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Validation of the Turkish version of “Test for Respiratory and Asthma Control in Kids (TRACK)” questionnaire

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Abstract

Background: Test for Respiratory and Asthma Control in Kids (TRACK) questionnaire is the first to measure both the risk and impairment domains of the current guidelines in preschool children. We aimed to measure the reliability, validity and responsiveness of the Turkish version of the TRACK. **Methods:** A total of 268 children (69.8% boys) were included in the study. Caregivers responded to three individual TRACK questionnaires, at each clinical visit (baseline, 1st month, and 3rd month). At each visit, physicians determined the control level and the treatment strategy based on the GINA guideline recommendations. **Results:** The internal consistency reliability of the Turkish version of the TRACK questionnaire was found to be 0.74, 0.74, and 0.76 at each of the three visits, respectively (reliability statistics, Cronbach's alpha). There was a significant difference between the mean TRACK scores of the patients in different asthma control status categories ($p < 0.001$). The test-retest reliability in stable patients was 0.90. The optimal cut-off scores according to the Youden index were 80 and 60 points for uncontrolled and very poorly controlled children, respectively. **Conclusion:** The Turkish version of the TRACK is an accurate and reliable tool for evaluating asthma control status among preschool Turkish children. Its widespread use may help physicians correctly assess control levels among children and may improve the quality of life for both patients and their caregivers.

Keywords

Asthma, children, questionnaire, reliability, responsiveness, Test for Respiratory and Asthma Control in Kids, validity

History

Received 1 May 2013

Revised 11 August 2013

Accepted 19 August 2013

Published online 2 September 2013

Introduction

Asthma remains the most common chronic disease in children. In particular, preschool children constitute a high-risk group for morbidity and mortality [1]. Despite recent advances in therapeutic treatment and our understanding of the pathophysiologic mechanisms in the disease, the prevalence of asthma continues to increase resulting in a higher health burden [2,3]. Hence, recent guidelines have emphasized the important role of achieving asthma control, including regular patient assessments and lung function screenings [4,5]. Since spirometry hinges on some independent factors (e.g. familiarity with techniques, adequate personnel training and age-related factors), it is not always an option in daily practice. Nevertheless, several control instruments have been developed for determining asthma control [6–9]. Unfortunately, these control tools were designed mostly for the adult population and school-aged children.

Owing to the unfeasibility of spirometry and the paucity of control tools, assessing asthma control in preschool children is challenging [4]. To fulfill this need, Murphy et al. [10]

developed a new instrument, based on the asthma control criteria of the National Asthma Education and Prevention Program (NAEPP) guideline [4], for children under the age of five who have been diagnosed with asthma or respiratory problems consistent with asthma. This caregiver-reported questionnaire, the “Test for Respiratory and Asthma Control in Kids (TRACK)”, includes four items across the impairment domain and an additional item for the risk domain. This simple and easy-to-use survey may aid decision-making by physicians thereby enabling them to identify controlled and uncontrolled patients. However, the questionnaire has not been previously validated in a language other than English.

In this study, we aimed to establish the reliability, validity and responsiveness of the TRACK when applied to Turkish children in addition to testing its clinical application in a foreign language.

Methods**Study design and population**

The study was conducted in the Pediatric Allergy and Asthma Department of Hacettepe University between January 2011 and January 2012. Children under five years of age were eligible: (1) if they had a history of two or more episodes of wheezing, shortness of breath, or coughing (that lasted more than 24 h) and (2) either a diagnosis of asthma or relief of

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respiratory symptoms with bronchodilator treatment. Children who had respiratory diseases other than asthma or chronic diseases were excluded (Figure 1). The study was approved by the local ethics committee of Hacettepe University. Written informed consent was obtained from each caregiver.

The study was designed and financed by the corresponding author and conducted by the authors. No funding was received from any company. Since the questionnaire is copyrighted by Astra Zeneca LP, written permission was received from the company before commencing the present study.

