

ADHERENCE AND ASTHMA CONTROL

TRACK as a complementary tool to GINA and NAEPP guidelines for assessing asthma control in pre-school children

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Abstract

Background: In this study, our goal is to evaluate the consistency between TRACK and the asthma control levels assessed according to the GINA and NAEPP guidelines in children younger than 5 years of age. **Methods:** Patients under 5 years old, who were followed up for recurrent wheezing for at least 1 year have been included. Parents were given the TRACK questionnaire and the control level of asthma according to GINA and NAEPP guidelines were determined by a pediatric allergist blinded to TRACK scores. Patients were classified into two groups regarding the compatibility of the control level between TRACK and both GINA and NAEPP guidelines. **Results:** A total of 365 questionnaires were evaluated. The TRACK cut-off point of 80 provided the most consistent balance between sensitivity and specificity for the compatibility with both GINA and NAEPP (for GINA 0.763 and 0.663, kappa = 0.487, $p < 0.001$ and for NAEPP 0.761 and 0.769, kappa = 0.524, $p < 0.001$, respectively). When 80 was taken as the cut-off value for TRACK, the compatibility rate of asthma control levels between TRACK and GINA and TRACK and NAEPP was 71.0 and 76.4%, respectively. About 70.1% of the patients who had TRACK scores over 80 and had mild asthma were grouped as controlled according to GINA and 50.0% of patients who had TRACK scores over 80 and had moderate to severe asthma was grouped as uncontrolled according to GINA ($p = 0.019$). **Conclusion:** TRACK is compatible with NAEPP and GINA in majority of asthmatic children under 5 years of age. Nevertheless, there is a discrepancy between guidelines and TRACK scores; therefore, it should be used in conjunction with a detailed clinical examination in order to make a better decision for assessing the control levels and management plan.

Keywords

Asthma control, GINA, NAEPP, pre-school children, TRACK

History

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Introduction

Asthma is one of the leading chronic diseases in childhood and appears to be increasing, causing a considerable morbidity [1]. Asthmatic children whose disease is not controlled have high rates of asthmatic exacerbations and hospitalization, thus the disease has a considerable social and economic burden [2,3]. Asthma is not curable but it is treatable and the best way to reduce the burden of the disease is to control it.

Achieving and maintaining a certain level of asthma control is fundamental to asthma management; international guidelines including the Global Initiative for Asthma and the National Asthma Education and Prevention Program have been widely used to assess the control level of asthma [1,4]. The establishment of a control-centered approach in asthma treatment has led to a more practical evaluation of disease

activity and therapy [1,4]. This has been important considering that due to the high prevalence of the disease, it is not only asthma specialists and pediatricians who care for patients suffering from the disease, but also general practitioners. However, determining the level of control is challenging, particularly in young children. They cannot perform the required lung function tests and respiratory symptoms external to asthma are often frequent in this age group [1,4].

A simple, applicable, accessible but validated tool to assess the level of asthma control is needed in preschool aged children [5]. Several validated tools have been created to determine the asthma control status of this age group [6–9] including the Asthma Control Test (ACT) for adults and children older than 12 years old, and the Childhood Asthma Control Test (C-ACT) for children between 4–11 years of age. These previously validated tools, however, were not specific to pre-school-aged children [10]. Test for Respiratory and Asthma Control in Kids (TRACK) has been created to fill this gap and is a validated test to assess the level of asthma control in young children with recurrent wheezing or respiratory symptoms consistent with asthma [5,10,11]. TRACK is a

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five-item questionnaire scored from 0 to 20 for a total score of 0 to 100 to be completed by caregiver or parent and based on the impairment and risk domains of the NAEPP guidelines [4,11].

In this study, we aimed to evaluate the consistency between TRACK and the asthma control levels assessed according to the GINA and NAEPP guidelines in children younger than 5 years of age.

Methods

Study design and population

Those patients under 5 years old, who followed up for at least 1 year at our Pediatric Allergy Clinic were included in the study. All participants had a history of wheezing, shortness of breath or cough attacks exceeding 24 h at least twice or featured an asthma diagnosis or improvement in respiratory symptoms with bronchodilators. Patients who had any other chronic pulmonary or systemic diseases were excluded. Parents were given the TRACK questionnaire before physical examination. At the first visit patients' control level of asthma according to GINA and NAEPP guidelines were determined by a pediatric allergist who was blinded to the TRACK scores. The severity of asthma at their first admission was defined according to GINA guideline and included retrospectively from outpatient clinic records. Further, symptoms at admission, family history of atopy, parental education levels, peripheral eosinophil counts, epidermal prick test (EPT) results and previous treatments were recorded.

