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Validity and the reliability of the Turkish version of the control of allergic rhinitis and asthma test for children (CARATKids)

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ABSTRACT

Aim: Asthma occurs in association with allergic rhinitis. Control of Allergic Rhinitis and Asthma Test for Children (CARATKids) is a questionnaire to assess control of both diseases. The aim of this study was to assess the validity and reliability of the CARATKids in Turkish children aged 6–12 years. **Methods:** After a cultural adaptation process, children with asthma and allergic rhinitis were recruited. CARATKids, childhood Asthma Control Test, total nasal symptom score, visual analog scale scores for asthma and rhinitis, peak nasal inspiratory flow and peak expiratory flow values were obtained at baseline and after 4–6 weeks. The patients were classified according to the control level for asthma and rhinitis and stable/unstable groups. Discriminative properties, internal consistency, test–retest reliability, responsiveness, validity and minimal clinically important difference (MCID) were assessed. Receiver operating characteristic curve analysis was performed. **Results:** About 174 patients were included. The Cronbach's alpha was 0.841. Correlation coefficients between CARATKids and external measures of control were 0.42–0.77, and between the score changes of CARATKids and external measures of control it was 0.56–0.78. Guyatt's responsiveness index was –1.88, within-patient change of CARATKids score was significant. The intra-class correlation coefficient was 0.973. The MCID was 4. A cutoff score of ≤ 5 on the CARATKids had a sensitivity of 100% to distinguish the controlled groups according to both the GINA and ARIA. **Conclusion:** CARATKids is a reliable and valid tool to assess asthma and allergic rhinitis control in Turkish children. A score of ≤ 5 on CARATKids defines controlled disease for both diseases simultaneously.

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Introduction

Childhood asthma is a highly prevalent chronic disease. Allergic rhinitis is both a risk factor for asthma and is frequently comorbid with asthma [1].

According to the united airway hypothesis, if allergic rhinitis becomes uncontrolled asthma control becomes difficult. Therefore, it is important to simultaneously control both diseases [2].

There are some questionnaires to assess control in asthma and allergic rhinitis, for example, Childhood Asthma Control Test (cACT) and Asthma Control in Children (CAN) for asthma, and Rhinitis Control Assessment Test (RCAT) for allergic rhinitis [3–5]. Yet, none of these questionnaires assess both asthma and allergic rhinitis simultaneously.

The CARAT was developed and validated to assess allergic rhinitis and asthma in adults [6,7]. The CARATKids has 13 items with yes/no answer format, of which 8 items are answered by the patients, and 5 items by the caregivers [8]. The CARATKids is a questionnaire that is used to assess the control of allergic rhinitis and asthma in children between the ages of 6 and 12 [8,9]. The CARAT and the CARATKids are the first questionnaires that makes it possible to assess the control of asthma and allergic rhinitis simultaneously.

The original version of the CARATKids is in Portuguese, and there are validity and reliability studies of the questionnaire published in Brazilian Portuguese, Dutch and Thai [10–12]. It is freely available for clinical use, and may be downloaded from the following website: www.caratnetwork.org

The aim of the current study was to assess the Turkish cultural adaptation, validity and reliability of the CARATKids in Turkish children with asthma and allergic rhinitis aged 6–12 years. Consequently, we hypothesized that the CARATKids would be a reliable instrument to assess the control of asthma and allergic rhinitis simultaneously in Turkish children.

Methods

The developers of the CARATKids questionnaire were contacted, and their permission was requested to develop the Turkish version of the questionnaire. Then, the CARATKids was translated from Portuguese to Turkish, and the translated version of it was backtranslated from Turkish to Portuguese by two independent professional translators. The first author of this manuscript compared the two translated versions, and decided to choose the version which was more clinically appropriate should there be any differences between the translations. The backtranslated version of the CARATKids was sent to its developers, and they also approved the translation. Subsequently, 10 patients were asked to complete the CARATKids, and the patients were further interviewed about the interpretation and wording of each of the questionnaire items. Yet, no problems with the comprehensibility of the items of the questionnaire were reported, so none of the items needed to be changed, and therefore the Turkish version of the CARATKids was finalized accordingly.