At baseline, data including demographic and clinical characteristics were recorded. Subsequent follow-up visits were scheduled for one month and three months. Caregivers completed the Turkish version of the TRACK survey at each visit. Each caregiver was also asked to rate the disease control status of their child on a scale of 1 to 5 (1 = completely controlled, 2 = well controlled, 3 = somewhat controlled, 4 = poorly controlled, 5 = not controlled at all) at the baseline visit. At follow-up visits, caregivers rated the change in disease control status on a Likert scale of 1 to 5 (1 = a lot better now, 2 = a little better now, 3 = about the same, 4 = a little worse now, 5 = a lot worse now). Physicians were blinded to the caregiver responses at all visits. At all visits, the physicians assessed each patient's asthma control level as controlled, partially controlled, or poorly controlled, based on the Global Strategy for Asthma Management and Prevention (GINA) guideline recommendations [5]. In addition, physicians determined treatment (step-up therapy, no change in therapy, or step-down therapy) according to the guideline criteria.

The Turkish version of the TRACK

The TRACK questionnaire (Supplementary material) was developed to evaluate respiratory symptoms of children

younger than five years old. The present questionnaire with only 5 items is the short version of a previous 33-item questionnaire and these 5 items were obtained through a stepwise regression used to select the items with the greatest discriminant validity in relation to guidelines-defined asthma control [10]. The items, with each item scored on a five point scale provide information about symptom frequency, night-time awakenings, and activity limitation frequency due to respiratory symptoms in the last four weeks. The frequency of required bronchodilator drug use in the last three months and the frequency of oral corticosteroid use in the past year were also considered. The sum of these items provides the total score, which ranges from 0 to 100. The higher scores indicate better disease control, whereas a score of less than 80 suggests potential respiratory problems [10].

The English language version of the TRACK questionnaire was translated into Turkish language in four steps: (1) Forward translation was performed by two independent, native Turkish speakers both of whom were fluent in English. (2) Reconciliation of the forward translations into one preliminary translation was developed by two independent pediatricians both fluent in English and Turkish. (3) Backward translation of the reconciled version into English was performed by two independent translators and an independent supervisor compared the text with the original questionnaire for conceptual equivalence. (4) Cognitive debriefing was conducted in 20 patients' caregivers representing the study population. Any uncertainties were discussed with the physicians by face-to-face interviews. All stages were completed in cooperation with the survey's copyright owner.

Reliability

The Cronbach's alpha (α) value was estimated from the TRACK survey responses to determine internal consistency at baseline and follow-up visits. The test-retest reliability was determined using the intra-class correlation (ICC) and by evaluating a subgroup of patients whose asthma control levels remained stable.

Validity

Construct validity was analyzed using factor analysis and the known groups validity method that compared mean TRACK scores among the patients who were categorized according to physician's assessment of disease control and treatment decision at baseline. Since the homogeneity of variances assumption was not satisfied, the Welch ANOVA test for known groups validity and the Tamhane test for post-hoc analysis were used to test for significant differences between the mean TRACK scores of the different disease control and treatment decision groups.

Responsiveness

The mean changes in TRACK scores among the patients who differed by level of change in the physician's and caregiver's evaluation of disease control status from baseline to the follow-up visits were compared by ANOVA test. The patients were categorized into three groups: improving, no change or worsening.