For patients older than 2 years old, EPTs were carried out on the volar aspect of the forearm with common airborne allergens, including animal dander, house dust mite, mixed grass and mixed tree pollens and molds. For children under 2 years, EPTs were carried out on the back with animal dander, house dust mite and molds and also with foods including milk, egg, wheat, soy, walnut, hazelnut and peanut. The test was considered as positive if the wheal was at least 3 mm larger than the negative control.

TRACK questionnaire

TRACK has been developed and validated in a cross-sectional [11] and longitudinal cohort [5]. In our study, we used the Turkish version of TRACK validated by Büyüktiryaki et al. [12]. The TRACK questionnaire consists of five questions, the first three of which are answered according to the last 4 weeks, fourth according to last 3 months and fifth according to last 12 months. TRACK questions include: (1) symptom frequency (wheezing, coughing and shortness of breath) (2) frequency of night awakenings due to symptoms (3) frequency of interference of symptoms with the child's activities (4) frequency of use of rescue medication in the last three months and (5) systemic corticosteroid use over the past year. Each answer is scored from 0 to 20 points on a 5 point Likert-type scale for a total score ranging from 0 to 100 [10]. Higher scores indicate better respiratory and asthma control; a score of less than 80 points suggests that a child's breathing problems might not be controlled [11].

Assessment of asthma control status (level) based on GINA and NAEPP guidelines

Patients' asthma control status was determined according to GINA and NAEPP guidelines by a pediatric allergist who was blinded to TRACK scores. The asthma control level was assessed by five specific items including the frequency of the daytime symptoms, nocturnal symptoms, use of rescue bronchodilators, degree of limitation in daily activities and exacerbations for both guidelines. According to the GINA criteria, patients are grouped as controlled, partly controlled and uncontrolled and according to NAEPP; they are grouped as well controlled, not well controlled and very poorly controlled [1,4].

The main difference between the two methods is that in case of any night-time symptom in last month and/or any exacerbation in the preceding year, that patient was not accepted as controlled according to GINA. However, the NAEPP defines patients as controlled if there is up to one occurrence of a night-time symptom in a month and/or one exacerbation in a year.

In order to obtain a binary split of the patients regarding the control level, patients with partly controlled and uncontrolled asthma according to GINA and patients with not well controlled and very poorly controlled asthma according to NAEPP are labeled as simply as *not controlled*. Patients with controlled asthma according to GINA and well controlled asthma according to NAEPP are labeled as *totally controlled* in our study.

Changes in treatment were decided by the pediatric allergist who was blinded to TRACK scores. Patients were grouped according to their treatment status as "step-up, step down and maintained". TRACK results of these groups were compared.

Grouping the patients as "compatible" and "not-compatible"

According to results of Murphy et al. [11], patients who had TRACK scores over 80 were accepted as *totally controlled*, whereas patients who had scores under 80 were accepted as *not controlled*. Patients were classified into two groups regarding the compatibility of control level both between TRACK and GINA and between TRACK and NAEPP. The patients having the same control levels in the two methods are defined as the "compatible" group, while the patients who have different control levels in the two methods are defined as the "not-compatible" group.

Ethical issues

The study was approved by Institutional Review Board. A written informed consent was obtained from the parents of all children.

Statistical analysis

Results were expressed as absolute numbers (percentile), mean and standard deviation (SD) or median and interquartile range. We made a ROC analysis in order to define the cut-off TRACK score level which had the highest sensitivity and specificity in total for the compatibility between GINA and

TRACK, and between NAEPP and TRACK. Subsequently, different TRACK cut-off levels were used to find the highest compatibility between the two tools. In order to compare different variables, Student *t*-test, Kruskal–Wallis tests, Mann–Whitney *U* test and Chi-square tests were used with the help of SPSS version 15.0 (SPSS Inc., Chicago, IL). The rate of consistency of the two methods was evaluated by

Table 1. General characteristics of patients (*n* = 365).

