/2010 May 31, 2010, Register number 48/10), and was performed in accordance with the provisions of the 1995 Declaration of Helsinki (as revised in Edinburgh in 2000). All participants signed consent forms and received clear information about the research aims, the voluntary nature of participation, the anonymity of the data, and results.

The patients completed the asthma control test (ACT) [14] and the RAPP questionnaire [7].

The RAPP scale included eight items with a five-point Likert-type response scale: never (0), rarely (1), sometimes (2), very often (4), always (5).

The RAPP data were analyzed to achieve the full potential of the IRT approach that includes different kinds of models derived from the seminal work [15] of George Rasch (1960). The Rasch model assumes unidimensionality—i.e. all items in a scale measure the same single latent trait—and local independence—i.e. there should be no correlation between a person's response to one item and those to any other items. His original model focused on dichotomous responses and confirms that the probability that a person will affirm an item is a logistic function of the difference between the person's ability (i.e. the person's level of the measured trait) and the difficulty of the item (the level of the measured trait expressed by the item). Graphically, this function is an S-shaped curve, ranging from 0 to 1 and called “item characteristic curve” (ICC): the greater the ability (x-axis), the higher the probability (y-axis) of endorsing an item, passing through a flex point where the ability's level is equal to the difficulty of the item, so that the probability of affirming the item is equal to 0.5. The Rasch model provides a measurement of person ability relative to item difficulty, both of which are expressed in the same unit size (logits).

This model was extended [16] to analyze polytomous items, i.e. items with a graded response scale as in a Likert-type item. The partial credit model (PCM) [17] postulates that each item has a unique rating scale structure, whereas in the rating scale model (RSM) [18], all items share the same rating scale structure.

Statistical analyses

Statistical analyses were performed using IBM SPSS software v. 20.0 and Winsteps 3.72.3 (Beaverton, Oregon).

To assess construct's validity, item's scalability, and the behavior of the RAPP questionnaire answering's scale, both the PCM and RSM measurements were estimated using a joint maximum likelihood method. The likelihood ratio (LR) test between PCM and RSM specifications was used to choose between the two models with the expectation to preserve the more parsimonious, that is the RSM. In case of non-significant test, the RSM model was used [19–21].

The assumption of unidimensionality was tested by performing post-hoc principal component analysis (PCA) of residuals, where a dimensionality score of ≤ 2 was taken as rule of thumb (i.e., residuals did not contain other significant dimensions).

In order to evaluate how well each item fitted the model, the information-weighted (INFIT) and outlier-sensitive (OUTFIT) indices were considered. These statistics measure information about responses given by people with an “ability” level close to (INFIT) or distant from (OUTFIT) the item difficulty level: values for both of these in the 0.5–1.5 range are considered satisfactory [22].

Item discrimination was determined by calculating a point-measure correlation (i.e., a correlation's measure between single item scores and the Rasch measure), considering values of ≥ 0.70 as acceptable.

The person separation index (PSI) and the reliability index (RI) indicate whether or not differences across patients' measurements depend on actual differences in respondents' “ability” rather than measurement errors. By convention, values of $\text{PSI} > 1.5$ together with $\text{RI} \geq 0.70$ were considered adequate. A value of $\text{RI} = 0.8$ means that the instrument statistically differentiates between at least three groups ($R = 0.9$ indicates the possibility of discriminating between 4 or more groups) [23,24].

Lastly, since a good instrument should behave in the same manner for all respondents, a DIF (differential item functioning) analysis was performed to test measurement invariance, applying the same measurement models to different subgroups of participants. A difference of at least 0.5 logits between groups was noticeable, and indicated an item bias [25]. In this study, DIF was tested for gender, age, and ACT.

Results

There were no missing data, and all 155 cases were analyzed using Winsteps software. Table 1 shows the percentage of answer for each items.

Overall, the items in the RAPP adequately fitted both model specifications for polytomous items (PCM and RSM), but the RSM was more parsimonious and desirable,

Table 1. RAPP items: Percentage distribution of answers.

