

## Validation of screening tool for diagnosis of childhood asthma by exclusion method

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## ABSTRACT

**Introduction:** In the 21<sup>st</sup> century, with growing concerns over over-diagnosis of asthma in children; the diagnosis of asthma is left as diagnosis by exclusion. On the same lines, an attempt had been made to device a criteria to exclude diagnosis of asthma. The criteria are labeled as other than asthma (OTA) criteria. It is assumed that if a case does not satisfy OTA tool, then it is likely to be asthma. This study had objectives of validation of screening tool by expert and validation of OTA tool by direct application on patients. **Materials and Methods:** This was an observational and prospective study only. Total 120 cases were enrolled. Questionnaire applied on all cases and all of the 120 cases were followed up on day 30 with clinical diagnosis and were included in results estimation. **Results:** According to the screening tool, out of 120 cases, 83 cases (69.2%) were found to have OTA while 37 cases (30.8%) were found to have non-OTA. However, among this study population, 94 cases (78.3%) had non-asthma and 26 cases (21.7%) had clinical diagnosis of asthma taken as gold standard. The association between clinical diagnosis and total score based diagnosis was found to be statistically significant ( $p=1.96E-07$ ). Sensitivity was 91.57% and specificity was 51.35% which helps detect OTA cases effectively. Predictive value of positive test is 80.85% and predictive value of negative test was 73.08%. OTA category has relative risk of 3.003 for diagnosis of non-asthma as compared to 0.262 for non-OTA category being almost 3 times in comparison to non-OTA category. Thus, OTA was consistent with non-asthma diagnosis. **Conclusion:** On direct application of patients in prospective study, this tool has proven its value as an effective screening tool. This was the first such study to diagnose asthma by exclusion, devising a criterion for other than asthma conditions.

**Key words:** Asthma by exclusion, Asthma screening tool, Childhood asthma, Other than asthma

Asthma is a globally significant non-communicable disease with major public health consequences for both children and adults, including high morbidity and mortality. Childhood asthma presents mostly as acute attacks leading to frequent hospital visits and hospitalizations. Worldwide around 300 million people are affected by asthma and it is estimated that another 100 million will be affected by 2025. Globally, asthma is ranked 16<sup>th</sup> among the leading causes of years lived with disability and 28<sup>th</sup> among the leading causes of burden of disease [1]. Asthma accounts for 1.1% of the overall global estimate of “disability-adjusted life years” per 100,000 for all causes [2]. It is a multifactorial disorder attributed to interactions between genetic susceptibility, host factors, and environmental exposures. Asthma has mean prevalence of 2.74. At the age of 6–7 years, it ranges from 4 to 32% [3]. Asthma hospital admission rate is an indirect indicator of the burden of severe asthma and it has started declining. In long-term 50-year perspective, the


“epidemic” of asthma admission bears no temporal relationship to two epidemics of asthma mortality (in 1960s and 1980s) [1].

In the 21<sup>st</sup> century, with growing concerns over over-diagnosis of asthma in children; the diagnosis of asthma is left as diagnosis by exclusion. On the same lines, an attempt had been made to device a criteria to exclude diagnosis of asthma. The criteria are labeled as other than asthma (OTA) criteria. It is assumed that if a case does not satisfy OTA tool, then it is likely to be asthma. This study aims at validation of the OTA criteria tool in excluding diagnosis of asthma by heuristic validation, content and constructive validation, and validation by direct application on cases helping one make a more reliable diagnosis of asthma.

This study had objectives of validation of screening tool by expert and validation of OTA tool by direct application on patients.

## MATERIALS AND METHODS

This study is an observational and prospective study. The study was initiated after obtaining permission and approval from the