Variable	<i>n</i> (%)
Male	253 (69.3)
Age in months (mean ± SD)	40.5 ± 10.9
Age at first wheezing episode, months (mean ± SD)	9.4 ± 7.7
Follow-up period in months (mean ± SD)	31.1 ± 10.9
Asthma severity	
Mild intermittent	76 (20.8)
Mild persistent	208 (57.0)
Moderate-severe persistent	81 (22.1)
GINA	
Controlled	169 (46.3)
Partly controlled	57 (15.6)
Uncontrolled	139 (38.1)
NAEPP	
Well controlled	209 (57.3)
Not well controlled	133 (36.4)
Very poorly controlled	23 (6.3)
Total TRACK score*	80 (33)
Allergic sensitization	76 (20.8)
Total IgE	96.9 ± 196.1
Eosinophil count*	200 (100–400)
Eosinophil (%)*	2.45 (1.1–4.2)
Concomitant atopic dermatitis	12 (3.3)
Concomitant allergic rhinitis	21 (5.8)
Parental atopy	78 (21.4)
Maternal education	
Illiterate	26 (7.1)
Elementary education	216 (59.2)
High school/University	123 (33.7)
Paternal education	
Illiterate	6 (1.6)
Elementary education	191 (52.3)
High school/University	168 (46.0)

*Median (interquartile range); mean ± SD: mean ± standard deviation; Parental atopy: Parental asthma and/or allergic rhinitis.

the McNemar test. A *p* value of <0.05 was considered significant.

Results

A total of 397 parents were surveyed in the study; however, some parents did not provide complete answers to all questions therefore excluding their result from analysis. As a result, 365 TRACK questionnaires were available to analyze.

The mean age of the patients was 40.5 ± 10.9 months and 253 (69.3%) of them were male. The mean follow-up period of the patients' was 31.1 ± 10.9 months and the greater majority of patients (*n* = 208, 57.0%) had mild persistent asthma. One-hundred and sixty-nine (46.3%) patients were considered to have controlled asthma according to GINA whereas 209 (57.3%) patients were classified as well-controlled according to NAEPP. General characteristics of patients are listed in Table 1.

When evaluated according to GINA, the differences between the TRACK scores of patients classified as controlled (median 90, IQR 15), partly controlled (median 65, IQR 28) and uncontrolled (median 65, IQR 40) were found to be statistically significant (*p* < 0.001). However, there were no differences between the TRACK scores of the partly controlled and uncontrolled groups (*p* = 0.750) (Figure 1a). There was a significant difference in TRACK scores among patient groups who were classified as well controlled (median 90, IQR 15), not well controlled (median 65, IQR 34) and very poorly controlled (median 45, IQR 45) according to NAEPP (*p* < 0.001; Figure 1b). Children who received step-up therapy had lower mean TRACK scores (53.4 ± 23.9) than the children whose therapies were stepped down (86.7 ± 15.6) or were maintained (75.2 ± 22.1; *p* < 0.001; Figure 2).

The median TRACK score for all patients was 80 [(57.5–90) (IQR 25–75%)]. According to ROC analysis, a TRACK cut-off point of 80 provided the most consistent balance between sensitivity and specificity for the compatibility with both GINA and NAEPP (for GINA 0.763 and 0.663, kappa = 0.487, *p* < 0.001 and for NAEPP 0.761 and

