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Factors associated with uncontrolled asthma in Porto Alegre, Brazil

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Abstract

The prevalence of uncontrolled and controlled asthma, and the factors associated with uncontrolled asthma were investigated in a cross-sectional study. Patients aged 11 years with confirmed asthma diagnosis were recruited from the outpatient asthma clinic of Hospital de Clínicas de Porto Alegre, Brazil. Patients were excluded if they had other chronic pulmonary disease. They underwent an evaluation by a general questionnaire, an asthma control questionnaire (based on the 2006 Global Initiative for Asthma guidelines), assessment of inhaled device technique and pulmonary function tests. Asthma was controlled in 48 of 275 patients (17.5%), partly controlled in 74 (26.9%) and uncontrolled in 153 (55.6%). In the univariate analysis, asthma severity was associated with asthma control ($P < 0.001$). Availability of asthma medications was associated with asthma control ($P = 0.01$), so that most patients who could purchase medications had controlled asthma, while patients who depend on the public health system for access to medications had lower rates of controlled asthma. The use of inhaled corticosteroid was lower in the uncontrolled group ($P < 0.001$). Logistic regression analysis identified three factors associated with uncontrolled asthma: severity of asthma (OR = 5.33, $P < 0.0001$), access to medications (OR = 1.97, $P = 0.025$) and use of inhaled corticosteroids (OR = 0.17, $P = 0.030$). This study showed a high rate of uncontrolled asthma in patients who attended an outpatient asthma clinic. Severity of asthma, access to medications and adequate use of inhaled corticosteroids were associated with the degree of asthma control.

Key words: Control level; Prevalence; Disease control; Associated factors; Treatment and control

Introduction

Asthma is a common chronic disease that causes substantial morbidity among affected individuals. Because asthma cannot currently be cured, the goal of asthma therapy is to attain asthma control (1). Asthma management guidelines, such as the Global Initiative for Asthma (GINA) (2), have been introduced to improve patient care and provide optimal long-term asthma control, thereby reducing the morbidity and mortality associated with the disease and the economic burden it entails (3).

Although the results of clinical trials advocate that asthma control can be reached in most patients (4), the epidemiologic evidence suggests that there is a significant gap between the treatment goals and the current level of asthma control achieved for the general population. Therefore, the challenge that remains is to find management strategies to ensure that this control is achieved and maintained (5).

Several factors have been identified as being individually associated with asthma control. These factors can be categorized as physiological, environmental, and behavioral (6). A better insight into their influence on asthma control could be of help to determine more efficiently the preventive measures with the greatest impact on disease control (7).

Since health care systems differ throughout the world, the relative importance of factors associated with asthma control is likely to vary among different countries. The understanding of these factors from studies within each country can aid in the development of a rational approach to the allocation of resources aimed at obtaining asthma

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control and reducing the morbidity of this disease and the economic burden it entails (6,8).

The objectives of the present study were to assess the prevalence of uncontrolled and controlled asthma in Southern Brazil according to the GINA (2) definition, and to identify the factors associated with uncontrolled asthma at the outpatient clinic of our hospital.

Material and Methods

Study design

This was a prospective cross-sectional study in which all patients who volunteered were sequentially included. On the same day each subject underwent an evaluation that included answering a general structured questionnaire and an asthma control questionnaire, an assessment of inhaled device technique, and pulmonary function tests. The protocol was approved by the Ethics Committee of Hospital de Clínicas de Porto Alegre (HCPA), and written informed consent was obtained from all patients or from their parents in case of patients younger than 18 years.

Population

Patients were recruited from the outpatient Asthma Clinic of HCPA, Porto Alegre, State of Rio Grande do Sul, Brazil. The study included patients aged 11 years or older with a physician's diagnosis of asthma. The diagnosis was confirmed by a member of the research team and at least two of the following three criteria were fulfilled: symptoms of asthma, reversible airflow obstruction (improvement of 12% or more and 200 mL in forced expiratory volume in one second (FEV_1) after administration of a short-acting β_2-agonist) or bronchial hyperresponsiveness to a bronchoconstricting agent. Patients should have had at least 2 previous visits to the asthma clinic for medical care.

Patients were excluded if they refused to participate, if they had chronic pulmonary diseases other than asthma such as emphysema, chronic bronchitis or bronchiectasis, or if they did not complete all the evaluations required by the study protocol.