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Institutional Ethics Committee, Ethics Committee for Academic Research Projects. Children aged 1 month to 12 years visiting the pediatric respiratory OPD were enrolled in the study after obtaining written informed consent from parent/guardian with no patient identifiers included in the case record form. Inclusion criteria comprised of all patients presenting to pediatric respiratory clinic at a tertiary care center in age group 1 month to 12 years. However, hospitalized and already on treatment patients for asthma were excluded from the study. Using time convenience sampling, total 120 cases were enrolled. A pattern of repeated cough, cold, wheezing, or breathlessness is considered to be OTA. OTA tool was internally validated heuristically taking each parameter into consideration by 10 experts practicing in childhood asthma. Tool was divided in major and minor criteria. Each criterion was framed in a question. Major criteria if present were given score of 2 and minor as Score 1. The tool was applied through a questionnaire to the parents of children presenting to Paediatric Respiratory Clinic. Questionnaire applied on all of the 120 cases was followed up on day 30 with clinical diagnosis. Total score equal to or more than 4 was categorized as OTA while score equal to or <3 as non-OTA. OTA tool was graded based on the total score of questionnaire in four grades. Grade 1 with total score between 17 and 20, Grade 2 with total score between 13 and 16, Grade 3 with total score between 9 and 12, and Grade 4 with total score 0–8. The results were studied to compare the predictability of OTA tool with clinical diagnosis on day 1 and day 30 of presentation. The clinical diagnosis after 30 days of presentation is taken as gold standard diagnosis in confirming or ruling out childhood asthma.

**RESULTS AND STATISTICAL ANALYSIS**

Among qualitative data, nominal data included gender of cases, diagnosis (OTA/non-OTA), gold standard clinical diagnosis (non-asthma/asthma), categorization of age, and total score, as per OTA tool. Among the study population of total 120 cases, mean age group was 6.04 years with standard deviations of 3.46 years, median 6.00 years, interquartile range 6.00, and mode 10.00 years (Fig. 1). Forty-eight female cases (40%) while 72 male cases (60%) were included in the study (Fig. 2). Mean number of major criteria fulfilled was 2.48 with standard deviation of 1.82 with interquartile range of 4.00 while mean number of minor criteria fulfilled was 4.12 with standard deviation of 2.01 with interquartile range of 2.00.

Association between qualitative variables was assessed by Chi-square test, with continuity correction for all 2 × 2 tables and by Fisher’s exact test for all 2 × 2 tables where Chi-square test was not valid due to small counts. In presence of small counts in tables with more than two rows, adjacent row data were pooled and Chi-square test reapplied. Continuity correction was applied for all 2 × 2 tables after pooling of data. (e.g., Association between clinical diagnosis and total score based categorization (≥4 [OTA] and 0–3 [non-OTA]). Among the total 120 cases, 6 cases (5.0%) were under Grade 1, 19 cases (15.8%) were under Grade 2,

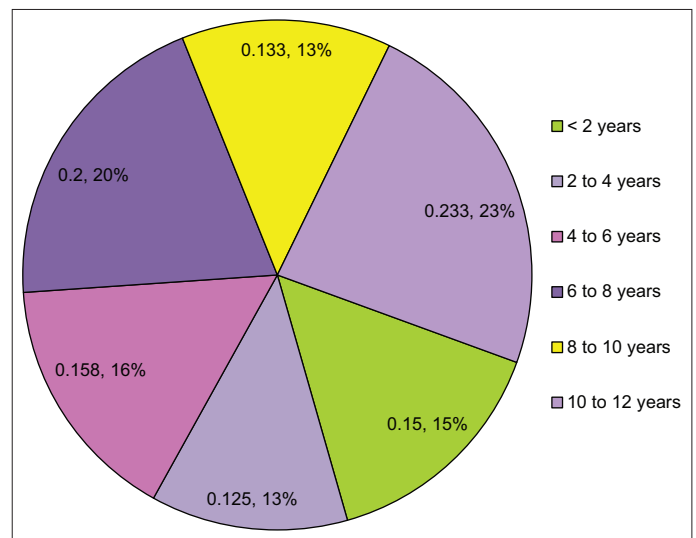


Figure 1: Age distribution among study population

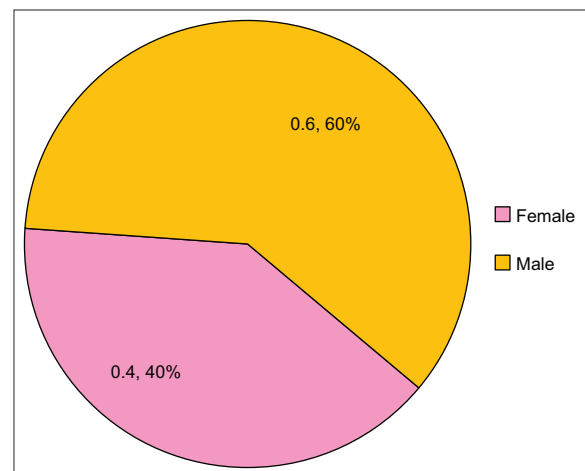


Figure 2: Gender distribution among study population

48 cases (40.0%) were under Grade 3, and 47 cases (39.2%) were under Grade 4 (Fig. 3). According to the screening tool out of 120 cases, 83 cases (69.2%) were found to have OTA while 37 cases (30.8%) were found to have non-OTA. However, among this study population 94 cases (78.3%) had non-asthma and 26 cases (21.7%) had asthma by clinical method. While using this screening tool, total score-based grade obtained after using questionnaire can be the factor which have an effect on clinical diagnosis and the same association was tested for the present study.

