Original Article

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Submission: 03-12-2018
Accepted: 09-02-2019

Access this article online

Quick Response Code:

Website: www.thoracicmedicine.org

DOI: 10.4103/atm.ATM_348_18

Asthma control and predictive factors among adults in Saudi Arabia: Results from the Epidemiological Study on the Management of Asthma in Asthmatic Middle East Adult Population study

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Abstract:

CONTEXT: Asthma control is suboptimal in the Middle East and North Africa (MENA).

AIMS: The aim of this study is to assess the level of asthma control in Saudi patients as per the Global Initiative for Asthma 2012 classification and explore its potential predictive factors.

SETTINGS AND DESIGN: Epidemiological Study on the Management of Asthma in Asthmatic Middle East Adult Population (ESMAA) is a multicentric, descriptive, epidemiological study assessing asthma management in the MENA region. In this article, we report the results of patients from Saudi Arabia included in the ESMAA study.

METHODS: Adult patients diagnosed with asthma at least 1 year before study entry were considered for inclusion. Asthma control level and its predictive factors were explored. Treatment adherence and quality of life (QoL) were assessed by MMAS-4© and Short Form 8 Health Survey QoL questionnaires, respectively.

STATISTICAL ANALYSIS USED: Descriptive statistics were done considering two-sided 95% confidence intervals. Logistic regression was used to explore the potential predictive factors of asthma control. All statistical tests were two-sided, and $P < 0.05$ was considered statistically significant.

RESULTS: Data of 1009 patients from Saudi Arabia were analyzed. Less than one-third of patients (30.1%) were found to have controlled asthma with significantly higher QoL. High level of asthma control was reported among male patients and those with high educational level, while age, body mass index, and adherence to treatment were found to have no effect on asthma control.

CONCLUSIONS: Asthma control remains suboptimal among Saudi population. This needs huge efforts to achieve acceptable levels of control and better QoL for asthma patients. Further studies are still needed in Saudi Arabia and the Middle East region.

Keywords:

Asthma, asthma control test, Epidemiological Study on the Management of Asthma in Asthmatic Middle East Adult Population, Global Initiative for Asthma, Middle East and North Africa, MMAS-4© questionnaire, Saudi Arabia, Short Form-8 Health Survey quality of life

With continuously increasing incidence rates, about 300 million people suffer from asthma worldwide. The reported

How to cite this article: AL-Jahdali H, Wali S, Salem G, Al-Hameed F, Almotair A, Zeitouni M, *et al*. Asthma control and predictive factors among adults in Saudi Arabia: Results from the Epidemiological Study on the Management of Asthma in Asthmatic Middle East Adult Population study. Ann Thorac Med 2019;14:148-54.

prevalence of asthma among the Saudi population varies from 4% to 25%.[1-4] However, due to the lack of solid and precise diagnostic criteria, reports of asthma prevalence vary and are not always accurate.[5-7]

It is thought that 60% of asthma cases are inherited. Other risk factors include tobacco exposure, occupational exposure, air pollution, house dust mite, cesarean section, severe respiratory tract infection, and obesity.[6,8]

Asthma can have severe long-term sequelae and even patients with moderate or mild asthma may experience airway remodeling leading to severe airway obstruction later in life.[9]

In multiple studies, asthma patients were found to have lower quality of life (QoL) in terms of functionality and productivity.[10,11] This highlights the importance of proper asthma management to provide symptomatic relief, prevent the development of permanent airway injury, and improve QoL of asthma patients.[5,7,9]

Although there have been great improvements in the field of asthma care, level of asthma control is still considered suboptimal in many countries.[7,10-12]

Despite the presence of large information on the level of asthma control and management in many sites, data from the Middle East are still insufficient, and only very few studies with relatively small samples are published. Moreover, demographic and disease-related factors associated with poor asthma control in this area are still not well documented.[13,14]

Epidemiological Study on the Management of Asthma in Asthmatic Middle East Adult Population (ESMAA) study[15] was carried out to assess the level of asthma control as per the Global Initiative for Asthma (GINA) 2012[16] in addition to potential factors affecting the level of asthma control in asthma patients attending routine consultation in public or private centers in the Middle East and North Africa (MENA) region. We report the results of patients from Saudi Arabia included in the ESMAA study.