Measures and procedures

After a scheduled outpatient consultation with an asthma specialist, all subjects were interviewed by a research team member using a structured questionnaire that evaluated the influence of the following variables: age, gender, race, marital status, educational level, socioeconomic status, smoking status, comorbid conditions, access to asthma medications and their regular use, type of inhaler device and its correct use, asthma severity.

The structured questionnaire included a checklist to evaluate patients' proper handling of their usual device for the inhaled steroid. All research members were instructed by the principal investigator about the proper handling of each device and on how to score each step of the process. All patients were asked to demonstrate their technique to the research team member using a placebo device. If the patient was using a metered-dose inhaler (MDI) the following steps were evaluated: a) the vigorous shaking of the device before use; b) exhaling prior to the activation of the device; c) keeping a correct distance of 3 to 5 cm between the device and the mouth, if not using a spacer, or a good seal around the spacer when using it; d) breathing in slowly and deeply; e) breath holding for as long as 10 s. If the patient was using a dry powder inhaler (DPI: Diskus, Turbuhaler, or Aerolizer), the following steps were evaluated: a) a complete exhalation just before the activation of the device; b) good sealing of the lips around the device; c) breathing in slowly and deeply; d) breath holding for as long as 10 s. Incorrect handling of a device was defined as improper technique resulting in incorrect performance of any of the predefined steps.

To assess disease severity we used the 2002 GINA classification system according to daily medication regimen (9), which divides patients into 4 severity categories (mild intermittent; mild, moderate and severe persistent asthma) based on frequency of symptoms, spirometric data, and intensity of drug therapy.

The classification of asthma control was based on the 2006 GINA guidelines (2). Asthma was considered to be controlled if all these features were present: daytime symptoms twice a week or less and no asthma attack in the last 3 months (requiring oral corticosteroids, hospitalizations or emergency visits), no limitations of activities, no nocturnal symptoms or awakenings, need for reliever/rescue treatment twice a week or less, normal airflow (FEV_1 and peak expiratory flow rate (PEF), equal to or greater than 80% of predicted value). Asthma was considered to be partly controlled if one or two of the above features were absent. Asthma was considered to be uncontrolled if more than two features were absent or if asthma had caused hospital/emergency department admission in the previous 12 months.

Pulmonary function was assessed with a computerized spirometer (Jaeger, v 4.31, Germany). Forced vital capacity (FVC), FEV_1 and FEV_1/FVC were measured three times, and the best trial was reported. All parameters were reported as percent of predicted for age, height, and gender (10).

PEF was measured using a portable Peak Flow Monitor (Vitalograph; Boehringer Ingelheim, Germany). Three successive expiratory maneuvers were performed, and the one with the highest value was recorded. The result was reported as percentage of predicted for age, height and gender (11).

Statistical analysis

All 3 outcome measures of asthma control were analyzed as dichotomous measures: controlled (controlled and partly controlled) and uncontrolled asthma.

Data are reported as number of cases (proportion),

mean ± SD or median (interquartile range). Categorical comparisons were performed by the chi-square test with adjusted standardized residuals, using Yates's correction if indicated or by the Fisher exact test. The Student *t*-test or the Mann-Whitney U-test was used for comparison between groups for continuous variables.

Multivariable analyses were performed by using logistic regression techniques with enter method. The odds ratio (OR) from this analysis is the OR for uncontrolled asthma. Selected variables with a $P < 0.10$ were introduced in the binary logistic regression, controlled by gender and age.

Data analysis was carried out using the SPSS software package, version 15.0. The level of significance was set at $P < 0.05$. All probabilities reported were two-tailed.

Results

From March 2007 through November 2008, 334 eligible subjects were examined in the study. Thirty patients refused to participate, 27 patients were excluded because they had another chronic pulmonary disease, and 2 patients were excluded because they failed to complete all evaluations required by the study protocol. Thus, 275 patients were included in the study.