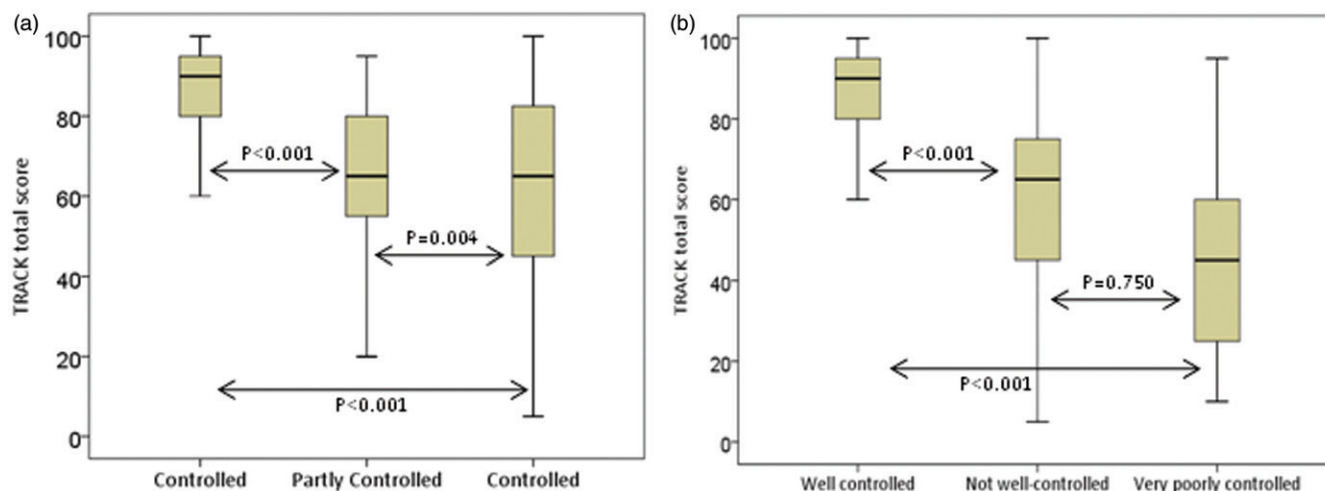


Figure 1. Comparison of total TRACK scores according to control levels of asthma defined by (a) GINA and (b) NAEPP. Mann–Whitney *U* test was used for paired comparisons and Kruskal–Wallis test was used for triple comparisons.

0.769, kappa = 0.524, $p < 0.001$, respectively; Tables 2 and 3; Figure 3).

When 80 was taken as the cut-off value for TRACK, and the groups were compared to control groups according to guidelines, control groups defined according to guideline criteria were divided into two groups (*totally controlled* and *not controlled*) for better statistical analysis as was explained in the methods section. The compatibility rate of asthma control levels between TRACK and GINA was 71.0%, and 76.4% between TRACK and NAEPP. *Compatible* and *not-compatible* groups of patients are compared with different parameters in order to find a variable predicting the discrepancy of the methods. There was no significant parameter such as gender, age, disease severity, duration of asthma, allergic sensitization, concomitant allergic disease, family history of atopy or parental education that could foresee the discrepancy

between the assessment of the control level of the patients (Supplemental Tables S1 and S2).

Within the group of patients whose TRACK scores reached over 80, patients *totally controlled* or *not controlled* according to both GINA and NAEPP were not different from each other in terms of age, duration of disease, peripheral eosinophil count and percent, level of parental education, presence of allergic sensitization, eczema, allergic rhinitis, food allergy and tobacco smoke exposure ($p > 0.05$). We have also examined the compatibility within severity groups of asthma. While 70.1% of the patients with TRACK scores over 80 having mild asthma were labeled as *totally controlled* according to GINA criteria, 50.0% of patients who had TRACK scores over 80 having moderate/severe asthma were labeled as *not controlled* according to GINA criteria ($p = 0.019$). Among the patients having TRACK scores over 80, being totally controlled and not controlled according to NAEPP criteria was not different between mild asthmatic and moderate/severe asthmatic patient groups.

Discussion

This is the first study that evaluates the compatibility between the TRACK questionnaires, GINA and NAEPP guidelines in terms of asthma control in children younger than 5 years of age. Our results suggest that TRACK correctly classifies respiratory control levels in approximately 71.0% of children according to GINA guidelines and 76.4% of children according to NAEPP guidelines.

Asthma guidelines emphasize the need to evaluate asthma control in order to guide asthma management decisions [1,4]. Monitoring asthma control and response to therapy is difficult to objectively assess in preschool children. There are some validated tools for assessment of asthma control status in children, including Asthma Control Test (ACT) and C-ACT, but these previous validated tools were not specific to

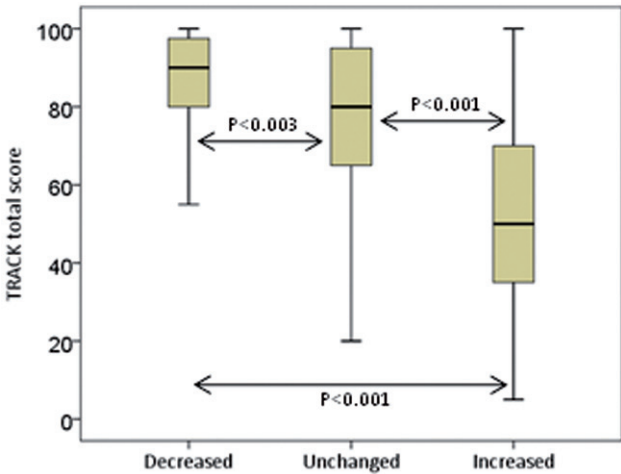


Figure 2. Comparison of total TRACK scores according to step-wise approach. Mann–Whitney *U* test was used for paired comparisons and Kruskal–Wallis test was used for triple comparisons.

