

Validation of a questionnaire (CARAT10) to assess rhinitis and asthma in patients with asthma

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Keywords

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Abstract

Background and aim: The Control of Allergic Rhinitis and Asthma Test (CARAT) was developed to be used in the concurrent management of these diseases, as recommended by the Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines. However, it was necessary to statistically identify and remove redundant questions and to evaluate the new version's factor structure, internal consistency and concurrent validity.

Methods: In this cross-sectional study 193 adults with allergic rhinitis and asthma from 15 outpatient clinics in Portugal were included. The CARAT questionnaire was reduced using descriptive analysis, exploratory factor analysis and internal consistency. Spearman's correlations were used to compare the CARAT scores with a medical evaluation and other measures of control, including the Asthma Control Questionnaire and symptoms' visual analogue scales. The performance against physician rating of control was summarized using the area under the curve (AUC) from receiver operating characteristic analysis. In addition, CARAT was compared with the physician's decision to reduce, maintain or increase treatment.

Results: The reduced version has 10 questions and 2 factors (CARAT10). The Cronbach's alpha was 0.85. All correlation coefficients of CARAT10 and factors with the different measures of control met the *a priori* predictions, ranging from 0.58 to 0.79. The AUC was 0.82. For the physician's decision groups of reduce, maintain or increase treatment, the mean (IC95%) scores of CARAT10 were 24 (21.4;26.6), 21 (19.4;21.9) and 15 (13.6;16.5), respectively.

Conclusion: CARAT10 has high internal consistency and good concurrent validity, making it useful to compare groups in clinical studies.

Abbreviations

ACQ5, Asthma Control Questionnaire; ACSS, Asthma Control Scoring System; ACT, Asthma Control Test; ARA, allergic rhinitis and asthma; ARIA, Allergic Rhinitis Impact on Asthma guidelines; ATAQ, Asthma Therapy Assessment Questionnaire; AUC, area under the curve; CARAT, Control of Allergic Rhinitis and Asthma Test; CARAT10, 10-question version of the Control of Allergic Rhinitis and Asthma Test; CARAT17, 17-question version of the Control of Allergic Rhinitis and Asthma Test; EQ-5D, EuroQol Questionnaire; ROC, receiver operating characteristic; VAS, visual analogue scale.

Allergic rhinitis and asthma (ARA) are prevalent allergic respiratory diseases that represent significant losses in the patient's quality of life and work/school performance, as well as an important socioeconomic burden. The Allergic Rhinitis Impact on Asthma guidelines (ARIA) guidelines recommend the optimal control of these diseases as the primary goal of their treatment (1, 2). A combined approach to the management of upper and lower airways disease has been extensively proposed (1, 3, 4).

Several tools have been developed to assess the patients' quality of life and symptoms' severity for asthma and for

rhinitis, but these questionnaires rarely assess both diseases simultaneously (5–9). More recently, asthma control questionnaires have also been proposed as an important tool to improve asthma outcomes (10–12). However, a tool for the concurrent assessment of ARA control was not available. This has led us to the development of the Control of Allergic Rhinitis and Asthma Test (CARAT) (13).

CARAT is a self-administered questionnaire to measure the degree of control of ARA in adult patients with a previous diagnosis of these diseases.

A high quality methodological approach to the development of a questionnaire is needed for accuracy and usefulness of the tool. The CARAT project has three phases: (i) the construction of an ARA control assessment tool, (ii) a cross-sectional study to reduce the number of questions and evaluate the questionnaire's internal consistency, factor structure and concurrent validity and (iii) a longitudinal study to assess its reproducibility, predictive validity and responsiveness. The first phase of the CARAT project included an item generation process based on related literature, followed by a web-supported consensus process and a feasibility study. It generated a 17-question version of CARAT (CARAT17), which must be evaluated to remove statistically redundant questions. A shorter version would also reduce the completion time allowing the use of CARAT in a wider range of clinical settings. Furthermore, the evaluation of the questionnaire's psychometric properties is necessary.

We aimed at describing the second phase of CARAT project, in which we establish the final version of the CARAT questionnaire by reducing the number of questions through an analytical process and evaluate its cross-sectional internal consistency and validity.