Items	Not at all	A little	Enough	Much	Very much
1 Stuffy or runny nose, sneezing, or itchy nose	16.1	21.3	32.3	19.4	11.0
2 Itchy eyes, watery eyes, sore eyes, and eyes redness	24.5	32.3	22.6	14.8	5.8
3 Difficulty in concentrating	34.8	26.5	20.6	11.6	6.5
4 Wheezing, cough, chest tightness, shortness of breath	23.2	38.7	21.3	10.3	6.5
5 Problems in sleeping (i.e., night awakenings)	36.8	33.5	13.5	11.6	4.5
6 Having to avoid certain areas and environments	33.5	27.1	21.3	14.2	3.9
7 Having to take drugs	31.0	23.9	14.2	21.9	9.0
8 Limitations in performing some activities (i.e., working, studying, sports)	31.6	28.4	21.3	13.5	5.2

because it assumes the equality of the rating scale structure for all items.

As the LR test was not significant ($\chi^2 = 38.8$; $df = 21$; $p < 0.05$), the RSM model was used.

Post-hoc PCA of residuals yielded a value of 2, confirming that data respected the unidimensional assumption.

Table 2 shows the scaled RAPP; items are presented in order of QoL level measured by the RAPP, starting from the most arduous, in terms of expressed difficulty. As the location decreased, the patient's QoL level increased; therefore, reporting a frequency of "sleeping problems" in the 2 weeks preceding the visit corresponded to the lowest QoL.

All the INFIT and OUTFIT statistics were in the 0.7–1.3 satisfactory range. The PT-Measure correlation values were similar and high for all items. Only one item (item 4) revealed a slightly lower correlation value.

The RAPP had adequate internal reliability and showed good ability to discriminate among different groups of participants: PSI was 2.89 and RI 0.89.

The item locations ranged from -0.69 to $+0.43$ logits, implying that the RAPP items are grouped in the middle of the logit scale, with no items covering either of the two extremes of the continuum of the person's level of QoL. This indicates that the scale does not work well for individuals with a medium or high QoL score.

The category probability curves of items are reported in Figure 1: the five response options for all items are well ordered and distributed, each one having a point at which it becomes the most likely response.

DIF analysis indicated that there were no differential item functioning issues for gender. Only one item showed a small level of DIF by age as follows: concentration difficulty (0.83 logits relatively easier in the group of older patients than in the 28- to 38-year-old group and 0.82 logits relatively easier in the group of older patients than in the 39- to 49-year-old group).

Four items showed a small level of DIF by ACT as follows: stuffy or runny nose, sneezing or itchy nose (rated 0.97 logits relatively easier in the totally controlled group than in the uncontrolled group and rated 0.56 logits relatively easier in the well-controlled group than in the uncontrolled group); itchy, watery, sore, and red eyes (rated 0.59 logits relatively easier in the totally controlled group than in the well-controlled group, rated 1.22 logits relatively easier in the totally controlled group than in the uncontrolled group and 0.63 logits relatively easier in the well-controlled group than in the uncontrolled group); wheezing, cough, chest tightness, and shortness of breath (1.79 logits relatively more difficult in the totally controlled group than in the well-controlled group and 2.46 logits relatively more difficult in the totally controlled group than in the uncontrolled group and rated 0.67 logits more difficult in the well-controlled group than in the uncontrolled group); and sleeping problems (0.97 logits relatively more difficult in the totally controlled group than in the well-controlled group and 1.49 logits relatively more difficult in the totally controlled group than in the uncontrolled group and 0.51 logits more difficult in the well-controlled group than in the uncontrolled group).

Table 2. Scaled RAPP: Items, location and fit statistics (rating scale model).

Items	Location Logits (SE)	INFIT MNSQ	OUTFIT MNSQ	PT-measure Corr.
5 Problems in sleeping (i.e., night awakenings)	0.43 (0.10)	1.07	1.05	0.70
6 Having to avoid certain areas and environments	0.20 (0.10)	0.85	0.83	0.74
3 Difficulty in concentrating	0.19 (0.10)	0.98	0.95	0.72
8 Limitations in performing some activities (i.e., working, studying, sports)	0.13 (0.10)	0.75	0.71	0.77
4 Wheezing, cough, chest tightness, shortness of breath	0.04 (0.10)	1.36	1.40	0.59
2 Itchy eyes, watery eyes, sore eyes, and eyes redness	-0.07 (0.10)	0.87	0.85	0.74
7 Having to take drugs	-0.21 (0.10)	1.11	1.08	0.73
1 Stuffy or runny nose, sneezing, or itchy nose	-0.69 (0.10)	1.02	1.05	0.72