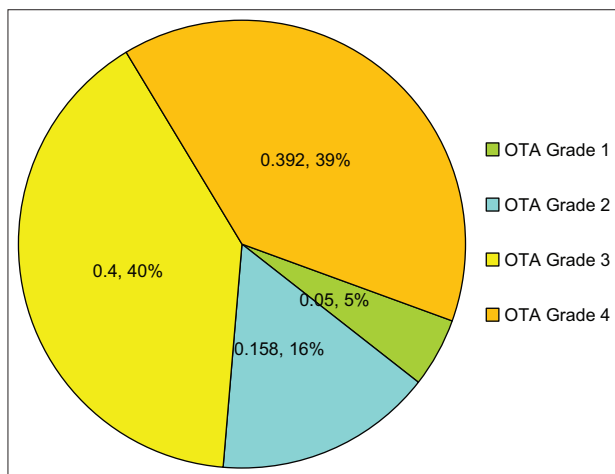
Among 120 cases enrolled for study, all 6 cases (100%) in Grade 1 and all 19 cases (100%) in Grade 2 found to have non-asthma. In Grade 3, out of total 48 cases, 44 cases (91.7%) had non-asthma. In Grade 4, out of total 10 cases with score between 4 and 8, 7 cases (70%) had non-asthma; while out of 37 cases with score between 0 and 3, 18 cases (48.6%) had non-asthma (Table 1 and Fig. 4).

The association between clinical diagnosis and total score-based diagnosis was found to be statistically significant (P=1.96E-07). In total 120 cases, 83 were OTA and 37 were non-OTA. Out of these 83 OTA cases, 76 cases (91.6%) were found to be true positive non-asthmatic by clinical diagnosis. Out of

**Table 1: Association among the cases between total score based grade and gold standard clinical diagnosis**

Total score based grade	Gold standard clinical diagnosis		Total	
	Non-asthma	Asthma		
Grade 1 (17–20)^				
No.	6	0	6	
%	100.0%	0.0%	100.0%	
Grade 2 (13–16)^				
No.	19	0	19	
%	100.0%	0.0%	100.0%	
Grade 3 (9–12)^				
No.	44	4	48	
%	91.7%	8.3%	100.0%	
Grade 4 (4–8)				
No.	7	3	10	
%	70.0%	30.0%	100.0%	
Grade 4 (0–3)				
No.	18	19	37	
%	48.6%	51.4%	100.0%	
Total				
No.	94	26	120	
%	78.3%	21.7%	100.0%	
<b>Chi-square tests</b>	<b>Value</b>	<b>Df</b>	<b>p-value</b>	<b>Association is-</b>
Pearson Chi-square <sup>s</sup>	31.562	4	2.35E-06	Significant
Pearson Chi-square <sup>^</sup>	30.889	2	1.96E-07	Significant

<sup>s</sup>4 cells (40.0%) have expected count less than 5. <sup>^</sup>Row data pooled and Chi-square test reapplied

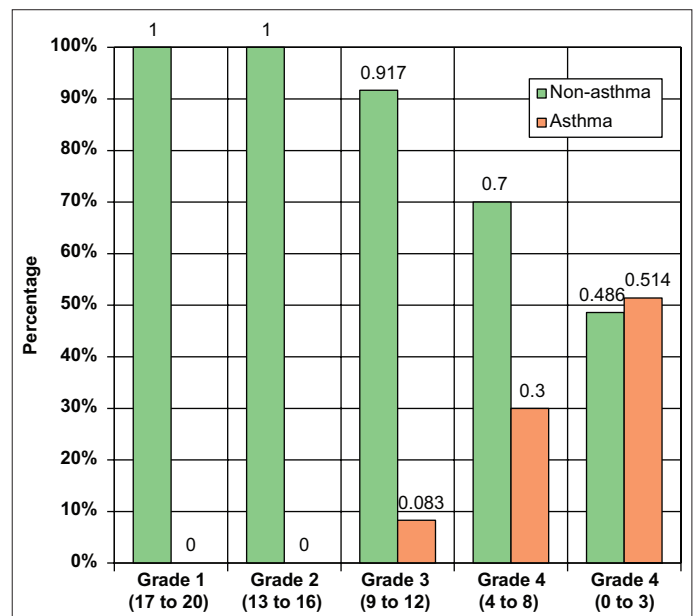


**Figure 3: Grade of OTA tool among cases**

total 37 non-OTA cases, 19 cases (51.4%) were found to be true negative asthmatic by clinical diagnosis.