Methods

Study design

ESMAA was a descriptive, epidemiological, cross-sectional study to assess the level of asthma control and explore the potential predictive factors associated with higher/lower control in asthma patients in the MENA region. In this report, data from Saudi patients were analyzed. GINA classification was considered for assessing asthma control level by the physician.[16]

Data source

General practitioners and/or specialists (pulmonologists and/or allergists) in the public and the private sectors in Saudi Arabia collected data from asthma patients attending routine consultation visits between December 2014 and December 2015. Participating physicians were selected from a national database according to their willingness to participate in the study and their academic degree. Sociodemographic data, disease characteristics, and treatment-related data were collected by the physician through asking the patients directly, while asthma control test (ACT), Short Form-8 Health Survey (SF-8), and MMAS-4© questionnaires were completed by the patients themselves.

Study population

We included patients older than 18 years who were diagnosed with asthma at least 12 months prior to enrollment in the study. Patients participating in another clinical trial, patients suffering from any psychiatric disorders or any other chronic respiratory disorders (except for rhinitis), patients consulted for an asthmatic attack during 4 weeks prior to enrollment, and pregnant women were excluded from the study. We obtained written informed consent from all participating patients.

Outcomes

The primary outcome of this study is the level of asthma control among included patients. According to the GINA 2012 classification, patients were classified as having controlled, partly controlled, or uncontrolled asthma. Table 1 describes 2012 GINA classification of current clinical control and future risk. We also used ACT questionnaire as a supportive endpoint for the GINA evaluation of asthma control.[17]

Adherence and QoL were evaluated using MMAS-4© questionnaire and SF-8 QoL questionnaire, respectively.[18,19]

Statistical analysis

The minimum sample size was calculated according to the asthma control (primary objective of the study), considering an accuracy degree between 2% and 5% and a type I risk $\alpha = 5\%$. The percentage of unemployable data and nonresponse to patient's questionnaire was estimated at 15%. The following equation was used: $N = (1.96)^2 p_0 q_0 / i^2$ where "p_0" is the percentage of patients whose asthma is well controlled, "q_0" is $1 - p_0$ while "i" is the accuracy degree.

All enrolled patients with no protocol deviations were considered for analysis. Descriptive statistics were carried out considering and two-sided 95% confidence intervals (CI) that were calculated by the Wilson method.

Table 1: 2012 Global Initiative for Asthma classification of current clinical control and future risk*

A. Assessment of current clinical control (in a given week over the past 4 weeks) controlled			
	Controlled **All items validated**	**Partly controlled** **One item at least present any week**	**Uncontrolled**
Daytime symptoms	None (≤2/week)	>2/week	≥3 items of partly controlled asthma
Limitation of activities	None	Any	Present any week
Nocturnal symptoms/awakening	None	Any	
Need for reliever/rescue treatment	None (≤2/week)	>2/week	
Lung function (PEF/FEV)	Normal	<80% (predicted or better)	
B. Assessment of future risk (of exacerbations, instability, rapid decline in lung function, side effects)			
Features associated with increased risk of future adverse events include: Poor clinical control, frequent exacerbations in the past year, any admission to critical care for asthma, low FEV, exposure to cigarette smoke, and high-dose medications			

*Global Initiative for Asthma (GINA). The global strategy for asthma management and prevention. 2012. Available at: http://www.ginasthma.org (accessed 31 July 2014). *Major global guidelines for the management of asthma.* GINA=Global Initiative for Asthma, FEV=Forced expiratory volume, PEF=Peak expiratory flow

Special software (Qualimetric Health Outcome Scoring Software, version 4.5) was used for calculating ACT scores and SF-8 scores including automatic handling of missing data.

Logistic regression was used to explore the potential predictive factors of asthma control.