Table 2. Sensitivity and specificity of different cut-off levels of TRACK for control decision according to GINA.

Cut-off levels (TRACK)	Sensitivity	Specificity	PPV	NPV	Compatibility between GINA and TRACK (%)	Kappa	<i>p</i> *
65	0.882	0.449	58.0	81.5	64.9	0.319	<0.001
70	0.876	0.510	60.6	82.6	68.0	0.374	<0.001
75	0.828	0.592	63.6	80.0	70.1	0.412	<0.001
80	0.763	0.663	66.1	76.5	71.0	0.422	<0.001
85	0.639	0.750	68.8	70.7	69.9	0.391	<0.001

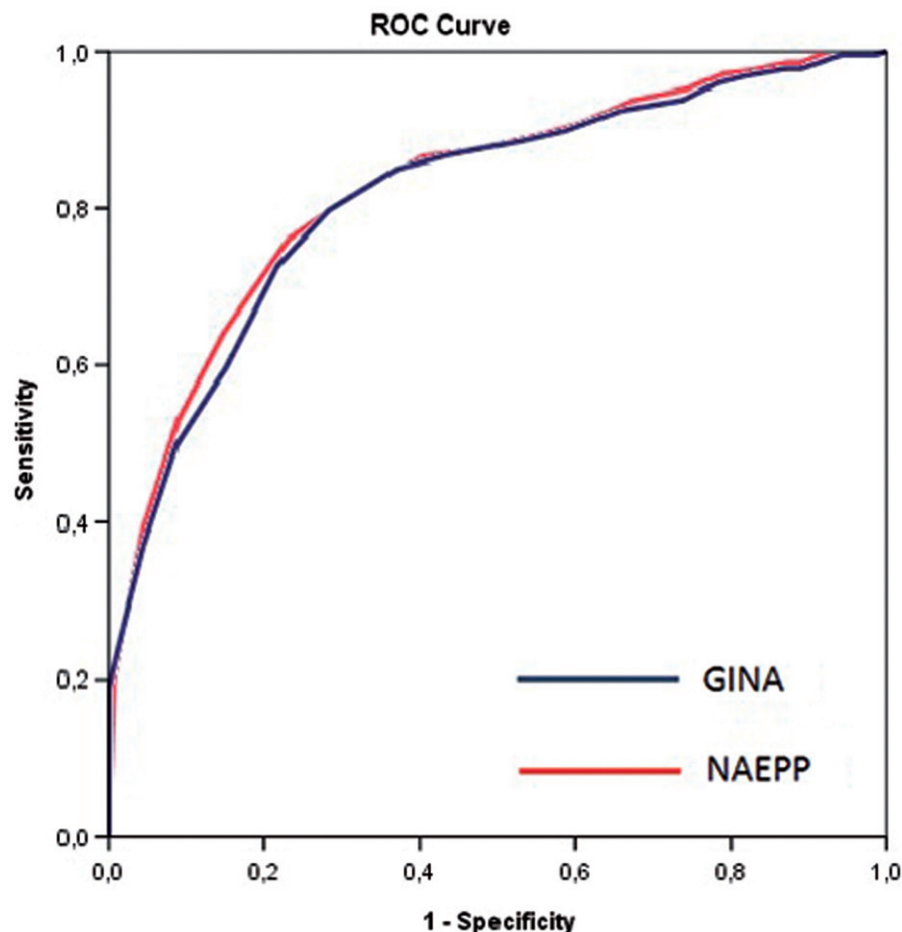
GINA, Global initiative for asthma; NPV, negative predictive value; PPV, positive predictive value; TRACK, Test for respiratory and asthma control in kids. *, McNemar test.

Table 3. Sensitivity and specificity of different cut-off levels of TRACK for control decision according to NAEPP.

Cut-off levels (TRACK)	Sensitivity	Specificity	PPV	NPV	Compatibility between NAEPP and TRACK (%)	Kappa	<i>p</i> *
65	0.876	0.526	71.2	75.9	72.6	0.418	<0.001
70	0.866	0.596	74.2	76.9	75.1	0.476	<0.001
75	0.818	0.686	77.7	73.8	76.2	0.509	<0.001
80	0.761	0.769	81.5	70.6	76.4	0.524	<0.001
85	0.641	0.853	85.3	63.9	73.2	0.474	<0.001

NAEPP, The National Asthma Education and Prevention Program; NPV, negative predictive value; PPV, positive predictive value; TRACK, Test for respiratory and asthma control in kids. *, McNemar test.