Hence, sensitivity was 91.57% and specificity was 51.35% which helps detect OTA cases effectively. Predictive value of positive test is 80.85% and predictive value of negative test was 73.08% (Table 2).

OTA category has relative risk of 3.003 for diagnosis of non-asthma as compared to 0.262 for non-OTA category being almost 3 times in comparison to non-OTA category. Thus, OTA was seen more in non-asthmatic patients according to clinical diagnosis. Only third question was found to be statistically significant predictor of diagnosis of “Non-OTA”; less the score on third question – more probability of non-OTA.



**Figure 4: Gold standard clinical diagnosis by total score-based grade**

Binary logistic regression (Forward Step-wise (Wald) Method) was used to assess predictors of “diagnosis” dependent variable and “questions” (Q1 to Q15) as independent (Predictor) variables. For major criteria – among total 120 cases, 37 cases (30.8%) did not show any major criteria. While 4 cases (3.3%) were positive for one criteria. Nine cases (7.5%), 8 cases (6.7%), 59 cases (49.2%), and 3 cases (2.5%) had total 2, 3, 4, and 5 major criteria present in total.

**Table 2: Association among the cases between gold standard clinical diagnosis×diagnosis**

Gold standard clinical diagnosis	Diagnosis		Total	
	OTA	Non-OTA		
Non-asthma				
No.	76	18	94	
%	91.6%	48.6%	78.3%	
Asthma				
No.	7	19	26	
%	8.4%	51.4%	21.7%	
Total				
No.	83	37	120	
%	100.0%	100.0%	100.0%	
Index	Estimate	Lower 95% CI	Upper 95% CI	
Sensitivity	91.57%	83.39%	96.54%	
Specificity	51.35%	34.40%	68.08%	
Predictive value of positive test	80.85%	71.44%	88.24%	
Predictive value of negative test	73.08%	52.21%	88.43%	
Likelihood ratio of positive test	1.8822	1.3431	2.6376	
Likelihood ratio of negative test	0.1642	0.0757	0.3565	
Youden's index	0.4292	0.2574	0.6010	
Risk estimate-relative risk (non-asthma/asthma)	Value	95% Confidence Interval		
		Lower	Upper	
For cohort diagnosis=OTA	3.003	1.582	5.700	
For cohort diagnosis=Non-OTA	0.262	0.163	0.422	
Chi-square tests	Value	Df	p-value	Association is-
Pearson Chi-square	27.774	1	1.36E-07	Significant
Continuity correction	25.302	1	4.90E-07	Significant

For minor criteria – among total 120 cases, 2 cases (1.7%) did not show any minor criteria. While maximum of 31 cases (25.8%) and 40 cases (33.3%) had total 3 and 4 criteria present.

## DISCUSSION

Childhood asthma is common and considered as substantial burden. The implementation of adequate educational programs directed to parents and health personal on prevention, diagnosis, and treatment of children with asthma and related comorbidity is clearly a pending task.

OTA tool is found to be a strong tool to rule out asthma. Considering that many cases of asthma present the initial symptoms early in the first few years of life, it should be the priority of public health policy to know the prevalence and risk factors of this disease, to develop control and treatment strategies that impact on morbidity and mortality of these diseases, and improve the quality of life of affected children and their families.