Table 1 shows the clinical characteristics of the patients. There were 206 (74.9%) females. Mean age was 51.0 ± 16.5 years (range: 11 to 86 years). There were 229 (83.3%) white and 46 (16.7%) non-white patients. One hundred and sixty-seven (60.7%) patients were never smokers, 98 (35.6%) were past smokers and 10 (3.6%) were current smokers. One hundred and sixty-four (59.6%) patients had no comorbid condition, 95 (34.5%) had one and 16 (5.8%) had two or more comorbid conditions. There were 38 (13.8%) patients with mild intermittent or persistent asthma, 93 (33.8%) with moderate asthma and 144 (52.4%) with severe persistent asthma. Asthma was controlled in 48 patients (17.5%), partly controlled in 74 (26.9%) and uncontrolled in 153 (55.6%). The mean FEV_1 was 69.3 ± 23.1% of predicted and the mean PEF was 64.3 ± 22.1% of predicted.

Table 2 summarizes the clinical characteristics of the sample and their relationship to asthma control classification. Patients with controlled and uncontrolled asthma were similar in regard to gender, age, race, body mass index, age at diagnosis, marital status, educational level, income level, smoking status, number of comorbid conditions, gastroesophageal reflux disease, and allergic rhinitis ($P > 0.05$). There was a significant association between asthma severity and asthma control ($P < 0.001$) so that most patients with mild and moderate asthma kept their disease under control, whereas most patients with severe asthma had uncontrolled status. FEV_1 and FVC were significantly lower in the uncontrolled group (63.9 ± 22.3 and 79.3 ± 14.7%, respectively) than in the controlled group (75.6 ± 22.5 and 83.3 ± 13.1%, respectively; $P < 0.001$ and $P = 0.032$). Also, PEF was significantly lower in the uncontrolled group than in the controlled group (58.2 ± 20.8 and 71.2 ± 21.6%, respectively; $P < 0.05$).

Table 1. Characteristics of the 275 patients who participated in the present study.

Characteristics	
Gender, N (%)	
Female	206 (74.9%)
Male	69 (25.1%)
Age (years), mean ± SD	51.0 ± 16.5
Race, N (%)	
White	229 (83.3%)
Non-white	46 (16.7%)
Smoking status, N (%)	
Never	167 (60.7%)
Past	98 (35.6%)
Current	10 (3.6%)
Comorbid conditions, N (%)	
None	164 (59.6%)
1	95 (34.5%)
≥2	16 (5.8%)
GINA severity classification, N (%)	
Mild, intermittent or persistent	38 (13.8%)
Moderate, persistent	93 (33.8%)
Severe, persistent	144 (52.4%)
GINA levels of asthma control, N (%)	
Controlled	48 (17.5%)
Partly controlled	74 (26.9%)
Uncontrolled	153 (55.6%)
FEV_1 % predicted, mean ± SD	69.3 ± 23.1%
PEFR % predicted, mean ± SD	64.3 ± 22.1%

N = number of cases; GINA = Global Initiative for Asthma; FEV_1 = forced expiratory volume in 1 s; PEFR = peak expiratory flow rate.

Table 3 shows the use of asthma medications and their relationship to the classification of asthma control. There was a significant association between access to asthma medications and asthma control ($P = 0.01$), so that most patients who privately acquired the medications had controlled asthma. The use of inhaled corticosteroids was significantly lower in the uncontrolled than in the controlled group (respectively, 83.7 *vs* 97.5%; $P < 0.001$). The use of oral corticosteroids was significantly higher in uncontrolled than in controlled asthma (8.5 *vs* 1.6%, respectively; $P = 0.026$). There were no significant differences with respect to the use of long-acting β_2-agonists, oral xanthine, inhaled corticosteroids + long-acting β_2-agonists, type of inhaler device, correct use of inhaler device, and correct use of a DPI ($P > 0.05$). The correct use of an MDI was less frequent in the uncontrolled group than in the controlled group (22.7

Table 2. Clinical characteristics of the patient sample and their relationship to asthma control classification.

