Research Article

Validation of the modified International Study of Asthma and Allergies in Childhood questionnaire: Is wheeze alone enough for determination of asthma symptoms prevalence?

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ABSTRACT

Background: The International Study of Asthma and Allergies in Childhood (ISAAC) protocol for asthma prevalence depended mainly on self-reported wheezing symptom in the past 12 months. **Objective:** To evaluate the prevalence of asthma symptoms using self-reported wheezing versus combination of symptoms and spirometric criteria. **Materials and Methods:** A multi-center cross-sectional study covering Northern, Eastern, Western and Central Sudan was conducted during 2009-2012. A modified ISAAC questionnaire for adults was distributed to university students, academic staff, employee and workers chosen randomly. 3974 respondents were included. Any subject with asthma symptoms was interviewed by another special questionnaire and had a bronchodilator reversibility test. **Results:** Average overall prevalence of asthma symptoms depending on wheeze only symptom was 10% with regional variation ranged from 6% in El Obeid (Western Sudan) to 13% in Kassala (Eastern Sudan).The use of combination of symptoms (wheeze + shortness of breath or nocturnal cough) was more correlated with the reversibility validated prevalence than wheezing alone in all study sites and total sample. **Conclusion:** Wheezing alone does not predict the true asthma prevalence and the use of combination of symptoms (wheeze plus) is essential to yield a valid asthma symptoms prevalence.

KEY WORDS: Asthma; Prevalence; International Study of Asthma and Allergies in Childhood; Sudan

INTRODUCTION

The International Study of Asthma and Allergies in Childhood (ISAAC) has been using standardized symptom-based questionnaires to describe the prevalence of asthma symptoms in children worldwide. ISAAC phase one has described the prevalence of asthma, allergic rhinoconjunctivitis, and atopic eczema in over 156 centers from 56 countries and has "mapped" the prevalence of these conditions in two age groups (6/7 and 13/14 years of age).[1,2] The prevalence of asthma symptoms in the ISAAC study depended mainly on self-reported wheezing in the past 12 months without test validation by pulmonary function tests (PFT). Validation of asthma diagnosis using PFT is essential for real estimation of asthma prevalence and consequently a real view of the problem magnitude. On the other hand, depending only on the questionnaire question "wheeze during the last 12 months" may be misinterpreted as any noisy chest, and therefore, overestimate the prevalence of asthma.

Pulmonary function has been essentially included in the European Community Respiratory Health Survey I (ECRHS I, 1991-1993) and the follow-up study, ECRHS II (1998-2002). These large studies have collected information on health status and a variety of factors known or thought to be associated with

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the risk of developing asthma and atopy through two stages: A brief questionnaire asking about respiratory symptoms (Stage 1); and a more detailed clinical examination (Stage 2) for those who responded positively to asthma symptoms which included an extended interviewer administered questionnaire; blood tests for total IgE and specific IgE; assessment of FEV_1 and FVC; and measurement of bronchial reactivity to methacholine.[3]

To determine if spirometry is essential for the early detection of chronic obstructive pulmonary disease (COPD) in general practice, compared to the screening value of a short questionnaire, the differential diagnosis between asthma and COPD study (DIDASCO, a prospective survey of the population aged 35-70 years visiting their general practitioner during a 12-week period) has revealed the difficulty of diagnosing COPD with screening questionnaires only and concluded that spirometry is essential for early diagnosis.[4]

This study aimed at evaluating the prevalence of asthma symptoms using self-reported wheezing versus combination of symptoms and spirometric criteria.

MATERIALS AND METHODS

A multi-center cross-sectional study covering Northern, Eastern, Western and Central Sudan was conducted during 2009-2012. The participants were adult Sudanese University students, academic staff, employees and workers, males and females aged 18 and above living in the study site for more than 1 year. Samples were taken using a multistage random sampling. The total universities in the four sites under study were 27 distributed as follows: Khartoum state (18 universities), western Sudan states (4 universities), Northern Sudan (3 universities), and Eastern Sudan (2 universities). Khartoum state population is the largest compared to rest of the sites which explain the large number of universities. A modified ISAAC questionnaire was distributed to university students, academic staff, employee, and workers.

Sample Size

With an expectation of 10% prevalence depending on a previous pilot study in Khartoum, Sudan, a minimum of 140 subjects will be included from each randomly selected college at different Sudanese universities. The sample size was calculated according to the formula:

$$N = (Z^2 \times P \times Q \times DE)/d^2$$

Where N = sample size; Z = standard deviation when significant level is 95% (1.96); P = previous prevalence (0.1); Q = (1-P) (0.9); d = desired margin of error (0.05); DE = design effect (2): Because the sampling is multistage.