Figure 3. ROC Curve.



preschool-aged children and a validated tool to assess asthma control is needed in this age group [6–9].

TRACK was the first of its kind to have been validated as a tool to assess asthma control in young children [11]. The TRACK questionnaire was developed by Murphy et al. [11] based on the NAEPP EPR-3 asthma management guidelines. The assessment of asthma control should include not only control of the clinical manifestations (symptoms, night waking, reliever use and activity limitation) but also control of the expected future risk to the patient such as exacerbations and side effects of treatment [1]. TRACK includes an assessment of both impairment and risk reflected in the NAEPP EPR3 asthma management guidelines [11]. Such questionnaires combined with clinical assessment have the potential to reflect the real level of asthma control and provide better management of disease.

NAEPP and international guidelines support validated questionnaires developed for assessing asthma control [1,4]. GINA is a widely used test to assess asthma control levels. In our study not only the NAEPP EPR3 control table for 0- to 4-year-old children, but also the GINA levels of asthma control table for children 5 years and younger, was used for assessing the asthma control level and to the best of our knowledge, this is the first study comparing TRACK questionnaire with GINA criteria.

Results of TRACK scores were evaluated according to NAEPP EPR3 guideline by Murphy et al. [11] and our results were in accordance with this study. The cut-off point of 80 provided the most consistent balance between sensitivity and

specificity for the compatibility with both GINA and NAEPP in our study. When 80 was taken as the cut-off value, TRACK correctly classified control levels in approximately 71.0% of children according to GINA guidelines and 76.4% of children according to NAEPP guidelines in our study. The kappa statistics reported for TRACK and GINA, and TRACK and NAEPP were 0.487 and 0.524, respectively, and these results are indicative of “moderate” agreement [13].

During asthma management, the stepwise treatment of asthma is decided according to control level but as was pointed out earlier, defining the level of asthma control proves difficult for preschool children. In our study, the mean TRACK score of those who were stepped up was significantly lower than the mean score of those who were stepped down and those who were maintained on treatment. This suggests that TRACK can help in predicting patients who need increased treatment due to poor asthma control.

There is no approved and validated gold standard for measuring asthma control. Even the GINA classification is described as a “working scheme based on current opinion and has not been formally validated”. Clinicians should be aware that control status can be potentially misclassified in approximately 25–30% of patients using currently available asthma control tools, including TRACK [11]. This was also the case in our study. Although TRACK had a good sensitivity and specificity at a cut-off point of 80 according to both GINA and NAEPP, there were patients who were defined as controlled according to TRACK but were categorized as *not controlled* according to GINA and

NAEPP. Control levels of 29.0% of patients were not compatible with GINA and control levels of 23.6% of patients were not compatible with NAEPP in our study. One of the reasons for the discordance of TRACK results from GINA and NAEPP classification may be the fact that the guidelines evaluate asthma control in three categories whereas TRACK divides patients into only two control groups. Further, patients and parents answering questionnaires are coming from different cultural and social groups thus have differences in their understanding of questions [14]. Patients and parents also differ in their perception of symptoms [15].

A similar level of inconsistency was previously reported between internationally used questionnaires including ACT, C-ACT and GINA [16,17]. No questionnaire should be considered a sufficient alternative for a detailed clinical evaluation, however an easy to perform and standard test such as the TRACK questionnaire is a useful supporting tool to assess asthma control, especially for busy pediatricians and family physicians [18]. Further, TRACK facilitates communication among parents, caregivers and physicians on asthma control and asthma management. Asthma control might be better measured by physicians and parents acting in partnership, and this partnership might in turn improve future asthma control outcomes.

When patients having TRACK scores over 80 were evaluated separately, discordance between the existing guidelines and TRACK were more pronounced in the moderate/severe asthmatic group compared with mild asthmatics. This may tell us that we must be more careful, especially when defining a patient as controlled according to TRACK questionnaire for patients who have moderate to severe asthma. But the discordance of TRACK with GINA among moderate/severe asthmatics may also be reflecting the difference in asthma control determination between GINA and NAEPP. TRACK shows better concordance with NAEPP in general since TRACK was developed using NAEPP guidelines for the criteria.