Univariate logistic regression was conducted where asthma was either considered as controlled (including partly controlled cases) or uncontrolled. The following factors were tested using univariate logistic regression: age, gender, body mass index (BMI), educational level, professional situation, medical insurance coverage, presence of allergic rhinitis, presence of gastroesophageal reflux disease, relevant chronic diseases, smoking status, physical exercise, duration of asthma since diagnosis, asthma disease characteristics, and treatment in the past 6 months in addition to the adherence to treatment. Odds ratio (OR) with its 95% CI was calculated for each potential predictive factor. Factors found to have a significant effect in univariate regression ($P < 0.10$) were included in a multivariate regression model considering a 0.10 level of significance.

ACT scores and SF-8 scores were compared between asthma control levels (as per the GINA classification) using an analysis of variance test as appropriate, while adherence to treatment was compared between asthma control levels using a Chi-square test.

All statistical tests were two-sided, and $P < 0.05$ was considered statistically significant.

Statistical analyses were performed using SAS software, version 9.4 (SAS Institute, Cary, USA).

Results

Baseline characteristics

A total of 1030 asthma patients were enrolled in the study, of which 1009 met the eligibility criteria and were included in the analysis. The mean (±standard deviation [SD]) age was 48.7 years (±15.9). Females constituted 65.3% of the sample. The mean (±SD) BMI was 30.7 kg/m^2 (±7.4). Table 2 describes sociodemographic characteristics of included patients. The mean (±SD) duration since diagnosis was 13.2 (±11.2) years. Other disease-related characteristics are described in Table 3.

Level of asthma control, quality of life, and adherence to treatment

A total of 993 were evaluable by the GINA classification for asthma control. Less than one-third of the patients (30.1%) (95% CI: 27.3%–33.0%) was found to have controlled asthma and 31.9% (95% CI: 29.1%–34.9%) were found to have partly controlled asthma, while 38.0% (95% CI: 35.0%–41.0%) were found to have uncontrolled asthma. Table 4 shows the assessment of future risk of included patients and ongoing asthma medications according to the GINA classification.

The mean (±SD) ACT score of these patients was 17.1 (±4.6) showing significant higher values among patients with better asthma control levels according to the GINA 2012 classification ($P < 0.001$). Patients with controlled asthma (30.1%) showed the highest mean (±SD) ACT score (20.1 ± 3.4), while the mean (±SD) score of patients with partly controlled asthma (31.9%) was 18.4 (±3.7). The mean (±SD) ACT score was lowest (13.7 ± 3.9) in patients with uncontrolled asthma (37.9%).

QoL was measured according to the SF-8 questionnaire. All SF-8 scores in the controlled patients group were significantly higher than the scores of the other groups ($P < 0.001$). Detailed results are shown in Table 5.

When calculating treatment adherence (according to MMAS-4© questionnaire), 27.4% of patients with controlled asthma showed good adherence, while 21.1% of patients with partly controlled asthma and 21.5% of patients with uncontrolled asthma showed good adherence with no significant difference of treatment adherence between the three groups ($P = 0.112$).

Table 2: Sociodemographic characteristics

Characteristic	*n* (%)
Age	
18-35	222 (22.0)
35-55	425 (42.1)
55-70	260 (25.8)
≥70	102 (10.1)
Sex	
Male	350 (34.7)
Female	659 (65.3)
BMI (kg/m^2)	
<18	17 (1.7)
18-25	189 (19.1)
25-30	306 (30.9)
>30	479 (48.3)
Level of education	
Cannot read and write	207 (20.5)
Primary	202 (20.0)
Secondary school	276 (27.4)
University degree	279 (27.7)
Higher education	44 (4.4)
Professional situation	
Active	386 (38.3)
Nonactive	622 (61.7)
Medical insurance coverage	
Yes	666 (66.2)
No	340 (33.8)
Smoking status	
Nonsmoker	820 (86.5)
Past smoker	75 (7.9)
Active smoker	53 (5.6)
Regular physical exercise	
Yes	618 (61.4)
No	389 (38.6)
Comorbidities (several answers allowed)	
Allergic rhinitis	529 (52.4)
Gastroesophageal reflux	251 (24.9)
Hypertension	163 (16.2)
Diabetes	141 (14.0)
Other (after reclassification)	111 (11.0)
Dyslipidemia	47 (4.7)
Thyroid disorder	44 (4.4)
Related chronic disease	31 (3.1)
Cardiovascular disease	22 (2.2)
Allergic disease	17 (1.7)
Musculoskeletal disease	11 (1.1)
Obesity	7 (0.7)