Methods

Study design and setting

This cross-sectional item-reduction study was conducted in 15 allergy or respiratory outpatient clinics, mostly hospital based, from the Portuguese regions of Norte, Centro, Lisboa, Alentejo and Açores. At each centre, several physicians could participate and were asked to include at least eight patients each. The study was conducted in the last trimester of 2008.

Participants

To ensure a broad usage of the questionnaire, all patients between 18 and 70 years of age, with a medical diagnosis of asthma and allergic rhinitis and at least 6 months of follow-up at the clinic, were eligible.

The study was approved by the local ethics committee, and each patient gave his/her written informed consent.

Data collection

In addition to CARAT17, data collection included instruments to assess control and quality of life, as well as a

medical evaluation. Regarding control, patients answered the Asthma Control Questionnaire (ACQ5) (10) and three visual analogue scales (VAS) concerning the presence of any airways symptoms, bronchial symptoms and nasal symptoms. Health-related quality of life was assessed by the EuroQol Questionnaire (EQ-5D) (14). The medical evaluation was carried out by the attending physician, who was blinded to the results of the questionnaires. The physician registered the patient's rhinitis severity and control, asthma severity and control, known allergies and current medication (data not shown), as well as his decision regarding treatment (increase, maintain or decrease treatment).

Statistical analysis

Descriptive statistics

The population was described using standard descriptive statistical techniques. The statistical analysis was carried out using SPSS 17.0 (SPSS Inc., Chicago, IL, USA). The level of significance was set at $P < 0.05$.

Item reduction

An exploratory factor analysis using principal components and varimax rotation was performed to identify the number of different factors within the questionnaire and the possible statistical redundancy of questions. We applied standard procedures of exploratory factor analysis with respect to the number of variables used in the analysis and the selection of number of factors. Internal consistency analysis was performed simultaneously and was taken into account for the item reduction. An item was considered redundant if one of the following occurred: responses over 90% in a single category of a variable; considerable cross-loading (>0.300 in more than one factor); low item-total correlation (<0.400); increased Cronbach's alpha if the item was deleted.

Description of CARAT10

The new version of the questionnaire has 10 questions (CARAT10). The time frame to which it refers is the previous 4 weeks. Seven questions address the frequency of symptoms, one sleep impairment, one activities limitation and the last one addresses the need for more medication (Additional file 1). The response options for all questions are 4-point Likert scales. The first 9 questions were scored from 0 (the response option reflecting complete absence of control) to 3 points. The question regarding medication increase had 3 response options ('Never' – 3 points, 'Less than 7 days' – 2 points, 'More than 7 days' – 0 points) and an option 'I'm not taking any medication' which was also attributed 3 points. The questionnaire's score was the sum of all questions. The range of possible scores for CARAT10 is 0–30, 0 being the complete absence of control.

The scores of CARAT10 were compared among categories of patients' characteristics, namely gender, age, severity of asthma and of rhinitis, using *t*-tests or ANOVA where appropriate. For this purpose, age was categorized in quartiles.

Evaluation of CARAT10

We studied the new reduced version's (CARAT10) discriminative properties – the ability to distinguish people at a single point in time. The internal consistency was assessed with Cronbach's alpha. The concurrent validity was studied using Spearman's correlation coefficients between the reduced version or its factors and control assessment instruments and the physician's assessment. *A priori* predictions for the correlation coefficients of the new version with the other control measures were as follows: (i) 0.6–0.8 with ACQ5; (ii) 0.6–0.8 with the symptoms VAS; (iii) 0.4–0.6 with the physician's assessment. Scatter plots were used to present these correlations.

