

STUDY REPORT SYNOPSIS

Prevalence of Asthma and Allergies among children in UAE: A cross-sectional study

Milestones:

First Subject In:	30 Apr 2019
Last Subject Out:	26 Jun 2019
Data Base Lock:	08 Dec 2019
Clinical Study Report:	08 Apr 2019

Phase of development:

A cross-sectional study

Sponsor:

AstraZeneca Gulf - GCC

Author:

This study was performed in compliance with Good Clinical Practice (GCP) and Good Pharmacoepidemiology Practice (GPP), including the archiving of essential documents.

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Background/rationale:

Asthma is currently the most common chronic inflammatory disorder in children worldwide, rendering it a leading cause of school absenteeism when poorly controlled. Asthma is a heterogeneous condition according to the Global Initiative for Asthma (GINA). It is characterized by various respiratory symptoms, including respiratory airflow limitations, shortness of breath, wheeze, chest tightness, and cough that vary over time and in intensity. The vast majority of what is known about the increasing prevalence of asthma and other allergies is the results of studies conducted in western countries; data from the Arab Gulf countries, such as the United Arab Emirates (UAE), are scarce. However, according to the previously published literature, the prevalence of asthma in the UAE was ranged between 6% and 13% in those aged between 6 and 14 years.

Moreover, 7.4% of the UAE's general population compared to 6.42% in Kuwait, 4.81% in Oman, and 3.61% in Saudi Arabia, suffer from asthma. Asthma etiology is still largely unknown, but it is recognized as a heterogeneous and multifactorial disorder, which includes a combination of non-modifiable (e.g., heredity and gender) and modifiable (e.g., environment and behavior) risk factors. In addition, Arab incense (Bokhor) contributes to the prevalence and severity of asthma in most Omani children.

Allergic rhinitis (AR) is a systemic inflammatory condition that is considered as an IgE-mediated disorder caused by exposure of the nasal mucosa to allergens. This leads to rhinorrhea, itching, airflow obstruction, sneezing, and disturbance of sleep. Perennial indoor allergens, seasonal pollens, and molds are the most common allergens that cause AR. The wheeze ever and wheeze during the last year were reported to be influenced by the gender; higher in males compares to females in Kuwait. Atopic dermatitis, a common chronic or recurrent inflammatory skin disease, is closely associated with asthma and allergic rhinitis. Atopic dermatitis is known to affect 15-20% of children worldwide; yet, there is still a scarcity of data on the prevalence or distribution of rhinitis and atopic dermatitis in UAE.

Epidemiology has the potential to improve our understanding by elucidating the risk factors for asthma and allergies and suggesting directions for future research. The International Study of Asthma and Allergies in Childhood (ISAAC) was designed to evaluate the prevalence of asthma and AR in children. Although some data has been published from Middle Eastern countries that participated in ISAAC, the sample size was small and involved one age group from 13 to 14 years only. Several other previous studies have also assessed the

prevalence of allergic diseases in the Middle East region among different age groups and different periods. However, these studies lack a standardized methodology. Therefore, our study aimed to describe the prevalence and severity of asthma and allergic diseases among children aged 6-7 years and 13-14 years in Dubai and the Northern Emirates.

Objectives:

Primary objectives

- To describe the prevalence of asthma (wheezing) and allergies (rhinitis and atopic dermatitis) in children living in Dubai and the Northern Emirates.

Secondary objectives

- To describe the severity of asthma and allergies in children living in Dubai and the Northern Emirates.

Exploratory objectives

- To estimate the prevalence of asthma and allergies in children exposed to Arabian incense (Bokhor) in Dubai and the Northern Emirates of the UAE.
- To estimate the prevalence of asthma and allergies in children exposed to tobacco smoke in Dubai and the Northern Emirates of the UAE.

Study design:

This study is multicenter, cross-sectional, which was planned to recruit children from March 2019 to June 2019 via school class registers. Students from government and private schools were included with the targeted age group. Data were collected on a total of 1944 children in the age group 6-7 years (Group I), and 1793 children in the age group 13-14 years (Group II). Age was missing for 158 of those children in Group I. Thus, the number of eligible children for the analysis was 1786, and 143 of those children in Group II, and thus the number of eligible children for the analysis was 1650.

The children in Group II were asked to complete the ISAAC core questionnaires by themselves. Case-definitions and severity were established by asking about cardinal symptoms, not by reference to labels or diagnosis. They also completed a video questionnaire that was developed in response to translation problems with written questionnaires and

obviated the need to describe symptoms verbally. The validity of the research instruments has been investigated.

The parents or legal guardians of Group I were asked to complete the ISAAC core questionnaires on asthma, rhinitis, and atopic dermatitis. The video questionnaire was not administered to this age group.

Data source: Standard ISAAC core questions for wheezing, rhinitis, and atopic dermatitis were used. The ISAAC questionnaire was validated by the World Health Organization (WHO), translated into many languages, and used in many countries. In this study, the Arabic and English versions were used. In addition, questions regarding exposure to Arabian incense “Bokhor” and smoking history were added in the environmental questionnaire.