BMI=Body mass index

Predictive factors of asthma control

In a univariate analysis comparing the pooled partially/completely controlled population versus the uncontrolled population, no significant difference was found between age groups (P = 0.550) or BMI groups (P = 0.107). Females were less likely to have controlled asthma than males (OR: 0.71 [95% CI: 0.54–0.93]). Regarding educational level, patients with higher education were almost four times more likely to have controlled asthma when compared to patients with less education (OR: 3.72 [95% CI: 1.74–7.92]). Patients without medical insurance coverage were more likely to have controlled asthma (OR: 1.44 [95% CI: 1.09–1.90]). Interestingly, nonsmokers did not show any significant difference in asthma control levels when compared to active smokers and past smokers (P = 0.824).

The ongoing use of inhaled corticosteroids, long-acting bronchodilators, and/or short-acting beta-agonists was not associated with a significant difference in level of asthma control (P = 0.699, P = 0.339, and P = 0.193, respectively).

In addition, patients using fixed combination (inhaled corticosteroids + long-acting beta-agonist) and those using antileukotrienes were more likely to have controlled asthma compared to patients not taking such medications (OR: 1.77 [95% CI: 1.29–2.44] and OR: 2.39 [95% CI: 1.82–3.14], respectively).

Discussion

The lack of sufficient data on asthma control in the Middle East, generally, and in Saudi Arabia, specifically, highlights a clear need for uniform and thorough data on asthma control in this geographical region. Our study addressed this issue and confirmed the largely inadequate asthma control in Saudi Arabia on a large sample of asthma patients.

Our analysis of 1009 adult asthma patients in Saudi Arabia, who were diagnosed at least 12 months prior to enrollment in the study, showed only 30.1% (95% CI [27.3%–33.0%]) of patients to have controlled asthma (according to the GINA classification).

Patients with controlled asthma had higher ACT scores (P < 0.001) and better QoL according to SF-8 questionnaire (P < 0.001). However, they did not show better medication adherence (according to MMAS-4© score) when compared to other groups (P = 0.112).

A study published in 2015 on 260 Saudi patients showed that 31.9% of the sample had controlled asthma.[13] This number is nearly similar to our results. Another study conducted in 1060 Saudi patients, published in 2008, showed 36% of patients to have well-controlled or completely controlled asthma (using ACT questionnaire).[20] Another study conducted in Jordan on 255 patients showed 30.6% to have a well-controlled asthma (using ACT questionnaire).[14] A Turkish study showed 50.5% of included asthma patients to have controlled asthma.[21] Although it is considered low, reported control levels in our study were relatively

Table 3: Disease-related characteristics

Characteristic	*n* (%)
Asthma diagnosis history (years)	
≤2	109 (10.8)
2-5	201 (19.9)
>5	699 (69.3)
Frequency of symptoms in the last 6 months	
Symptoms less than once per week	540 (54.2)
Symptoms more than once per week and less than once per day	333 (33.4)
Symptoms on a daily basis	123 (12.3)
Mild exacerbation	
Yes	663 (65.7)
No	346 (34.3)
Exacerbation likely to affect activities and sleep	
Yes	187 (18.5)
No	822 (81.5)
Frequent exacerbation	
Yes	75 (7.4)
No	934 (92.6)
Nighttime symptoms (several answers allowed)	
No more than twice per month	633 (62.7)
More than twice per month	159 (15.8)
More than once per week	112 (11.1)
Frequent nighttime symptoms	124 (12.3)
Short-acting B2 agonist use daily	39 (3.9)
Physical activity limited	45 (4.5)
Spirometry	
PEF ≤60% of predicted value	141 (19.7)
PEF 60-80% of predicted value	254 (35.5)
PEF ≥80% of predicted value	320 (44.8)
Asthma treatment reported during the past 6 months (several answers allowed)	
Inhaled corticosteroids	197 (19.6)
Long-acting bronchodilator	90 (9.0)
Oral corticosteroids	76 (7.6)
Fixed combination (inhaled corticosteroids + long-acting beta-agonist)	833 (82.9)
Antileukotrienes	367 (36.5)
Theophylline	55 (5.5)
Anticholinergic bronchodilator	96 (9.6)
Short-acting beta-agonist	546 (54.3)
Nasal corticosteroids	41 (4.1)
Antihistamine	12 (1.2)
Other	83 (8.3)