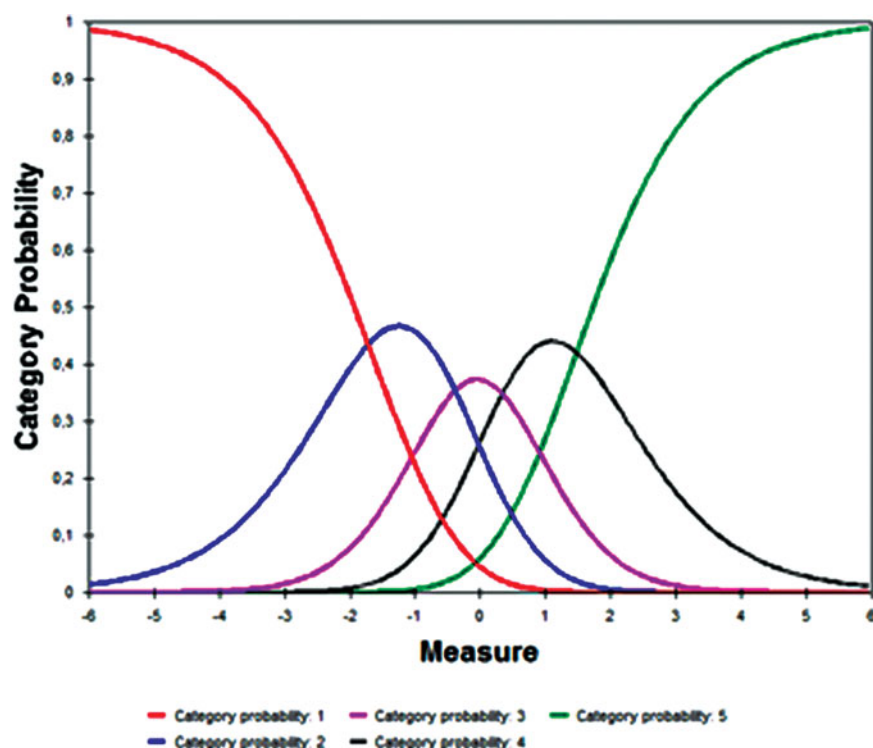


Figure 1. Category probability curve.

Discussion

The objective of the present study is to evaluate the psychometric adequacy of the RAPP based on Rasch analysis. These findings indicate that the RAPP is a powerful tool and support the assertions of the classical test perspective on the psychometric properties of the RAPP [7]. Overall, the criteria for reliable and valid measurement were met. From a clinical perspective, this allows physicians to confidently interpret scores as good indicators of QoL of patients with asthma. Performance of scale items and response categories was analyzed in depth by exploiting the features offered by the Rasch models [10–13].

The RAPP revealed a unidimensional construct, as indicated by the fit statistics and PCA of the residuals; patients reacted to a five-point Likert rating scale in the desirable manner.

Rasch analysis allows items and persons to be measured on the same logit scale and enables simultaneous comparison of item difficulty and person ability. This feature is of great importance and is not available in the CTT perspective.

A well-targeted tool has evenly spaced, well-fitting items that cover the full range of person abilities.

However, in this study, a large floor effect with a small ceiling effect was observed for the RAPP, with the majority of our patients actually reporting a very good quality of life. It was evident that there are no items targeting persons with higher QoL, so the instrument would probably be more appropriate for more compromised patients.

The presence of ceiling and floor effects is characteristic of HRQoL instruments since they have been constructed for use in a wide range of populations [26]. Thus, findings may be a reflection of the sample's characteristics, i.e., healthy patients.

Our study shows the great value of Rasch analysis, which adds sophistication and refinement to traditional psychometric methods, and provides detailed diagnostic item-level data. The study proves the RAPP to perform well on most aspects of the assessment: all items fit the construct, the level of discriminative ability is high, it shows unidimensionality, and the response scale functions as expected while the amount of DIF stays small, the latter not being of a problematic magnitude. Poor targeting of item difficulty to person's ability showed to be the serious problem for the overall scale.

A limitation of this study is that results were obtained on an Italian sample only, owing to the current availability of such data. Considering that validation of an instrument is a lengthy, even endless process [27], international studies will need to be performed to further test the psychometric properties of the RAPP.

Conclusions

This is the first study to use the Rasch model to evaluate the psychometric properties of the RAPP. The results uphold those of previous traditional testing and confirm that no changes to the questionnaire are required. This study provides further evidence to support the use of the

RAPP as a valid tool for the routine assessment of HRQoL in patients diagnosed with rhinitis and asthma.

Declaration of interest

The authors declare no financial or personal conflict of interest.

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