Table 1 Description of the patients included ($n = 193$). *0–10, 0 being absence of control; #1–10, 1 being no disturbance; \$0–100, 0 being the worst imaginable health state

Gender n (%)	
Male	62 (32.1)
Female	131 (67.9)
Age mean (SD) years	37.5 (13.84)
Physician assessment	
Severity n (%)	
Asthma	
Intermittent	36 (20)
Mild persistent	52 (29)
Moderate persistent	81 (45)
Severe persistent	12 (6)
Rhinitis	
Intermittent	44 (27)
Persistent	116 (73)
Mild	81 (51)
Moderate/severe	78 (49)
Control* median (p25–p75)	
Asthma	7 (4–8)
Rhinitis	8 (5–9)
Treatment decision n (%)	
Reduce	11 (6)
Maintain	107 (58)
Increase	67 (36)
ACQ5 score median (p25–p75)	0.8 (0.2–1.75)
<0.5 n (%)	70 (36)
0.5–1.5 n (%)	67 (35)
>1.5 n (%)	55 (29)
VAS# median (p25–p75)	
All symptoms	4 (2–6)
Bronchial/pulmonary symptoms	4 (2–7)
Nasal symptoms	3 (2–6)
EQ-5D %with any problem	
Mobility	13
Self-care	2.1
Usual activities	23.0
Pain/discomfort	37.7
Anxiety/depression	39.8
EQ-5D VAS\$ median (p25–p75)	75 (60–90)

ACQ5, Asthma Control Questionnaire; EQ-5D, EuroQol Questionnaire; VAS, visual analogue scale.

Receiver operating characteristic (ROC) analyses were conducted to evaluate the performance of CARAT10 against physician rating of control. For this, we derived dichotomous variables from the physician ratings of control as described by Nathan et al. (11). ROC curves for CARAT10 and for each of factors of the questionnaire were plotted, and the areas under the curves (AUC) were computed.

The CARAT10 scores in the three groups of physician's treatment decision (reduce, maintain or increase treatment) were compared using the Kruskal–Wallis test. An error bar graph was used to present this comparison.

Results

This study included 193 patients, assessed by 34 physicians in 15 outpatient clinics. The sample's characteristics are described in Table 1.

Overall, 0.58% of all questions were not answered. The items with most missings were 'Nasal pruritus' and 'Throat symptoms' (4 missings each – 2.1%).

The item reduction began with the elimination of the item 'Hospitalization', a dichotomic variable that had 99% of answer 'No'. Then, using exploratory factor analysis and internal consistency analysis, a 10-question version of the

Table 2 Factor analysis of items in the initial* and final solutions. Loading to a factor of each item is represented in bold and grey background, and the items with cross-loading are represented in bold italic

Item	Initial solution 16 items			Final solution 10 items	
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2
Nasal obstruction	0.094	0.545	0.428	0.662	0.151
Sneezing	0.182	0.751	0.151	0.767	0.221
Nasal pruritus	0.153	0.831	0.069	0.737	0.218
Rhinorrhoea	0.241	0.680	0.147	0.789	0.110
Throat symptoms	0.213	0.470	0.600		
Ocular symptoms	0.230	0.714	0.125		
Dyspnoea	0.757	0.176	0.298	0.148	0.845
Wheezing	0.699	0.111	0.442	0.157	0.821
Chest tightness	0.672	0.258	0.272	0.181	0.794
Cough	0.263	0.022	0.745		
Daily activities limitation	0.559	0.154	0.420	0.152	0.742
Waking up at night	0.516	0.185	0.441	0.188	0.730
Symptoms in the morning	0.065	0.248	0.711		
Absenteeism	0.648	0.149	–0.145		
Medication increase	0.510	0.203	0.335	0.244	0.576
Nonscheduled consultation	0.701	0.195	0.040		

*The initial solution had 16 items, following the elimination of the item 'Hospitalization', given the high frequency of one of the categories (99%).

Table 3 Comparison of CARAT10 scores according to different patients' characteristics

	CARAT 10 Mean (sd)	Min–Max	<i>P</i>
Gender			0.02
Male	20.4 (6.27)	2.0–30.0	
Female	18.0 (7.0)	2.0–30.0	
Age in years (quartiles)			0.39
<27	19.0 (5.0)	10.0–28.0	
27–35	18.8 (6.5)	3.0–30.0	
36–47	19.9 (7.5)	2.9–30.0	
>47	17.5 (7.8)	2.0–30.0	
Physician assessment			
Severity			
Asthma			<0.001
intermittent	22.8 (4.5)	11.0–30.0	
mild persistent	18.9 (6.9)	2.0–29.0	
moderate persistent	17.5 (7.1)	3.0–30.0	
severe persistent	15.6 (6.9)	2.0–27.0	
Rhinitis			
intermittent	21.7 (5.8)	9.0–30.0	0.004
persistent	18.1 (7.2)	2.0–30.0	
mild	19.8 (6.0)	2.0–30.0	0.006
moderate/severe	16.9 (7.5)	2.0–30.0	

questionnaire (CARAT10) was obtained. It has 2 factors – one with 4 items, the other with 6 items (Table 2).