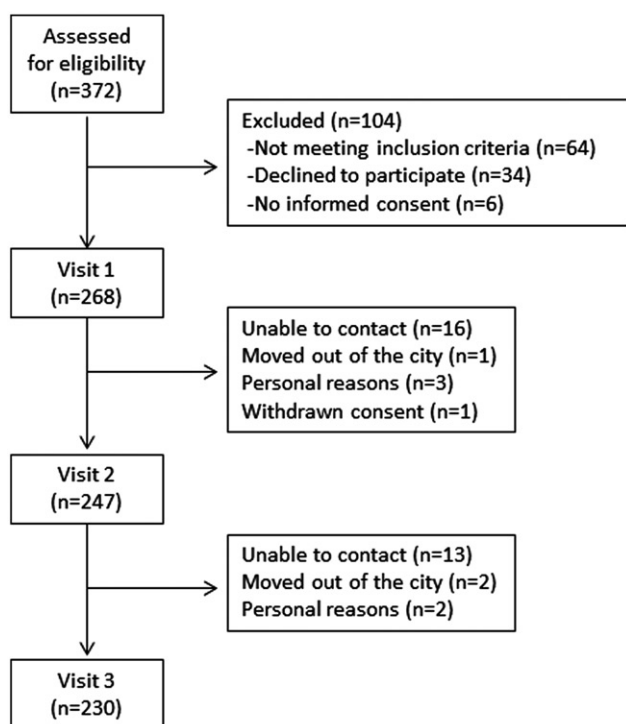


Figure 1. Study population. A total of 372 patients and their caregivers assessed for eligibility and 104 patients were excluded.

Screening accuracy

The accuracy of TRACK for screening patients was evaluated using receiver operating characteristic (ROC) curve analyses at baseline. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy were analyzed at various cut-off points to determine the validity of the TRACK survey in screening “controlled” patients. Physician assessment of disease control was the criterion measure. All assessments were categorized as “controlled” versus “partially or poorly controlled”. The optimal cut-off point was determined according to the Youden index. Similarly, analyses were then performed to screen “poorly controlled” patients. This time, the physicians’ assessments of disease control were categorized as “controlled or partially controlled” versus “poorly controlled”.

Results

Study population

A total of 268 children (69.8% boys) with a mean age of 2.44 ± 0.66 years were included in the study. Two hundred and forty-seven children and caregivers participated in the 2nd visit and 230 children and caregivers participated in all three visits. The demographic characteristics of the patients at baseline are presented in Table 1. Thirty-nine percent of the children were under two years old. Most caregivers (69%) were aged between 25 and 34 years. Sixty percent of the children were reported as having a completely- and well-controlled disease status by their caregivers.

Reliability

The internal consistency reliability of the Turkish version of the TRACK was found to be 0.74 at baseline, and 0.74 and 0.76 at the second (1st month) and third (3rd month) follow-up visits, respectively (reliability statistics, Cronbach’s alpha). If item 5 (OCS use in the past 12 months) was removed, the internal consistency reliability increased to 0.77, 0.82, and 0.82 at baseline, and 2nd and 3rd follow-up visits, respectively. The ICC for test-retest reliability was 0.90 for cases whose disease control status remained stable over the 1st and 2nd visits.

Construct validity

The results revealed that all items load on the same factor, i.e., that the factorial analysis confirmed only 1 factor. The factor loads of each TRACK question ranged between 0.462 and 0.815 (Table 2).

Discriminant validity

All three groups (categorized using a physicians’ guidelines-based control table as controlled, partially controlled, or poorly controlled) were differentiated by their TRACK scores at baseline and at each individual follow-up visits (Table 3). As expected, the mean TRACK scores were highest among patients categorized as controlled at baseline, at the 2nd visit, and 3rd visit ($F=412.5$, $p<0.001$; $F=284.79$, $p<0.001$; and $F=212.45$, $p<0.001$, respectively). Similarly, patients with poorly controlled disease had the lowest mean TRACK scores at all visits. Discriminant validity analyses of the recommended treatment changes demonstrated that physician

Table 1. Characteristics of patients at baseline.

	Study group ($n = 268$)
Gender n , M/F ($M\%$)	187/81 (69.8)
Age ^a	2.44 ± 0.66
Age groups	
0–2 years (%)	105 (39.2)
3–4 years (%)	163 (60.8)
Total IgE kU/L ^a	76.2 ± 7.8
Eosinophil % ^a	3.68 ± 0.33
Aeroallergen sensitization (%)	9.3
Family atopy (%)	19.1
Atopic dermatitis (%)	10.1
Breastfeeding ^a (months)	14.25 ± 0.48
Caregiver age, n (%)	
18–24 years	41 (15.3)
25–35 years	185 (69.0)
35–44 years	42 (15.7)
≥ 45 years	0
Caregiver education, n (%)	
High school not completed	115 (42.9)
High school graduate	93 (34.7)
Undergraduate or graduate degree	60 (22.4)
Caregiver disease control rating, n (%)	
Completely controlled	119 (44.4)
Well-controlled	44 (16.4)
Somewhat controlled	34 (12.7)
Poorly controlled	29 (10.8)
Not controlled at all	42 (15.7)

^aMean $\pm$ standard error of the mean (SEM).