PEF=Peak expiratory flow

better than a report from Asia-pacific countries were only 7.6% of the patients were well-controlled.[10] Percentage of patients with well-controlled asthma was also lower in Latin America countries (7%) according to a study published in 2013.[11] Moreover, a study conducted in 8000 European patients showed that only 20.1% of participants have a controlled asthma (according to the GINA classification).[22] All these figures highlight that asthma control is an important issue because most asthma patients have suboptimal control of their disease.[7]

Possible reasons for this low asthma control include failure in guidelines implementation, which emphasizes the need of more practical and homogenous guidelines for diagnosis and treatment.[23]

Certainly, attempts to improve adherence to asthma medications have not been succeeding.[12] Our study also showed low levels of adherence to treatment among included patients. However, we did not find adherence to be associated with different likelihood of having an uncontrolled disease ($P = 0.112$). In the overall results of ESMAA study, good medication adherence was found to be significantly associated with asthma control ($P < 0.001$).[15]

Our results showed better levels of asthma control to be associated with better QoL ($P < 0.001$). Similar results were also reported in the previous studies where lower levels of asthma control were associated with less productivity and decreased functionality.[10,11]

Patients with higher levels of education in our study were shown to have a more likelihood of having a controlled asthma. These results are consistent with previous research that showed less education to be associated with inadequate control levels.[11,13,20,21]

Females in our study had significantly lower levels of asthma control than males; this is consistent with the previous studies.[11,13,20] On the other hand, several studies did not find any association between gender and asthma control levels.[14,24]

Although cigarette smoking is a known risk factor for most respiratory diseases, our study did not find a significant association between uncontrolled asthma and active smoking. This may be due to the relatively low percentage of active smokers in our sample (5.6%). Turktas *et al*. observed similar findings regarding the relationship between smoking status and asthma control.[21]

Limitation for this study can be the level of subjectivity associated with collected data. We did not address the factors leading to uncontrol in details. For example, the proper inhaler device technique is very important in optimum drugs delivery and therefore asthma control.

Al-Jahdali *et al*. documented in their study that improper asthma inhaler device technique is associated with poor asthma control;[25] unfortunately, we did not check proper use of inhaler in this study; however, the large sample size and inclusion of patients from many specialized and general practitioner clinics across the Kingdom make its results more generalizable with the need for further studies to confirm our results.

Table 4: Assessment of future risks and ongoing asthma treatment according to the current clinical asthma control according to the Global Initiative for Asthma