In our study, total 15 leading questions were asked with first five questions framed on major criteria of OTA and rest 10 questions framed on minor criteria of OTA. First five questions were scored as 2, in case, if answer was YES. Rest 10 questions were scored 1 for YES answer. Affirmative answers pointed toward OTA diagnosis, thus, diagnosing asthma by exclusion. Major criteria questions included association of episodes with fever,

early night sleeping discomfort more than early morning (night awakenings), evidence of upper respiratory tract involvement (tonsillitis, adenoiditis, sinusitis, mouth breathing/nose block, and foreign body inhalation), or chronic diseases (heart disease, renal disease, hypocalcemia, microcephaly, failure to thrive with significant neonatal insult, or delayed development) or persistent patch radiographically beyond 3 months of initial insult. All these criteria strongly deviated the diagnosis away from asthma and which can be commonly mistaken and treated as asthma in routine practice. Minor criteria included age of onset below 4 years, probability of first episode as asthma, no family history of same, responding to antibiotics, and failing asthma line of treatment including steroids for 2 weeks, or persistent symptoms lasting for months, normal IgE or eosinophil count, normal spirometry, and no hyperinflation on chest X-ray. Minor criteria had less weightage as seen in daily practice while diagnosing asthma and also while applying on patients according to previously available or known investigation and treatment data of patients as this was non-invasive study.

Diagnostic efficacy of this screening tool was tested in diagnosing asthma by exclusion, unlike International Study of Asthma and Allergies in Childhood (ISAAC) questionnaire which also had tested for allergic rhinitis and atopic dermatitis along with wheezing [4]. Our study was carried at tertiary care center in pediatric respiratory clinic in age group 1 month to

12 years old, excluding hospitalized and already diagnosed with asthma patients. Particularly school population, however, was not included in the study. Our questionnaire was formulated for parents, unlike, ISAAC questionnaire which was for self-completion and, hence, the inclusion of specific age groups only in the study population. Previously available investigation reports or history of previous treatment if any was also included in our study, thus, making it more practical and easy to use in routine system.

There is scarcity of data on tools for diagnosis of asthma in children, yet, they are most affected by asthma [5-7]. Apart from all these ISAAC studies, few more studies were found in the literature for comparison with our studies. Main objective was to find the efficacy of their screening questionnaire and prevalence of asthma in population. In Uganda, symptom-based screening tool for asthma syndrome had shown sensitivity of 75.4% (95% CI 71.6–79.2), specificity 85.7% (95% CI 82.6–88.7) for children <2 years and sensitivity 93.3% (95% CI 88.9–97.8), specificity 91.1% (95% CI 87.1–96.8) for children 2–5 years [8]. Gowraiah *et al.* reported that asthma in children is mainly associated with history of previous episodes of acute respiratory symptoms and wheeze attacks. This study emphasizes the need to look at a combination of acute and recurrent asthma symptoms in diagnosis of asthma [9]. A study based on Japanese Pediatric Asthma Guidelines and best asthma control test for preschoolers reported the assessment accuracy as area under the ROC curve of 0.8873 (95% CI 0.8485–0.9199) and 0.8604 (95% CI 0.8049–0.9159) for development and validation datasets, respectively [10]. Another study reported prevalence of asthma as 15.7% by questionnaire and 21.4% by health claims data.

Questionnaire diagnosis was less sensitive (59.0%) with specificity (95.9%) for asthma; however, when children with asthma-related symptoms were excluded from the study, the sensitivity increased (83.6%), and specificity remained high (93.6%) [11]. A simple asthma prediction tool in Switzerland, UK reported the scaled Brier scores for the internally validated model and tool as 0.20 and 0.16, and the areas under the ROC curves were 0.76 and 0.74, respectively [12]. Frank *et al.* proposed importance of positive predictive value in reflecting frequency of disease in population with three sets of questionnaire [13]. While Wolf *et al.* validated screening instrument and proposed “wheezing after play” as significant predictor in diagnosis of asthma [14]. Glasgow *et al.*, Redline *et al.*, and Busi *et al.* tested parent versus student questionnaire and their results [15-17]. All the studies were being evaluated against clinical diagnosis as. The literature review on PubMed for 122 papers on different definitions of childhood asthma revealed three most important operationalizations: A questionnaire filled in by parents and or child (58%), interview with the parents and/or child (20%), and a clinical examination by a health professional (7%) [18]. As far as our knowledge, none of the Indian studies are found in the literature that has validated screening tool for diagnosis of childhood asthma by exclusion which includes symptom based questions as well as available investigations at the time of presentation.