Table 2. Loadings of the TRACK.

Items	Item loadings
1	0.766
2	0.815
3	0.757
4	0.725
5	0.462

Eigenvalue: 2.561, % of variance explained: 51.22

recommendations to step-up therapy were received by children with the lowest mean TRACK scores at baseline and the follow-up visits ($p<0.001$) (Table 3).

Screening accuracy

The screening accuracy of the TRACK scores at different cut-off points is presented in Table 4. Higher cut-off points revealed higher sensitivity along with lower specificity, whereas lower cut-off points yielded lower sensitivity and higher specificity. To differentiate “controlled” patients from “partially or poorly controlled” patients, the optimal cut-off point, according to the Youden index, was a score of 80 (sensitivity 94.4% and specificity 95.4%). In addition, we also identified a cut-off value of 60 for differentiating between “poorly controlled” and “partially controlled or controlled” patients (sensitivity 90.3% and specificity 84.0%, respectively).

Responsiveness

Based on caregiver- and physician-determined patient disease control statuses from baseline to follow-up visits, mean patient score changes were evaluated to determine the

Table 3. Assessment of the discriminant validity of the TRACK questionnaire.

	Physicians' ratings of disease control			Statistical test F, <i>p</i> Value
	Controlled	Partially controlled	Poorly controlled	
Baseline TRACK score ^a	<i>n</i> = 104 89.07 (7.94)	<i>n</i> = 100 62.60 (14.36)	<i>n</i> = 64 40.0 (13.27)	12.5, <0.001
2nd visit TRACK score ^a	<i>n</i> = 149 87.34 (9.03)	<i>n</i> = 77 60.64 (14.56)	<i>n</i> = 21 33.33 (11.54)	284.79, <0.001
3rd visit TRACK score ^a	<i>n</i> = 147 87.14 (12.88)	<i>n</i> = 59 61.86 (13.64)	<i>n</i> = 24 33.33 (13.56)	212.45, <0.001
	Recommended change in therapy			Statistical test F, <i>p</i> Value
	Step-down therapy	No change in therapy	Step-up therapy	
Baseline TRACK score ^a	<i>n</i> = 28 86.43 (13.04)	<i>n</i> = 119 81.18 (15.29)	<i>n</i> = 121 50.87 (18.04)	120.24, <0.001
2nd visit TRACK score ^a	<i>n</i> = 37 86.48 (14.28)	<i>n</i> = 182 76.38 (18.67)	<i>n</i> = 28 47.32 (16.63)	50.62, <0.001
3rd visit TRACK score ^a	<i>n</i> = 54 87.31 (11.96)	<i>n</i> = 142 77.36 (19.58)	<i>n</i> = 34 47.05 (21.91)	49.19, <0.001

^aMean (SD).

Table 4. Screening accuracy of the TRACK scores at different cut-off points.

Cut-off scores	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	False-positive rate (%)	Accuracy (%)
Controlled						
90	98.1	59.3	78.1	95.5	21.9	82.5
85	95.0	77.8	86.4	91.3	13.6	88.0
80	94.4	95.4	96.8	92.0	3.2	94.7
75	85.6	97.2	97.9	82.0	2.1	90.2
70	75.6	99.1	99.2	73.3	0.8	85.0
65	64.4	99.1	99.0	65.2	1	78.3
60	55.6	100	100	60.3	0	73.5
Poorly-controlled						
75	100	62.1	44.3	100	55.7	70.8
70	98.4	70.4	50.0	99.3	50.0	76.8
65	95.2	78.2	56.7	98.2	43.3	82.0
60	90.3	84.0	62.9	96.6	37.1	85.4
55	83.9	89.8	71.2	94.9	28.8	88.4
50	69.0	94.7	79.6	91.1	20.4	88.8

Table 5. Responsiveness of the TRACK scores in relation to the change in physician asthma control ratings at visits 2 and 3.