	Controlled (*n*=299)	Partly controlled (*n*=317)	Uncontrolled (*n*=377)	Total (*n*=993)
Predictive characteristics of an increased risk of adverse events (several answers allowed)				
No predictive characteristics of increased risk of adverse events ticked	50 (16.7)	39 (12.3)	25 (6.6)	114 (11.5)
Poor clinical control	78 (26.1)	96 (30.3)	200 (53.1)	374 (37.7)
Exposure to cigarette smoke	84 (28.1)	47 (14.8)	34 (9.0)	165 (16.6)
Frequent exacerbations in past year	67 (22.4)	67 (21.1)	63 (16.7)	197 (19.8)
Low FEV/PEF	14 (4.7)	38 (12.0)	39 (10.3)	91 (9.2)
High-dose medications	45 (15.1)	57 (18.0)	36 (9.5)	138 (13.9)
Number of admission to critical care for asthma	7 (2.3)	3 (0.9)	4 (1.1)	14 (1.4)
Ongoing asthma treatment reported at the time of the study (several answers allowed)				
Inhaled corticosteroids	56 (18.9)	49 (15.5)	68 (18.1)	175 (17.4)
Long-acting bronchodilator	23 (7.8)	22 (6.9)	34 (9.0)	79 (7.9)
Oral corticosteroids	10 (3.4)	12 (3.8)	28 (7.4)	50 (5.0)
Fixed combination (inhaled corticosteroids + long-acting beta-agonist)	202 (68.2)	243 (76.7)	310 (82.4)	767 (76.3)
Antileukotrienes	59 (19.9)	97 (30.6)	169 (44.9)	329 (32.7)
Theophylline	9 (3.0)	11 (3.5)	30 (8.0)	50 (5.0)
Anticholinergic bronchodilator	16 (5.4)	26 (8.2)	44 (11.7)	86 (8.6)
Short-acting beta-agonist	165 (55.7)	153 (48.3)	179 (47.6)	511 (50.8)
Nasal corticosteroids	13 (4.4)	14 (4.4)	14 (3.7)	41 (4.1)
Antihistamine	4 (1.4)	0 (0.0)	6 (1.6)	10 (1.0)
Other	14 (4.7)	14 (4.4)	26 (6.9)	54 (5.4)

PEF=Peak expiratory flow, FEV=Forced expiratory volume

Table 5: Short Form-8 Health Survey questionnaire[a]: Subscores and component summary scores according to the investigator assessment of current clinical asthma control according to the Global Initiative for Asthma

	Mean±SD				*P*[b]
	Controlled	Partly controlled	Uncontrolled	Total	
Physical functioning	44.8±7.7	42.4±7.8	36.9±8.1	41.0±8.6	<0.001
Role physical	45.1±8.1	43.4±8.6	37.1±8.5	41.5±9.1	<0.001
Bodily pain	51.4±8.5	47.9±9.3	43.3±9.2	47.2±9.6	<0.001
General health	49.2±6.8	47.1±7.1	42.0±7.6	45.8±7.8	<0.001
Vitality	48.8±8.1	47.4±8.3	44.4±8.3	46.7±8.5	<0.001
Social functioning	47.0±8.3	45.7±8.9	40.8±9.4	44.2±9.3	<0.001
Role emotional	45.4±7.4	44.4±8.0	40.2±8.2	43.1±8.2	<0.001
Mental health	46.5±8.9	44.9±9.3	41.2±9.7	44.0±9.6	<0.001
Physical component summary	47.5±7.7	44.6±8.1	37.8±8.5	42.9±9.1	<0.001
Mental component summary	47.3±9.2	46.0±9.3	41.8±10.2	44.8±9.9	<0.001

[a]Results are expressed as scores which range from 0 to 100; 100 indicates the highest level of QoL, [b]*P* value of analysis of variance. SD=Standard deviation, QoL=Quality of life

Many studies have investigated asthma control in Saudi patients;[13,20] however, strengths of our epidemiological study are not only assessing the level of asthma control in the same population, but also looking for an association between asthma control and patients' characteristics, QoL, and treatment adherence.

Conclusion

We conclude that asthma control remains suboptimal among Saudi population. This needs huge efforts from health-care professionals and patients to achieve acceptable levels of asthma control.

Acknowledgment

Permission to use MMAS-4© was granted by Dr. Donald E. Morisky. Use of the ©MMAS is protected by US Copyright laws. Permission for use is required. A license agreement is available from Donald E. Morisky, MMAS Research LLC 14725 NE 20th St. Bellevue WA 98007 or from dmorisky@gmail.com.

Editorial support of this article was provided by Maha Abulfetoh and Omnia Aboutaleb on behalf of DATACLin Contract Research Organization and was funded by AstraZeneca.

Financial support and sponsorship

This study was funded by AstraZeneca which took no part in the analysis or interpretation of the presented data.

Conflicts of interest

There are no conflicts of interest.

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