When defining the cutoff point at which results from a screening test is deemed to be positive or negative, consideration has to be taken of the balance between false positive results (which can lead to extra distress because of unnecessary further investigations) and false negative results (which result in some cases of disease being missed). In clinical practice, simple

**Table 3: Definition and significance of individual criterion in OTA tool**

Question serial number in questionnaire	Major/Minor Criteria	Definition of criteria	Significance (p value)
1	Major	If most (50%) episodes come with fever	0.996
2	Major	There is early night sleeping time discomfort but no early morning discomfort	0.408
3	Major	There is obvious evidence of tonsillitis, adenoiditis, sinusitis, mouth breathing/nose block, foreign body inhalation, reflux	4.36E-09
4	Major	There is obvious evidence of other chronic disease like heart disease, renal disease, low calcium, microcephaly or failure to thrive or significant neonatal insult or delayed milestones	0.408
5	Major	Radiological evidence of persistent patch 3 months apart or Radiological evidence of specific parenchymal disease suspect	1.000
6	Minor	Age of onset <4 years	0.686
7	Minor	First episode	1.18E-09
8	Minor	No family history	0.043
9	Minor	No known allergy or sensitivity	0.009
10	Minor	Repeatedly treated with antibiotics	0.408
11	Minor	Does not respond in 2 weeks to asthma line therapy or symptoms; despite steroid use	0.005
12	Minor	Symptoms lasting months despite any asthma line therapy	0.938
13	Minor	IgE not raised, no eosinophilia	0.778
14	Minor	Spirometry normal (applicable if age >5 years)	0.538
15	Minor	X-ray no hyper inflation	0.625

**Table 4: Grading system for quantification of OTA tool**

Grades	Total score between	Diagnosis	Number of cases	Percentages	Remarks
I	17 and 20	OTA	6	5.0	Definite probability of non-asthma
II	13 and 16	OTA	19	15.8	Moderate probability of non-asthma
III	9 and 12	OTA	48	40.0	Mild probability of non-asthma
IV	4 and 8	OTA	10	8.3	Chance probability of non-asthma
	0 and 3	Non-OTA	37	30.8	Likely to be asthma
Total number of cases			120	100	

scoring system for identifying patients requiring further review is attractive.

In all these criteria, when binary logistic regression applied to know the significance of individual criteria, major criteria number 3 was found to be statistically significant ( $P=4.36E-09$ ). All other criteria were masked under presence of these criteria. Thus, it depicted that “obvious evidence of tonsillitis, adenoiditis, sinusitis, mouth breathing/nose block, foreign body inhalation, and reflux” deviated diagnosis away from asthma. Other criteria found that statistically significant were minor criteria like “first episode” ( $P=1.18E-09$ ), “no family history” ( $P=0.043$ ), “no known allergy or sensitivity” ( $P=0.009$ ), and “does not respond in 2 weeks to asthma line therapy or symptoms; despite steroid use” ( $P=0.005$ ) (Table 3).

The presence of these criteria suggested that patient is non-asthmatic. Use of this tool can avoid injudicious empirical treatment of asthma.

Higher the score for OTA tool high is the probability for non-asthma diagnosis and lower the score more possibility of asthma as proved by Chi-square test as association between clinical diagnosis and this grading system was found to be statistically significant ( $P=1.96E-07$ ). We have proposed the system of quantification for diagnosis of asthma by grading our tool in four different grades based on the total score obtained after application on patients (Table 4).

The results were found to be important after completing this study in age group 1 month–12 years in this parent-based questionnaire. It gave important clues to think of other common conditions like upper respiratory pathology when a child present with recurrent respiratory symptoms. Asthma has been treated blindly without diagnosis of same commonly in routine practice. This tool will help avoid such inadvertent treatment and direct treating doctors toward diagnosis.

Hereby, we propose asthma diagnosis not only by investigations such as spirometry, serum IgE levels, or eosinophils count; but also on history and clinical tool like OTA exclusion.

## CONCLUSION

Necessity of a screening model like OTA tool is of utmost importance to avoid over-treatment of many patients who present with recurrent respiratory symptoms. This study was more logical as approach to asthma diagnosis by exclusion. This tool is designed to look for sensitivity and specificity with respect to

clinical diagnosis. On direct application of patients in prospective study, this tool has proven its value as an effective screening tool.

Furthermore, classification of OTA tool has Grade 1, 2, 3, and 4 which is likely to be clinically beneficial in probability of ruling out asthma diagnosis. This tool will be of immense help for clinicians, paraclinical workers, community health workers, and parents to predict diagnosis of non-asthma in children presenting with recurrent respiratory illness for mass screening of asthma by this 5-min application of questionnaire. This was the first such study to diagnose asthma by exclusion, devising a criterion for OTA conditions.

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