CARAT10 had a mean (standard deviation) score of 18.8(6.85), with a minimum score of 2 ($n = 2$) and a maximum score of 30 ($n = 5$).

In the internal consistency analysis, the Cronbach's alpha was 0.89 for CARAT17 and 0.85 for CARAT10, with 0.76 for Factor 1 and 0.86 for Factor 2.

The scores of CARAT10 among categories of gender, severity of asthma and severity of rhinitis were different; while for age categorized in quartiles, the scores were not statistically different (Table 3).

All the correlation coefficients of CARAT10 and its factors with ACQ5, symptoms VAS and the physician's assessment met the *a priori* predictions (Table 4, Fig. 1) and were statistically significant ($P < 0.001$). Also significant was the

correlation between CARAT10 and the EQ-5D VAS, with a Spearman correlation coefficient of 0.48.

Receiver operating characteristic curves of CARAT10 score and its factors are shown in Fig. 2. The areas under the curve for CARAT10, factor 1 and 2 are, respectively, 0.82, 0.80 and 0.82.

A statistically significant difference ($P < 0.001$) was found in the CARAT10 scoring in the 3 groups of the physician's treatment decision (reduce, maintain or increase treatment). The comparison is shown in Fig. 3.

Discussion

This article describes the development and evaluation of a short 10-question version of the Control of Allergic Rhinitis and Asthma Test (CARAT10). It is the second phase of a project that aims to the creation and validation of a tool to simultaneously assess the control of both diseases. A series of methodological steps have been followed to assure the final quality of the questionnaire (15).

The reduction in the initial version of the tool (CARAT17) was necessary to remove statistical redundancy which would affect the scoring and interpretation of the questionnaire, maintaining good validity and reliability. In the exploratory factor analysis, two independent factors were extracted from the final reduced version, and the items' allocation matched exactly the initially proposed theoretical allergic rhinitis and asthma subdomains (Table 4).

The new version of the questionnaire was shown to have good discriminative properties – internal consistency and concurrent validity. CARAT10's internal consistency was very similar to that of CARAT17, supporting the item reduction process. The CARAT10 internal consistency was satisfactory (16) for the questionnaire and for each of the subdomains. Moreover, it has similar or better internal consistency than questionnaires used for assessing asthma control, which ranges between 0.72 and 0.84 (11, 17). This level of internal consistency seems to support the concept of a questionnaire assessing the control of allergic rhinitis and asthma simultaneously (1, 18).

For the evaluation of the CARAT10's concurrent validity and considering the lack of a gold standard, we used different 'external measures' that take into account both the

Table 4 Spearman's correlations of CARAT10, its factors and external measures of asthma and allergic rhinitis control. *A priori* predictions for the correlation coefficients of the new version with the other control measures were as follows: 1) 0.6–0.8 with ACQ5; 2) 0.6–0.8 with the symptoms VAS; 3) 0.4–0.6 with the physician's assessment. The correlations between the measures of similar domain are shown in bold

	ACQ5 score	Visual analogue scale			Physician assessment	
		All symptoms	Bronchial/pulmonary symptoms	Nasal symptoms	Asthma control	Rhinitis control
CARAT10	–0.71	–0.69	–0.69	–0.61	0.57	0.52
Factor 1 (rhinitis related)	–0.38	–0.53	–0.45	–0.67	0.32	0.58
Factor 2 (asthma related)	–0.79	–0.62	–0.70	–0.42	0.62	0.36

ACQ5, Asthma Control Questionnaire.