For the reliability and validity study, patients aged 6–12 years with a diagnosis of asthma and allergic rhinitis for at least 3 months presenting to the Pediatric Allergy and Clinical Immunology outpatient clinic of Tokat State Hospital between October 2017 and March 2018 were enrolled to this study. Any patients with a respiratory or chronic disease diagnosis other than asthma and allergic rhinitis or any patients or their caregivers who could not complete the questionnaire for any reason were excluded from the study. Ethical approval for the study was obtained from the clinical research ethics committee of Tokat Gaziosmanpasa University.

The patients were assessed twice 4-to-6 weeks apart. At each visit, they were asked to complete the CARATKids, the cACT and a visual analog scale (VAS) for asthma and allergic rhinitis. At both visits, the values for peak expiratory flow (PEF) and peak nasal inspiratory flow (PNIF) were recorded.

Patients were classified as uncontrolled, partially controlled, and controlled according to GINA criteria,

and mild and moderate-to-severe according to ARIA criteria at both visits [13,14].

The CARATKids consists of 13 questions, which are answered either as Yes or No. The first 8 questions are answered by the patient, and the last 5 questions by their caregivers. The patients and their caregivers were asked to answer the questions of the CARATKids by taking into account the previous 4 weeks [8].

The Childhood Asthma Control Test (cACT) consists of 7 questions, and the first 4 questions are answered by the patients, whereas the last 3 questions are answered by the caregiver regarding the control of asthma over the past 4 weeks. The total score of the cACT might range from 0 to 27. The Turkish version of the cACT has been shown to be a reliable and valid tool [15].

Total scores of the cACT were classified as uncontrolled disease if the score was ≤ 19 , and as controlled disease if the score was ≥ 20 .

The VAS scores were marked by the patients on a 10 cm line where the 0-cm-end was defined as bad, and the 10-cm-end as good separately for both asthma and allergic rhinitis. In line with previous research, a VAS score of >6 was defined as controlled disease [16,17].

Children self-assessed their total nasal symptom score (TNSS), which is used to rate the symptom severity for nasal obstruction, rhinorrhea, sneezing, ocular pruritus, and postnasal drip on a scale of 0 (absent) to 3 (severe). Patients' severity of allergic rhinitis was grouped as moderate-to-severe if the TNSS was ≥ 6 , and as mild if the TNSS was <6 [18,19].

PEF values and PNIF values were recorded using a PEFmeter device (Expirite Peak Flow Meter) and a PNIFmeter device (Clement Clarke, Harlow, England) after adhering to a standard measurement procedure, where the best value of three consecutive measurements was chosen [20,21]. PEF and PNIF values were recorded at both visits.

By subtracting the first visit CARATKids, cACT, VAS-asthma, VAS-rhinitis, TNSS, PEF and PNIF values from the second visit CARATKids, cACT, VAS-asthma, VAS-rhinitis, TNSS, PEF and PNIF values, Δ CARATKids, Δ cACT, Δ VAS-asthma, Δ VAS-rhinitis, Δ TNSS, Δ PEF and Δ PNIF were calculated.

Patients whose cACT scores or TNSS values changed <3 between the two visits were defined as cACT stable and TNSS stable patients respectively, whereas patients whose cACT scores or TNSS values

changed ≤ -3 or ≥ 3 between the two visits were defined as cACT unstable patients [10,11,22,23]. Patients whose both VAS-asthma and VAS-rhinitis values changed -1 , 0 or 1 between the two visits were defined as VAS stable patients, whereas patients whose either VAS-asthma or VAS-rhinitis values changed ≤ -2 or ≥ 2 between the two visits were defined as VAS unstable patients. Patients who were categorized as stable according to each of their cACT, VAS and TNSS value changes were defined as stable patients, whereas patients who were categorized as unstable according to any of their VAS, cACT or TNSS value changes were defined as unstable patients.

