

STUDY REPORT SUMMARY

Evaluation of Asthma Management in Middle East North Africa Adult population

Descriptive study on the management of asthma in an asthmatic Middle East Africa adult population

Background/Rationale:

Asthma is a substantial burden to both the individual and to the public health care system. Management of chronic asthma is based on disease control and severity. Despite availability of effective treatments and an increasing number of international recommendations, available data for Europe, the USA and Asia-Pacific show that asthma control levels are unsatisfactory. Few data on asthma control in countries in the Middle East and North Africa are available.

This epidemiological study was designed to evaluate asthma control levels asthmatic patients attending routine consultations with a general practitioner or a specialist in 11 Middle East and North African countries. Asthma control was assessed according to the 2012 Global Initiative for Asthma (GINA) guidelines, available at the time the study was initiated. Patients were classified as having controlled, partly controlled or uncontrolled asthma by the treating physician.

Objectives:

Primary objective

1. To assess the asthma control level in patients treated in public or private consultations according to the GINA 2012 classification.

Secondary objectives

1. To describe the general and socio demographic patient's characteristics at enrolment: sex, age, BMI, educational level, occupation, co morbidities, smoking status, and social security coverage.
2. To describe the characteristics of the disease at enrolment.
3. To assess the asthma control level with the ACT questionnaire.
4. To describe the therapeutics used in the basic asthma treatment during the six months prior to inclusion.
5. To determine the average frequency of reliever use in the previous week.
6. To identify predictive factors of asthma control, such as age, sex, BMI, smoking status, adherence to treatment, asthma history, co morbidity.
7. To evaluate the patient's quality of life.
8. To assess patient's compliance to treatment.

Methods:

A descriptive, epidemiological, multicentre study was conducted in a random sample of general practitioners and/or specialists (pulmonologists and/or allergists) from the public and the private sectors, using a database of physicians managing asthma patients in Middle East and North African countries to determine the level of asthma control. A total of 11 countries participated including the United Arab Emirates (UEA), Kuwait, Qatar, Saudi Arabia, Egypt, Tunisia, Iraq, Lebanon, Jordan, Iran, and Algeria.

Adult asthma patients who had been diagnosed with asthma for at least one year prior to enrolment, not associated with any chronic respiratory diseases (excepting allergic rhinitis), without an acute asthma episode within 4 weeks before enrolment, and attending a routine private or public consultation were eligible. Each physician was to enrol on average 10 eligible patients, increased to 40-50 patients in Saudi Arabia and 30 to 35 in the UAE and Kuwait following protocol amendments. Overall 7245 patients were planned to be included (reduced from 8645 following an amendment).

Data were collected during a single patient consultation, after informed consent was obtained. All study procedures (clinical assessment, Asthma Control Test [ACT], Morisky, and SF-8 QoL questionnaires) were completed during the consultation.

The primary variable was asthma control according to GINA 2012 describing current clinical control as controlled, partly controlled, or uncontrolled on the basis of the past 4 weeks and establishing future risk of exacerbations, instability, rapid decline in lung function, and side effects. Secondary variables included general and demographic baseline patient and disease characteristics, patient-derived assessment of asthma control during the last 4 weeks prior to inclusion as per the ACT, QoL as per the SF-8 questionnaire, treatment adherence as per the Morisky questionnaire and establishment of risk for predictive factors in non-optimal asthma control, as measured by the odds ratio (OR) with regression analyses.

Results:

Patient and disease characteristics

A total of 7306 patients were included from 11 countries between 11 June 2014 and 30 December 2015 (2.7% to 14.3% enrolled by country). Most were included in Algeria, Egypt, Iran and Saudi Arabia (13.7% to 14.3% per country of the patient population). A total of 577 sites participated including a median of 10 (range 1-240) patients. Seventy patients were excluded from the analysed population, giving 7236 patients (99.0%) in total.