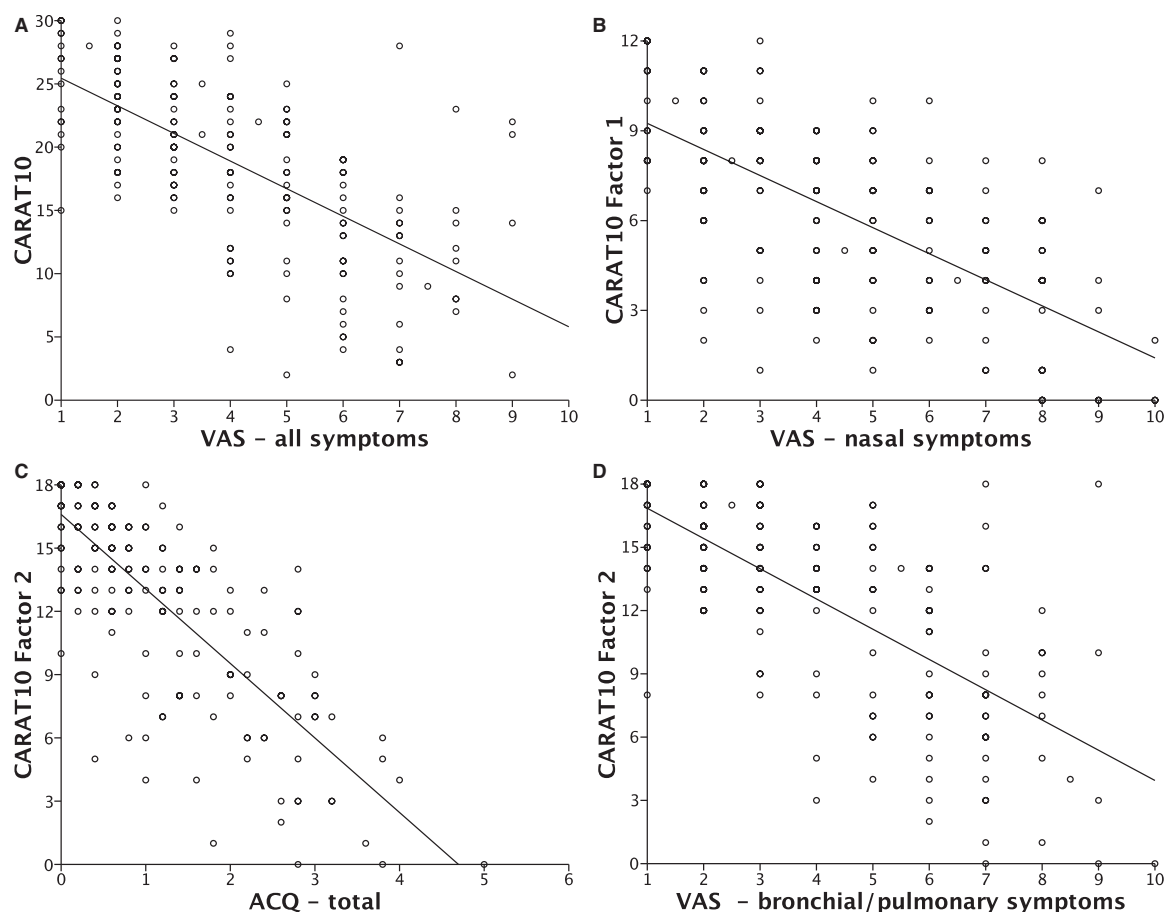


Figure 1 Scatter plots showing the correlations between CARAT10 and its factors with the all symptoms' visual analogue scale (VAS),

the nasal symptoms' VAS, the bronchial/pulmonary symptoms' VAS and Asthma Control Questionnaire (ACQ5).

patients' and physicians' views. All correlations met the *a priori* predictions and are similar or better than those of widely used asthma questionnaires (10, 11, 17). Symptoms VAS were recently proposed as an adequate instrument to measure the severity of allergic rhinitis (19). A good correlation was observed between the CARAT10 allergic rhinitis subdomain and a nasal symptoms VAS. The correlation between CARAT10 asthma subdomain and ACQ5 was similar to that of previously observed between the Asthma Control Scoring System (ACSS) and ACQ5 (17) and between the Asthma Control Test (ACT) and the Asthma Therapy Assessment Questionnaire (ATAQ) (20). Correlation with the physicians' assessment was as good as could be expected and greater than that of ACT (11). In a similar manner, the AUC that summarizes the performance against the physician rating of control was better for CARAT10 when compared with ACT published results (0.82 and 0.77, respectively).