SPSS 22.0 was used for the statistical analyses. The level of significance was set at $p < 0.05$. Categorical variables were presented as absolute frequencies and proportions, continuous variables were presented as mean and standard deviation (SD) or median and interquartile range. Pearson or Spearman correlation tests were used according to the variables' distributions.

The internal consistency of the questionnaire was calculated by Cronbach's alpha.

Responsiveness of the questionnaire was evaluated by Guyatt's responsiveness index and within patient change values. Additionally, responsiveness was also calculated by comparing the median values of the CARATKids score change between the first and the second visits in the stable and unstable groups.

Concurrent validity was reported by evaluating the correlations between the CARATKids scores and external measures of control (cACT, TNSS, VAS-asthma, VAS-rhinitis).

Longitudinal validity of the questionnaire was evaluated by the correlation of the CARATKids score change between the first and the second visits (Δ CARATKids), and the external measures of control score changes (Δ cACT, Δ TNSS, Δ VAS-asthma, Δ VAS-rhinitis) between the first and the second visits.

A priori predictions for the correlation coefficients of concurrent and longitudinal validity were defined based in previous studies and ranged from 0.4 to 0.8.

Test-retest reliability was evaluated by intra-class correlation coefficients (ICC) of the CARATKids scores between the first and second visits in stable patients.

Discriminative properties of the CARATKids were tested by categorizing the patients into different groups based on their cACT scores, VAS-rhinitis scores, VAS-asthma scores, TNSS, GINA severity classifications and ARIA severity classifications.

The MCID for the CARATKids was established using distribution based and anchor-based methods. For the distributional method, the criterion of $1.96 \times \text{SEM}$ was used [24]. For the anchor method, we used the anchors of cACT and VAS-asthma for asthma control, and of TNSS and VAS-rhinitis for rhinitis control. Patients were categorized according to changes in these measures, and for each category, the absolute mean difference in the CARATKids score between the first and the second visits was calculated. The outcome corresponding to the minimal change was considered as the MCID. To evaluate meaningful differences in the CARATKids scores according to the anchor-based method, changes in the cACT scores from baseline, the following criteria were used: no difference (Δ cACT = $-1/0/1$), minimal difference (Δ cACT = $-3/-2/2/3$), and moderate-to-large difference (Δ cACT $< -3/>3$). For the changes in the VAS scores from baseline were used: no difference (Δ VAS = $-1/0/1$), minimal difference (Δ VAS = $-3/-2/2/3$), and moderate-to-large difference (Δ VAS $< -3/>3$). In the case of TNSS, the criteria were as follows: no change ($-2/-1/0/1/2$), and clinically relevant change ($\leq -3/\geq 3$) [10,11,25,26].

To establish the optimal cutoff score for the CARATKids to discriminate the controlled groups according to their cACT, TNSS, GINA, ARIA, VAS-asthma and VAS-rhinitis severity classifications, area under the receiver operating characteristic curve (ROC) analyses were used. Sensitivity and specificity values of the questionnaire were calculated, and cutoff points of the CARATKids were obtained.

Results

A total of 174 patients were recruited for the study. The mean age of the patients was 8.72 ± 2.15 years. About 96 of the patients (55%) were boys, and 78 (44%) of them were girls. The number of patients who were also present at the second visit was 138 (79%).

The severity distribution of the patients according to the GINA and ARIA guidelines, cACT scores, and VAS-asthma and VAS-rhinitis scores at the first and the second visits is presented in Table 1.

The median score of the patients' CARATKids scores at the first visit was 9 (4–11), and at the second visit it was 2 (2–4). There was a significant difference in the CARATKids scores between the two visits ($p < 0.001$).

The median score of the patients' CARATKids scores according to their severity classifications at the

Table 1. The severity distribution of the patients.