ISAAC Questionnaires

1. Core questionnaire on wheezing.
2. Core questionnaire on rhinitis.
3. Core questionnaire on atopic dermatitis.
4. Smoking questions of the environmental questionnaire.
5. Video questionnaire on wheezing (only for 13-14 years age group, if applicable)

The date of data collection was documented, and the study population was investigated before the main pollen season of the UAE, i.e., the summer months (July and August). Demographic data (school name, initials, date of birth, the city of residence, ethnicity, and sex) were obtained from the school register.

Inclusion criteria: Children who met the following criteria were included in the study:

- Children with age 6-7 years or with age 13-14 years at the time of questionnaire completion and residing in Dubai and the Northern Emirates of UAE.
- Children aged 6-7 years or 13-14 years; whose legal guardians give their consent.
- Able to give assent in the 13-14 years group.
- Able to comprehend and answer the questionnaire themselves in the 13-14 years group.

Exclusion criteria: Children who met the following criteria were excluded from the study:

- Aged 13-14 years and unable to answer the questionnaire due to physical or mental disability.
- Parent/legal guardian refuses sign/return consent for the 6-7 years group and the 13-14 years group.

Statistical methods:

A two-step stratified cluster random sampling was used for each age group based on the related information that was provided by the Knowledge & Human Development Authority (KDHA) in the Ministry of Health (MOH), the first step was to select randomly a number of schools in each district/gender/type of school strata. The second step was to randomly select a number of students from the selected school. The number of schools in each stratum and the number of students randomly selected from each school was based on the strata size and school size, respectively. Once the number was chosen, then school selection was done within each strata using complete randomization.

The analysis was done on children whose age was in the appropriate age range. Those with missing age were excluded from the analysis.

Descriptive statistics using mean and standard deviation were used for age, and frequency distribution was used for categorical variables such as gender, nationality.

Main outcomes such as asthma/wheezing and allergies were summarized using frequency distributions and 95% confidence intervals. The Wald confidence interval was used unless cell counts fell below 5, in which case the Clopper Pearson confidence interval was used. The severity of the symptoms was only summarized using frequency distributions.

The prevalence of ~~people~~ children with all three symptoms: wheezing, sneezing, and itching was computed using the single ever variables for those and at two time periods: ever and in the past year. Moreover, 95% confidence intervals for those were also computed.

Association between variables and the main outcome of ever asthma was done at the bivariate level using the Chi-square tests and bivariate logistic regression models. The multivariate

logistic regression model included all the variables that had a p-value of 0.20 or less at the bivariate level.

All analyses were done using IBM-SPSS (version 25, USA). A p-value of 0.05 or less was considered statistically significant.

Similar analyses, as described for the 6/7 years old, were done in the older age group. In addition, results from video viewing were summarized using frequency distribution along with a 95% confidence interval and were compared between boys and girls using the Chi-square test or Fisher's exact test. Moreover, combined wheezing as per video views was defined as any occurrence of wheezing during the day, while exercising or during the night was computed for the two time periods: ever and last year and analyzed in a similar manner as described above.

Results: Data were collected on a total of 1944 children in the age group 6-7 years (Group I), and 1793 children in the age group 13-14 years (Group II). Age was missing for 158 and 143 of these children in Group I and II respectively, and therefore ~~thus~~ the final number of eligible children for the analysis was 1786 and 1650- in the groups. The prevalence of asthma, wheezing, AR, hay fever, and eczema in Group I were 11.9%, 44.2%, 46.5%, 22.1%, and 12.9%, respectively. In Group II, the prevalence of asthma, wheezing, AR, hay fever, and eczema were 9.8%, 33.1%, 51.3%, 19.9%, and 14.6%, respectively. As observed, the prevalence of asthma, wheezing, and hay fever was higher in Group I than in Group II. Regarding the severity of asthma, wheezing caused disturbed sleep in 13.8% in (Group I and 15.8% in Group II, while 5.1% in Group I and 7.8% in Group II experienced that asthma limited the speech between breaths in. In Group I, the prevalence of last year sneezing, runny or blocked nose accompanied by itchy watery eye was 8%, and it was reported by 6.6% that rhinitis interfered with their daily activity, While in Group II, the prevalence of the same symptoms was reported by 13.8% (95% CI: 12.1%, 15.4%), and it was reported by 42.2% that rhinitis interfered little with their daily activity. In the same group, there were significant differences in all variables related to nocturnal cough between males and females. In particular, females reported significantly higher prevalence for all three questions related to nocturnal cough. On the other hand, males reported a higher prevalence of ever wheezing during exercise. In terms of asthma risk factors, ever asthma was significantly higher in Group I among males as compared to females (13.9% vs. 10.0%, $p=0.021$), among those exposed to incense (16.7% vs. 8.7%, $p<0.001$), and among those whose fathers were smokers

(17.5% vs. 10.3%). Similarly, in Group II, ever asthma was significantly higher among Arab compared to South Asians (12.0% vs. 4.5%, $p < 0.001$), among those exposed to incense (10.9% vs. 7.0%, $p = 0.018$), among those whose fathers were smokers (13.1% vs. 8.9%, $p = 0.023$). Interestingly, multivariate analysis showed that father smoking and exposure to incense were not associated with the prevalence or severity of asthma in neither groups.