The total sample of respondents was 3974 subjects which is consistent with ECRHS protocol for asthma prevalence in adults which recommends inviting at least 3000 subjects for questionnaire study.[3]

The study was approved by the Research Ethics Committee of the National Ribat University, Khartoum, Sudan. All participants were informed about the objectives and the need of this study; self confidentiality was assured and their consent to participate was taken.

The Questionnaire

A modified translated ISAAC questionnaire for adults was filled out by all the randomly chosen participants. The questionnaire covered personal data, asthma symptoms, allergy symptoms, and environmental factors. An additional validated questionnaire especially designed for asthma which included asthma history, diagnosis, symptoms severity, and trigger factors for asthma symptoms was filled by all those with positive response to asthma symptoms. Asthma severity grade was classified according to the International Union Against Tuberculosis and Lung Disease classification (IUTLD, the union) into intermittent (less than weekly symptoms); mild persistent asthma (weekly symptoms), moderate persistent (daily symptoms), and severe persistent (continuous symptoms).

Spirometric Test

Bronchodilator reversibility using MicroPlus spirometer was done to all those who claimed to have asthma symptoms. The procedure was first explained to the subject and he/she was asked to take a deep breath (maximum inspiration to the total lung capacity) and expire forcibly and as long as possible into the spirometer; the best repeatable and acceptable reading of FEV_1 according to the ATS/ERS standardization of spirometry[5] was recorded as the initial reading (before bronchodilator); then, two puffs (400 mcg) of inhaled short acting bronchodilator (Salbutamol) were given to the subject usually via spacer to ensure good drug penetration; then, using the same procedure, another measurement of FEV_1 15 min later was performed and recorded as post-bronchodilator reading. The difference in FEV_1 before and after the inhaler was then calculated and taken as a percentage of the initial values. An increment of 12% in FEV_1 (according to GINA guidelines) was considered positive reversibility validating the diagnosis of asthma.

Data Analysis

Descriptive statistical data analysis was performed using SPSS software (Statistical Package for Social Science program), version 16.

RESULTS

The study included 3794 subjects, 1807 (45.5%) were males and 2167 (54.5%) were females aged 18 and above recruited from four sites in the Sudan: El Obeid (West), Dongola (North),

Kassala (East), and Khartoum (Central Sudan). The average overall prevalence of asthma symptoms depending on wheeze only symptom was 10%: (10.7% in Khartoum (Central), 6.7% in El Obeid (Western), 9.6% in Dongola (Northern), and 13% in Kassala (Eastern). The use of combination of symptoms (wheeze + shortness of breath or nocturnal cough) was more correlated with the PFT validated prevalence than using wheezing alone in all study sites and total sample, (Table 1). The overall sensitivity of the bronchodilator reversibility test was 37% (n = 169); 22.4% in Khartoum (n = 55); 42 % in Dongola (n = 10), 26% in Kassala (n = 37), and 57% in El Obeid (n = 16) with overall 63% false positive rate by ISAAC questionnaire. The sensitivity of bronchial reversibility test as a validation test for asthma diagnosis tended to increase as asthma severity grade increases (Figure 1).

DISCUSSION

In this study prevalence of asthma depending on wheezing in the past 12 months as guided by the ISAAC study ranged from 6% in El Obeid (Western Sudan) to 13% in Kassala (Eastern Sudan) with an average prevalence of 10% in the total sample which was consistent with international and regional studies adopting similar ISAAC method,[6,7] but to some extent higher than other surveys using other methods, e.g., physician diagnosed asthma. Because of the few studies, data on asthma prevalence in adults are scarce in Arab as well as in African countries. In a Jordanian schoolchildren survey, the reported wheezing prevalence was 8.3%, but physician diagnosed asthma was 4.1%.[8] Among the US adults asthma ranged geographically from 8.6% (northeast) to 10.5 in the west part.[9] In addition to differences in surveillance methods, this variation in asthma prevalence gives a clue to the pathogenesis of asthma and allergy, which might be due to disparity in genetics due to population diversities.[10] Females slightly more affected than males in the total asthmatics sample, which is consistent with many studies conducted in asthma prevalence in adults.[11-13] However, a recent Nigerian study in adults has revealed nearly 2:1 male to female ratio in asthma prevalance.[14]