	First visit Number of patients(%)	Second visit Number of patients(%)
GINA		
Well controlled	57(33)	60(43)
Partially controlled	60(34)	44(32)
Uncontrolled	57(33)	34(25)
ARIA		
Mild	66(38)	81(59)
Moderate–severe	108(62)	57(41)
cACT		
Controlled	75(43)	69(50)
Uncontrolled	99(57)	69(50)
VAS–asthma		
Controlled	51(29)	63(46)
Uncontrolled	123(71)	75(54)
VAS–rhinitis		
Controlled	39(22)	63(46)
Uncontrolled	135(78)	75(54)
TNSS		
Mild	63(36)	73(53)
Moderate–severe	111(64)	65(47)

Table 2. The comparison of the median CARATKids scores between the severity classification groups at the first and the second visits.

	First visit CARATKids score Median (25%–75% ICR)	Second visit CARATKids score Median (25%–75% ICR)
GINA		
Well controlled	3(2–5)	2(2–4)
Partially controlled	8.5(8–10)	6(4–10)
Uncontrolled	11(9–13)	11(10–13)
ARIA		
Mild	3.5(2–8)	2(2–4)
Moderate–severe	10(9–11)	11(9–11)
cACT		
Controlled	4(3–8)	2(2–3)
Uncontrolled	11(9–12)	10(4–13)
VAS–asthma		
Controlled	3(2–4)	2(2–4)
Uncontrolled	10(8–11)	10(2–13)
VAS–rhinitis		
Controlled	3(2–8)	2(2–3)
Uncontrolled	9(8–11)	10(6–11)
TNSS		
Mild	3(2–9)	2(2–4)
Moderate–severe	9(3–13)	10(8–12)

Note. All p values <0.001.

first and the second visits, and group comparisons are presented in Table 2.

Correlations between the CARATKids score at the first visit and cACT, VAS–asthma, VAS–rhinitis and TNSS and the correlations between the Δ CARATKids scores and Δ cACT, Δ VAS–asthma, Δ VAS–rhinitis, Δ TNSS are presented in Table 3. The correlation coefficients between the CARATKids score at the first visit and PEF and PNIF values at the first visit were 0.156 ($p = 0.04$) and -0.123 ($p = 0.107$), respectively). The correlation coefficients between the Δ CARATKids score and Δ PEF and Δ PNIF values were -0.111 ($p = 0.196$) and -0.268 ($p = 0.02$), respectively.

The cutoff scores of CARATKids to distinguish the controlled groups according to the cACT,

Table 3. The correlations between CARATKids/ Δ CARATKids scores and other allergic rhinitis and asthma control measurement parameters.

	cACT	VAS–asthma	VAS–rhinitis	TNSS
CARATKids	$r: -0.770$ $p < 0.001$ Δ cACT	$r: -0.694$ $p < 0.001$ Δ VAS–asthma	$r: -0.422$ $p < 0.001$ Δ VAS–rhinitis	$r: 0.584$ $p < 0.001$ Δ TNSS
Δ CARATKids	$r: -0.789$ $p < 0.001$	$r: -0.582$ $p < 0.001$	$r: -0.566$ $p < 0.001$	$r: 0.631$ $p < 0.001$

VAS–asthma, VAS–rhinitis, TNSS, GINA and ARIA guidelines are presented in Figure 1. The calculated cutoff scores were ≤ 5 for GINA and ARIA, ≤ 8 for cACT, ≤ 7 for VAS–asthma, ≤ 3 for VAS–rhinitis and ≤ 4 for TNSS.

The cutoff score, sensitivity and specificity value, and positive (+LR) and negative (–LR) likelihood ratios of the CARATKids scores to distinguish the controlled group according to the GINA and ARIA guidelines were calculated. The sensitivity was 100% and the specificity was 91.11% at the most balanced cut off score of ≤ 5 from ROC curve analysis. At this cutoff score the +LR (CI) was 11.25 (6.6–19.3) and the –LR (CI) was 0. The performance of the CARATKids' Score for each scoring option at different cutoff scores in identifying controlled disease is presented in Table 4.