A limitation of this study is the lack of comparison with objective tests such as lung function. Nevertheless, several 'external measures' were used in the evaluation of concurrent validity. Moreover, longitudinal validation studies to assess CARAT10's evaluative properties, to establish a

scoring system and the minimal clinical important difference are necessary. These studies are currently in progress. As with any questionnaire, validation will be required for the use of CARAT10 in specific populations and settings (21).

In summary, this study, with more than 30 physicians and a large sample of patients with ARA from different clinical settings, showed that CARAT10 questionnaire has high internal consistency and construct validity, making it useful to compare groups in clinical studies.

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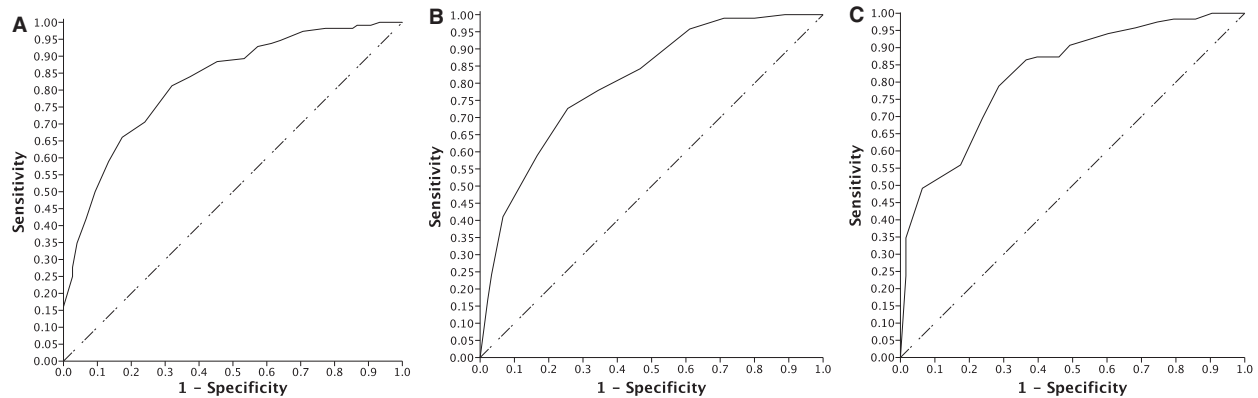


Figure 2 Receiver operating characteristic curves of CARAT10 score against physician rating of control (A), factor 1 against physician rating of rhinitis control (B) and factor 2 against physician rating

of asthma control (C). The areas under the curves are, respectively, 0.82, 0.80 and 0.82.

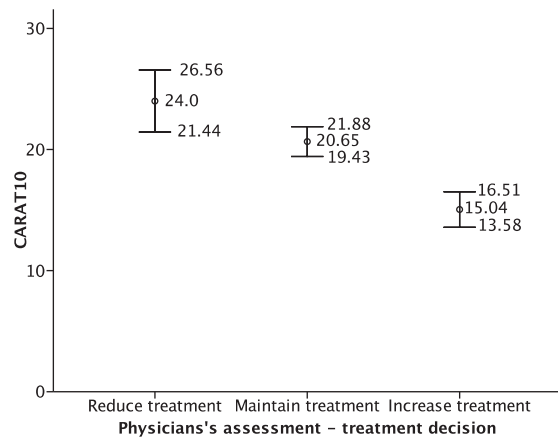


Figure 3 Error bar comparing the scoring of CARAT10 in the three groups of the physician's treatment decision. The comparison of the 3 groups was statistically significant using the Kruskal–Wallis test ($P < 0.001$).

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Authors contributions

JAF is responsible for the CARAT project and participated in all stages and tasks, LNS participated in the analysis and collaborated in the process of writing the manuscript draft, ASS participated in data collection and analysis and collaborated in the process of writing the manuscript draft, MMA participated in study design and reviewed the manuscript; LFA participated in study design, led the data analysis and reviewed the manuscript, LF, MBF and JB provided critical review during the project and reviewed the manuscript.

Conflicts of interest

None to be declared.

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