	Better	Same	Worse	<i>F</i> , <i>p</i> Value
(a) Change in physician control ratings from baseline (visit 2)				
Change in TRACK scores, <i>N</i> = 104	<i>N</i> = 101	<i>N</i> = 42		
26.4 (18.1)	1.0 (11.2)	-29.9 (18.7)	151.1, <0.001	
mean (SD)				
(b) Change in physician control ratings from baseline (visit 3)				
Change in TRACK scores, <i>N</i> = 100	<i>N</i> = 90	<i>N</i> = 40		
29.1 (22.1)	-1.9 (13.6)	-25.1 (18.2)	122.5, <0.001	
mean (SD)				

Table 6. Responsiveness of the TRACK scores in relation to the change in caregivers' asthma control reports at visits 2 and 3.

	Better	Same	Worse	<i>F</i> , <i>p</i> Value
(a) Change in caregivers' reports from baseline (visit 2)				
Change in TRACK scores, <i>N</i> = 105	<i>N</i> = 84	<i>N</i> = 58		
18.7 (21.9)	4.0 (21.9)	-12.6 (25.3)	37.2, <0.001	
mean (SD)				
(b) Change in caregivers' reports from baseline (visit 3)				
Change in TRACK scores, <i>N</i> = 97	<i>N</i> = 83	<i>N</i> = 50		
21.8 (24.6)	-4.6 (22.0)	-12.5 (24.1)	36.1, <0.001	
mean (SD)				

responsiveness of the TRACK questionnaire (Tables 5 and 6). At the 2nd and 3rd visits, the mean TRACK score changes were significantly different between the groups (both $p < 0.001$). TRACK scores increased in parallel with improved physician disease control ratings.

Discussion

In this study, the Turkish version of the TRACK survey was found to be reliable and valid at evaluating asthma control in children younger than five years old in clinical settings.

This is the first study confirming the value of the TRACK questionnaire in a foreign language. Responsiveness to changes in disease control over time is also demonstrated and enhances the utility of the questionnaire.

Use of a simple questionnaire might help implement asthma control parameters among physicians and reduce morbidity and health-care expenditures [11]. Most of the currently available questionnaires cannot be feasibly used with children under five years old [6–8]. In addition, all of the questionnaires assess the frequency of respiratory symptoms

and relief medication use. Recently, Murphy et al. [10] developed a tool for evaluating children under five to satisfy this need. The new questionnaire assesses not only the NAEPP guideline defined impairment domain but also the risk domain. As loss of lung function can develop in the first years of life [12], it is crucial to identify children with high risk. Given the lack of objective parameters to evaluate this age group [13], the questionnaire has significant potential to benefit international clinical practice. However, the validity of the questionnaire must be confirmed for different cultures.

The validity, reliability and change response results of our study support those of the original validation study of the TRACK questionnaire [10,14]. The ICC was higher than the recommended standard of 0.8, denoting good test-retest reliability [15]. The unidimensional structure of the questionnaire which was found by factor analysis confirmed the construct validity. Known-groups method analyses showed that the survey differentiated between patients with different levels of disease symptom severity. As expected, patients with “controlled” asthma (defined based on the physicians’ rating scale) had higher TRACK scores than those with “uncontrolled” asthma. In addition, children whose disease control improved had increased TRACK scores, whereas children whose control worsened had decreased scores.