The distribution-based method gave MCID estimates for the CARATKids score of 3.44; therefore, the SEM was 1.75. For the mean change in CARATKids scores corresponding to a minimal change in cACT, VAS–asthma, VAS–rhinitis and TNSS were 3.97, 3.65, 3.49, 5.47, respectively, according to the anchor-based method. Overall, these results determine a MCID of 4 except for the groups analyzed according to the TNSS (Table 5).

In the internal consistency analysis, Cronbach's alpha was 0.841 (Internal consistency was good) for CARATKids. ICC coefficient was 0.973 ($n = 30$) in the stable group in the test–retest reliability analysis.

In the assessment of responsiveness the median score for the CARATKids score changes in unstable patients was 5 (2–7), whereas in the stable patients it was 1 (0–2). When the two groups were compared with each other, there was a significant difference ($p < 0.001$). The calculated Guyatt's responsiveness index was -1.88 .

Discussion

In the current study, the largest study so far investigating the psychometric properties of the CARATKids [8,10,11], we have shown the Turkish version of the CARATKids questionnaire is a valid and reliable tool

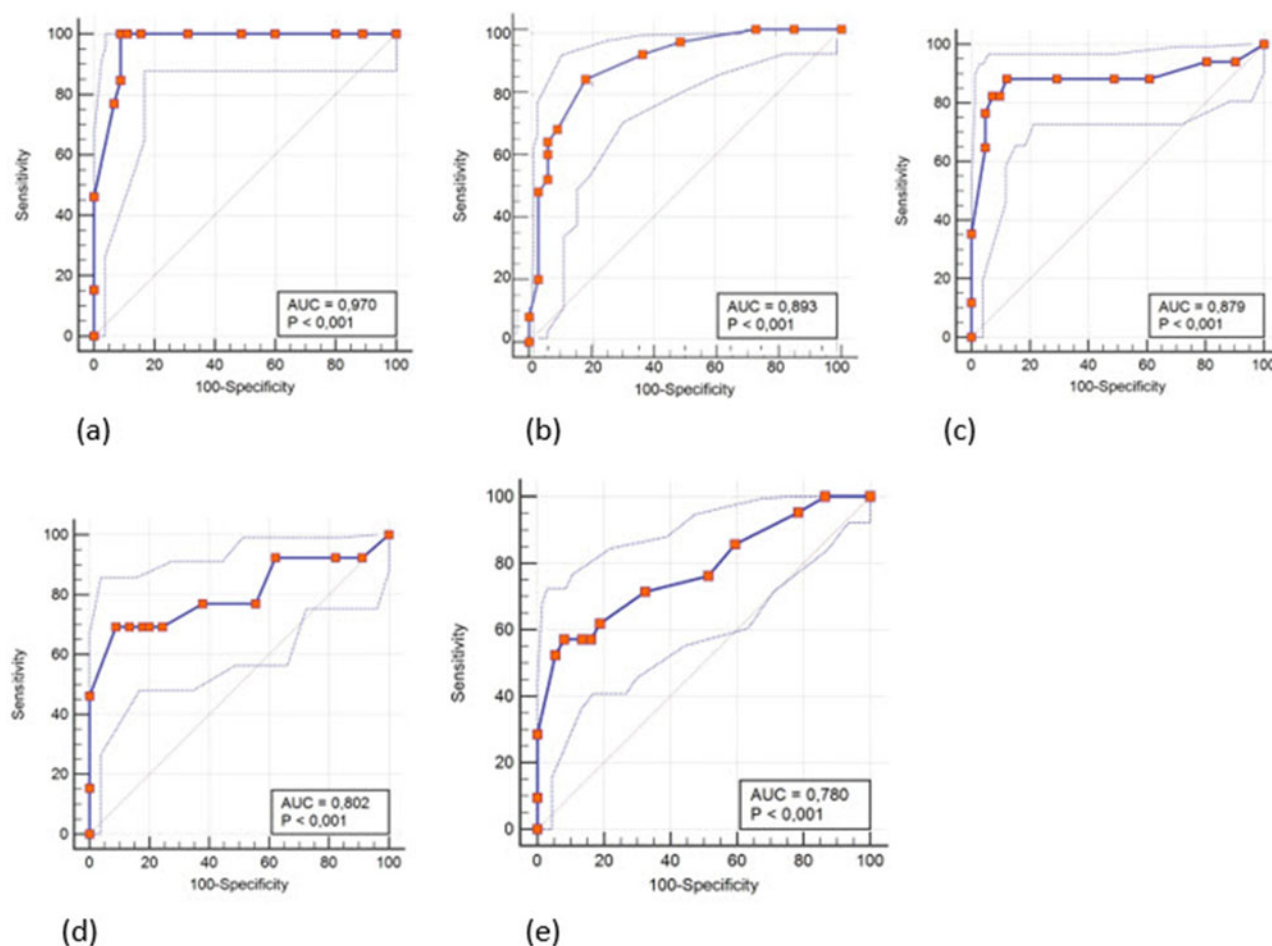


Figure 1. Area under the receiver operating characteristic curves (AUCs) of the Control of Allergic Rhinitis and Asthma Test for Children (CARATKids) for asthma/allergic rhinitis control by the GINA and ARIA controlled groups (a), the childhood Asthma Control Test (cACT) (b), by the Visual Analog Scale-asthma (VAS-asthma) (c), by the Visual Analog Scale-rhinitis (VAS-rhinitis) (d) and by the Total Nasal Symptom Score (TNSS) (e).

Table 4. The performance of the CARATKids' for each scoring option at different cutoff scores in identifying controlled disease.

	≤2	≤3	≤4	≤5	≤6	≤7	≤8
GINA and ARIA							
Sensitivity	0.46	0.76	0.84	1	1	1	1