Median patient age was 45 years (range 18-98), with 26.6% of the population under 35 years, and 6.0% aged 70 years or older. Females accounted for 57.1% of the population. Median BMI was 27.7 kg/m² (range 13.3-85.1 kg/m²), and 34.1% of the population was obese (BMI >30 kg/m²). Overall, 63.1% had been educated to either secondary school or university level, while nearly 10% could not read or write; 69.1% had medical insurance coverage. Most patients (89.2%) were non-smokers or previous smokers and 58.5% had allergic rhinitis.

Patients had been diagnosed a mean of 12.5 (\pm 10.1) years prior to study inclusion. Symptoms over the past 6 months occurred less than once a week in 53.1% of patients; 22.6% experienced an impact on daily activities and sleep, while 10.3% had frequent night-time symptoms. PEF \geq 80% of predicted was reported in 39.3% of 6584 evaluable patients .

All patients had used asthma therapeutics for routine asthma management during the 6 months prior to inclusion, and 4.5% were not using any medication at the time of the consultation. Combination therapy of fixed-dose inhaled corticosteroid with a long-acting beta agonist was the most widely (70% over the past 6 months; 65% at the time of consultation), and with another treatment in 38% of patients. Anti-leukotrienes (alone or in combination) were used by approximately one-quarter of the population.

Primary endpoint: Asthma control according to GINA

A total of 7179 patients of the 7236 analysed population (99.2%) were assessable for GINA asthma control by the treating physician. Asthma was considered controlled in 29.4% of patients (95% CI, 28.4% to 30.5%), partly controlled in 29.1% (95% CI, 28.1% to 30.2%), and uncontrolled in 41.5% (95% CI, 40.3% to 42.6%), giving a 70.6% rate of pooled partially controlled or uncontrolled asthma (95% CI, 69.5% to 71.6%).

Some variation relative to the mean 29.4% controlled asthma was seen between countries; with lower rates in Jordan (14.8%) and Iraq (17.5%), and higher rates in Kuwait (42.6%), Qatar (41.1%) and Tunisia (40.2%). More patients with controlled or partly controlled asthma (GINA 2012) were taking fixed combination ICS/ LABA alone (34.9% for controlled, 29.1% for partly controlled, 20.1% for uncontrolled), while fixed combination ICS/LABA with other treatments were more frequent in patients with uncontrolled asthma (31.6% for controlled, 38.8% for partly controlled, 41.7% in uncontrolled). Patients with controlled asthma were less likely to be taking anti-leukotrienes and theophylline (alone or in combination).

Only 18.1% of patients had no predictive characteristics for an increased risk of a future asthma event. The more frequent characteristics were current poor control (35.5%) and cigarette smoke exposure (34.0%).

Secondary endpoints: ACT, Morisky and SF-8 questionnaires

The median overall ACT score was 19 (range 5 to 25), equivalent to partly-controlled asthma level. ACT scores correlated with patient assessment (ACT) of levels of asthma control. A similar trend was apparent when correlating ACT scores with the investigator assessment, with increasing median ACT scores from patients in the uncontrolled GINA group (score=14) to those in the controlled GINA group (score=22; $p < 0.001$).

Mean values for all eight QoL SF-8 sub-scores were slightly below 50 for all domains. The lowest median SF-8 scores were seen in the uncontrolled GINA group and highest in the controlled GINA group ($p < 0.001$).

Good adherence (a score of 4) was reported in 23.6% of the population according to the Morisky questionnaire; 39.6% had trouble remembering to take their medication, and 55.7% stopped taking the medication when they felt better. Better compliance was seen in patients with GINA controlled asthma (31.6%) versus uncontrolled (17.8%; $p < 0.001$).

Multivariate analysis including univariate significant factors ($p < 0.10$) comparing the pooled completely/partially controlled versus uncontrolled patients showed a higher likelihood of uncontrolled asthma ($p < 0.001$) in patients without good adherence (OR, 0.55 [95% CI, 0.49;0.63]), who were active smokers (OR, 0.57 [95% CI, 0.48;0.67]), without medical insurance (OR, 0.65 [95% CI, 0.58;0.72]), or diagnosed >5 years earlier (OR, 0.73 [95% CI 0.62;0.88]). More educated patients were less likely to have uncontrolled asthma (OR, 2.31 [95% CI 1.72;3.09]).

Conclusion:

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