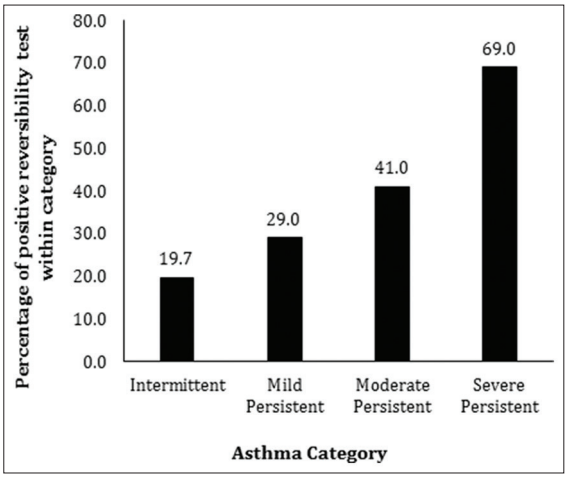

Figure 1: Reversibility test results among different asthma categories in the total asthmatics sample

In ISAAC study, the prevalence of asthma is dependent on wheezing in the past 12 months as a predominant indicator of asthma symptoms. According to phase III of this study,[1] prevalence of asthma in children aged 13 and 14 years in low and middle income countries is high (≥10%). In Khartoum (Sudan), it was found to be 12.5%. This means that for every 100 children aged 13/14, at least 12 children have asthma symptoms; a result that puts asthma in children as one of the major challenges. Wheezing alone could be misinterpreted as any noisy chest, and therefore, overestimates the prevalence of asthma. In Kassala site in this study, the prevalence of asthma depending on wheezing alone was 13%, but when wheezing was combined with shortness of breath, the prevalence was reduced to the half and almost similar results were seen in other study sites (Table 1). The significant difference between asthma prevalence depending on wheezing alone and wheezing plus shortness of breath or nocturnal cough supports the importance of using combination of asthma symptoms to obtain valid asthma prevalence. Combination of symptoms is also supported by international studies; a Swedish study in adults by Ekerljung et al. has shown that prevalence of wheeze in the previous 12 months raged (15.9-17.3%) but wheezing with breathlessness apart from cold ranged 3.2-4.1%.[15]

In our study, asthma diagnosis by the modified ISAAC questionnaire was validated by reversibility test. The validated asthma prevalence does not correlate with wheeze-only prevalence but close to asthma prevalence using combination of symptoms particularly wheezing plus shortness of breath (Table 1), another supporting evidence for using combination of symptoms (wheezing plus) to get a real estimation of asthma prevalence. In a recent multicenter study conducted in

Table 1: Prevalence of asthma symptoms depending on wheeze-only compared to combination of symptoms and reversibility (PFT) validated asthma in the study sites and total sample

Asthma prevalence criteria	Study site (%)				Total sample (%)
	Elobeid	Dongola	Khartoum	Kassala	
Wheeze-only symptom	6.8	9.6	10.7	13	10
Wheeze+shortness of breath	5	4.5	4.5	6.3	5
Wheeze+nocturnal cough	5	5.9	4.6	8	6
PFT validated	4	4	2.4	4.4	3.6

PFT: Pulmonary function tests

five Latin American cities, asthma prevalence was evaluated in middle-aged and older adults using ISAAC questionnaire in addition to spirometric reversibility test. 12% change in FEV_1 was considered significant reversibility, i.e., a protocol similar to our study. Out of the 1242 individuals reporting wheezing in the last 12 months, only 184 (14.8%) had also significant reversibility. The study concluded that wheezing in the last 12 months alone does not correlate strongly with reversibility in spirometry.[16]

An important finding in our study that the sensitivity of reversibility test tended to increase as asthma severity grade worsens from intermittent to persistent (Figure 1). This can be explained by the fact that in intermittent asthma the subject's best peak expiratory flow (PEF) is ≥ 80% of the predicted PEF and hence asthma candidates may be symptom free at the time of testing. This suggests using additional tests to confirm the diagnosis of asthma and hence decreasing false negative results in subjects with PEF is ≥80%. Provocation tests are usually suggested using methacholine, histamine or exercise. However, these tests require hospital-based set up for safety and reliability purposes.[17]

Because our sample size is mainly university students and workers, this may questions its generalization to the whole community. However, the university students and staff, in fact, represent the Sudanese community as Sudanese universities are open for anyone to join. Moreover, when we did a pilot community prevalence survey including randomly selected 121 adult subjects from four sites in El Obeid (Western Sudan), it showed a prevalence of current wheeze of 10.7% which is slightly higher than the present survey using university students and workers in El Obeid but is almost similar to general prevalence for Sudanese adults (10%).On the other hand, our study on adults is equivalent to the ISAAC children study which recruited its sample from schoolchildren.

CONCLUSION

In conclusion, wheezing alone does not predict the true asthma prevalence and the use of combination of symptoms (wheeze plus) is essential to yield a valid asthma symptoms prevalence. For confirmation of asthma diagnosis, bronchial provocation tests can be included in asthma prevalence protocols as the bronchial reversibility test might show false negative results particularly in subjects with intermittent symptoms.

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