ROC curve analysis revealed that a score of 80 was the ideal cut-off score for Turkish children, which best balanced the sensitivity and specificity for discriminating between controlled and uncontrolled patients. The cut-off value used in our study was exactly the same as the development study [10]. Patients with scores below 80 should be evaluated attentively for factors that might be influencing asthma control such as triggers, treatment adherence and comorbidities. To date, four questionnaires have defined cut-off values used to categorize controlled and uncontrolled patients [6–8,16]. However, only two have established cut-off values for differentiating poorly controlled patients [6,17]. As an innovative contribution, this study also determined a cut-off value of 60 for identifying poorly controlled patients – a cut-off point which was not investigated in the development study.

The benefits of including the question related to oral corticosteroid use are arguable since the item refers to a 12-month period. Considering that young children experience more asthma exacerbations [18] and recent exacerbations may be an indicator of ensuing ones [19], including the oral corticosteroid item may provide an advantage.

The use of such an easily applicable tool provides benefits in gauging treatment efficacy, facilitating dialogue between physicians and parents, and enhancing collaboration with parents in the disease management process [17]. Having caregivers complete the TRACK questionnaire before the visit will save physicians time by immediately providing them with information about control status. Additionally, the questionnaire will also provide an opportunity for clinics to operationalize the guideline recommendations. The questionnaire does not precisely assess asthma control per se, but should be considered a complimentary tool for physicians to use in evaluating patient disease status and treatment options.

We enrolled 268 children in the study, but 21 and 38 children missed the 2nd and 3rd visits, respectively.

Such a 3-step prospective analysis should be accepted as a reliable study, although there is a 14% attrition in the study population (Figure 1).

In conclusion, the Turkish version of the TRACK questionnaire was found to be reliable, valid and responsive in assessing respiratory symptoms and asthma control in children younger than five years old. TRACK scores may facilitate daily clinical practice and enhance awareness among both physicians and caregivers of disease control. In addition, extended use of this survey may be helpful in standardizing patient management and follow-up.

Authors’ contributions

SBE had primary responsibility for protocol development, outcome assessment and data analysis, and prepared the article with BB.

BB participated in the development of the protocol and the analytic framework for the study, performed statistical analyses, prepared the article, and had primary responsibility for patient screening.

SUM, YST, CO, YEA, SOU and TA supervised the design and execution of the study, contributed to the preparation of the article, and helped with patient screening.

Declaration of interest

The authors report no conflicts of interest.

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TRACKTM Test for Respiratory and Asthma Control in Kids

Score

1. During the past 4 weeks, how often was your child bothered by breathing problems, such as wheezing, coughing, or shortness of breath?

Not at all	Once or twice	Once every week	2 or 3 times a week	4 or more times a week
☐ 20	☐ 15	☐ 10	☐ 5	☐ 0

2. During the past 4 weeks, how often did your child's breathing problems (wheezing, coughing, shortness of breath) wake him or her up at night?

Not at all	Once or twice	Once every week	2 or 3 times a week	4 or more times a week
☐ 20	☐ 15	☐ 10	☐ 5	☐ 0

3. During the past 4 weeks, to what extent did your child's breathing problems, such as wheezing, coughing, or shortness of breath, interfere with his or her ability to play, go to school, or engage in usual activities that a child should be doing at his or her age?

Not at all	Slightly	Moderately	Quite a lot	Extremely
☐ 20	☐ 15	☐ 10	☐ 5	☐ 0

4. During the past 3 months, how often did you need to treat your child's breathing problems (wheezing, coughing, shortness of breath) with quick-relief medications (albuterol, Ventolin®, Proventil®, Maxair®, Proair®, Xopenex®, or Primatene® Mist)?

Not at all	Once or twice	Once every week	2 or 3 times a week	4 or more times a week
☐ 20	☐ 15	☐ 10	☐ 5	☐ 0

5. During the past 12 months, how often did your child need to take oral corticosteroids (prednisone, prednisolone, Orapred®, Prelone®, or Decadron®) for breathing problems not controlled by other medications?

Never	Once	Twice	3 times	4 or more times
☐ 20	☐ 15	☐ 10	☐ 5	☐ 0

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