Specificity	1	0.93	0.91	0.91	0.88	0.84	0.68
cACT							
Sensitivity	0.20	0.48	0.52	0.60	0.64	0.68	0.84
Specificity	0.96	0.96	0.93	0.93	0.93	0.90	0.81
VAS-asthma							
Sensitivity	0.35	0.64	0.76	0.82	0.82	0.88	0.88
Specificity	1	0.95	0.95	0.92	0.90	0.87	0.70
VAS-rhinitis							
Sensitivity	0.46	0.69	0.69	0.69	0.69	0.69	0.76
Specificity	1	0.91	0.86	0.80	0.75	0.75	0.62
TNSS							
Sensitivity	0.28	0.52	0.57	0.57	0.57	0.61	0.71
Specificity	1	0.94	0.91	0.86	0.83	0.81	0.67

Table 5. Minimal clinically important difference (MCID) of CARATKids.

	Absolute Δ CARATKids score mean (SD)
Δ cACT	
No change (−1/0/1)	1.87 (2.18)
Minimal change (−3/−2/2/3)	3.97 (4.21)
Moderate/large change ($\leq -4/\geq 4$)	5.76 (3.07)
Δ VAS-asthma	
No change (−1/0/1)	2.65 (2.59)
Minimal change (−3/−2/2/3)	3.65 (4.89)
Moderate/large change ($< -3/>3$)	6.16 (2.93)
Δ VAS-rhinitis	
No change (−1/0/1)	2.25 (4.04)
Minimal change (−3/−2/2/3)	3.50 (2.56)
Moderate/large change ($< -3/>3$)	5.92 (2.93)
Δ TNSS	
No change (−2/−1/0/1/2)	2.62 (3.58)
Clinical relevant change ($\leq -3/\geq 3$)	5.47 (2.69)

to assess the control of asthma and allergic rhinitis in children aged 6–12 years.

The internal consistency of the CARATKids was good and higher than the previously reported for the

Portuguese, Dutch and Brazilian versions as well as higher than internal consistencies of other questionnaires used for the similar purpose, for example, cACT, CAN and TRACK [3,4,27].

In the concurrent validity analyses, the correlation coefficients between the CARATKids scores and the cACT, VAS (asthma/rhinitis) and TNSS values were in line with the previous studies (0.42–0.77). Whereas the correlation coefficients of the longitudinal validity between the Δ CARATKids scores and the Δ cACT, Δ VAS (asthma/rhinitis) and Δ TNSS values were higher (0.56–0.78) than previously reported values in the longitudinal validity analyses [8,10,11].