Our study also reveals that validated versions of TRACK translated to other languages can be used easily and usefully. It can easily be answered by parents and seems not be effected by their education levels; it generally provides the correct decision about the control level of asthma and treatment in most of the patients.

In conclusion, TRACK is a validated tool that is easily used to assess the asthma control level of children under 5 years of age, and is compatible with NAEPP and GINA in majority of patients. However, it should be used in conjunction with a detailed clinical evaluation in order ensure a better decision for control levels and management plan.

Declaration of interest

The authors report no conflicts of interest.

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Table S1. Comparison of the characteristics of compatible & non-compatible groups to investigate the reasons of discrepancy between GINA and TRACK based control.

Variable	Compatible group* n=259(%)	Not compatible group n=106 (%)	P
Male	174(67.2)	79(74.5)	0.167
Age in months (mean $\pm$ SD)**	40.0 $\pm$ 10.8	41.6 $\pm$ 11.3	0.185
Age at first wheezing episode (mean $\pm$ SD)**	9.0 $\pm$ 7.5	10.1 $\pm$ 8.0	0.221
Follow-up period in years (mean $\pm$ SD)**	30.9 $\pm$ 10.7	31.5 $\pm$ 11.5	0.641
Family history of atopy	17(16.0)	61(23.6)	0.112
Asthma severity			
Mild intermittent	53(20.5)	23(21.7)	0.633
Mild persistent	151(58.2)	57(53.8)	
Moderate persistent	53(20.5)	26(24.5)	
Severe persistent	2(0.8)	0(0)	
Sensitization	52(20.4)	24(22.6)	0.633
Concomitant atopic dermatitis	25(9.7)	10(9.4)	0.949
Concomitant allergic rhinitis	27(10.4)	10(9.4)	0.818
Parental asthma	44(17.0)	12(11.3)	0.173
Maternal education			
Illiterate	20(7.7)	6(5.7)	0.124
Elementary education	160(61.8)	56(52.8)	
High School/University	79(30.5)	44(41.5)	
Paternal education			
Illiterate	6(2.3)	0(0)	0.210
Elementary education	138(53.3)	53(50.0)	
High School/University	115(44.4)	53(50.0)	

*The “compatible” group is consisting of patients whose control level of TRACK and GINA based measurement of control are compatible with each other; **analysis made by student-t test, the rest was analyzed with chi-square test; mean $\pm$ SD: mean $\pm$ standard deviation

Table S2. Comparison of the characteristics of compatible & non-compatible to investigate the reasons of discrepancy between NAEPP and TRACK based control.

Variable	Compatible group* n=279(%)	Not compatible group n=86 (%)	P
Male	193(69.2)	60(69.8)	0.917
Age in months (mean $\pm$ SD)**	40.5 $\pm$ 10.7	40.3 $\pm$ 11.8	0.876
Age at first wheezing episode (mean $\pm$ SD)**	9.3 $\pm$ 7.8	9.6 $\pm$ 7.3	0.752
Follow-up period in years (mean $\pm$ SD)**	31.2 $\pm$ 10.7	30.7 $\pm$ 11.7	0.705
Family history of atopy	63(22.6)	15(17.4)	0.309
Asthma severity			
Mild intermittent	55(19.7)	21(24.4)	0.616
Mild persistent	159(57.0)	49(57.0)	
Moderate persistent	63(22.6)	16(18.6)	
Severe persistent	2(0.7)	0(0)	
Sensitization	58(21.0)	18(21.2)	0.974
Concomitant atopic dermatitis	27(9.7)	8(9.3)	0.918
Concomitant allergic rhinitis	27(9.7)	10(11.6)	0.584
Parental asthma	46(16.5)	10(11.6)	0.274
Maternal education			
Illiterate	23(8.2)	3(3.5)	0.140
Elementary education	168(60.3)	48(55.8)	
High School/University	88(31.5)	35(40.7)	
Paternal education			
Illiterate	6(2.2)	0(0)	0.252
Elementary education	149(53.4)	42(48.8)	
High School/University	124(44.4)	44(51.2)	

*The “compatible” group is consisting of patients whose control level of TRACK and NAEPP based measurement of control are compatible with each other; **analysis made by student-t test, the rest was analyzed with chi-square test; mean $\pm$ SD: mean $\pm$ standard deviation