PEF and PNIF values had low correlation coefficients the CARATKids scores, which was in line with the expectations and also with the results of the only other study by Amaral et al. [11]. The weak associations are expected as these physiologic parameters measure large airways obstruction and nasal obstruction, respectively, not disease control.

The current study also revealed that the discriminative properties of the CARATKids questionnaire were robust. Groups classified as controlled, partially controlled or uncontrolled according to cACT, TNSS, VAS (asthma/rhinitis) values and GINA and ARIA guidelines could be distinguished from each other by the CARATKids scores, where the groups with lower CARATKids scores corresponded to better controlled asthma and allergic rhinitis.

There may be different ways to define the best cutoff scores. In some studies the best values for sensitivity and specificity are emphasized, whereas in others the most balanced value may be reported. Furthermore, clinicians are used to a yes/no decision in diagnostic tests and having two cutoff values creates a “grey area” between the two scores that may be difficult to use in routine care. Therefore we have provided in Table 5 the two-level cutoff scores, and we also presented the most balanced cutoff scores according to both the GINA and ARIA guidelines. This will enable the clinicians to choose whichever cutoff score they prefer to use. When the cutoff scores of the CARATKids to distinguish the controlled groups according to the cACT, TNSS and VAS scores were evaluated separately, our results demonstrated that the optimal threshold for identifying controlled disease was a score of 2 or less, and a score of 8 or greater for identifying uncontrolled disease. These scores provided fewer false-negative results to maximize sensitivity, and false-positives result to maximize specificity, respectively. In addition to previous reports, in the current study, cutoff scores of the CARATKids were calculated to distinguish the controlled groups according to both the GINA and ARIA guidelines, and the results showed that the CARATKids had a sensitivity value of 100% and a

specificity value of 91.11% at the most balanced cutoff score of ≤ 5 . This result has demonstrated that all patients who score 5 or less on the CARATKids would be in the controlled group. Since the CARATKids was developed to assess the control of both asthma and allergic rhinitis, determining a cutoff score for both conditions was essential.

The MCID value was calculated by both the anchor based, and distribution based methods, and unlike some of the previous CARATKids studies in which the MCID value was 3 [10], in the current study's the MCID was 4. In the current study, the number of participants was higher than the previous studies as was the mean change in CARATkids score between visits. Further, in one of those studies, the participants' age range was 6–18. These may be the reasons why this one-point difference in the MCID occurred.

In the test-retest reliability analysis, the current study's ICC value was higher than the other CARATKids validation studies [8,11], and also higher than the values obtained from other validated tools to assess asthma control in children, such as the cACT(3) and the ACQ [28].

We calculated the GRI results of the patients who were stable according to each of the scores on the cACT, TNSS and VAS–asthma and VAS–rhinitis, that is, who were classified as stable. All the remaining patients were classified as unstable. Therefore, the results of the GRI of the current study might be more reliable than previous studies since in these studies the patients were classified as stable according to any one of these measures of control. We observed a large responsiveness, and the GRI was similar to the original CARATKids study [8].

The strengths of the current study are (i) more participants than previous CARATKids studies were recruited for this study, (ii) participants were not categorized as unstable only by evaluating the parameters for either asthma or rhinitis control, but for both asthma and rhinitis control, which enabled for a more precise assessment of the CARATKids. Since the data were collected from a single center, the results may not be completely generalized to the general population, and this is the main limitation of the study.

Conclusions

In conclusion, the CARATKids is a valid and reliable questionnaire to assess the external measures of control in asthma and allergic rhinitis in Turkish children aged 6–12 years. With the possibility of application of this questionnaire in Turkish children the monitoring

of these frequently comorbid conditions will be more practical and may help to improve the children's outcomes.

Disclosure statement

No potential conflict of interest was reported by the authors.

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