Variable	Controlled (N = 122)	Uncontrolled (N = 153)
Gender, N (%)		
Female	85 (41.3%)	121 (58.7%)
Male	37 (53.6%)	32 (46.4%)
Age (years), mean ± SD	51.5 ± 16.6	50.6 ± 16.5
Race, N (%)		
White	100 (43.7%)	129 (56.3%)
Non-white	22 (47.8%)	24 (52.2%)
BMI (kg/m^2), mean ± SD	27.3 ± 5.1	27.5 ± 5.4
Age at diagnosis (years), median (IR)	30.0 (40.0)	22.0 (36.5)
Marital status, N (%)		
Married/cohabiting	64 (43.5%)	83 (56.5%)
Divorced/separated	20 (58.8%)	14 (41.2%)
Widowed	7 (25.9%)*	20 (74.1%)*
Never married	31 (46.3%)	36 (53.7%)
Educational level, N (%)		
≤8 years of school	74 (44.6%)	92 (55.4%)
>8 years of school and <high school	40 (44.9%)	49 (55.1%)
Higher education (≥high school)	8 (40.0%)	12 (60.0%)
Income level per annum, N (%)		
<US$8,300	80 (41.7%)	112 (58.3%)
US$8,300-27,660	40 (50.0%)	40 (50.0%)
>US$27,660	2 (66.7%)	1 (33.3%)
Smoking status, N (%)		
Never	71 (42.5%)	96 (57.5%)
Past	4 (40.0%)	6 (60.0%)
Current	47 (48.0%)	51 (52.0%)
Comorbid conditions, N (%)		
None	72 (43.9%)	92 (56.1%)
1	46 (48.4%)	49 (51.6%)
≥2	4 (25.0%)	12 (75.0%)
Reflux disease, N (%)	33 (37.5%)	55 (62.5%)
Allergic rhinitis, N (%)	61 (44.9%)	75 (55.1%)
GINA severity classification, N (%)		
Mild, intermittent or persistent	31 (81.6%)*	7 (18.4%)*+
Moderate, persistent	54 (58.1%)*	39 (41.9%)*
Severe, persistent	37 (25.7%)*	107 (74.3%)*
FVC % predicted, mean ± SD	83.3 ± 13.1	79.3 ± 14.7+
FEV_1 % predicted , mean ± SD	75.6 ± 22.5	63.9 ± 22.3+
PEF % predicted, mean ± SD	71.2 ± 21.6	58.2 ± 20.8+

N = number of cases; BMI = body mass index; IR = interquartile range; GINA = Global Initiative for Asthma; FVC = forced vital capacity; FEV_1 = forced expiratory volume in 1 s; PEFR = peak expiratory flow rate. Outcome measures of asthma control analyzed as dichotomous measures: controlled (controlled and partly controlled) and uncontrolled asthma. Chi-square test for categorical variable. *Standard adjusted residual >1.96 or <-1.96 implies significantly different percentages. Student *t*-test or Mann-Whitney U-test for continuous variables. +P < 0.05 compared to controlled group.

vs 44.2%, respectively; P = 0.017).

Logistic regression analysis identified three independent factors associated with uncontrolled asthma. Severity of asthma (OR = 5.33, P < 0.0001), access to asthma medications dependent on the public health system (OR = 1.97, P = 0.025) and regular use of inhaled corticosteroids (OR = 0.17, P = 0.030) were associated with risk of uncontrolled disease (Table 4).

Table 3. Use of asthma medications and their relationship to asthma control classification.

Variable	Controlled (N = 122)	Uncontrolled (N = 153)
Access to asthma medications, N (%)		
Dispensed by the public health system only	26 (21.3%)	42 (27.5)$^{+}$
By private acquisition only	88 (72.1%)*	86 (56.2)*
Dispensed by the public health system and by private acquisition	8 (6.6%)*	25 (16.3)*
Regular use of asthma control medications, N (%)		
IC, N (%)	119 (97.5%)	128 (83.7%)$^{+}$
LABA, N (%)	68 (55.7%)	81 (52.9%)
Oral xanthine	1 (0.8%)	7 (4.6%)
Oral corticosteroids, N (%)	2 (1.6%)	13 (8.5%)$^{+}$
IC + LABA, N (%)	68 (46.6%)	78 (53.4%)
Use of inhaler devices, N (%)		
MDI	47 (38.8%)	72 (49.7%)
Aerolizer	56 (46.3%)	49 (33.8%)
Turbuhaler	10 (8.3%)	11 (7.6%)
Diskus	7 (5.8%)	11 (7.6%)
Others	1 (0.8%)	2 (1.4%)
Correct use of inhaler device, N (%)	70 (58.3%)	66 (48.5%)
Correct use of MDI, N (%)	23 (44.2%)	17 (22.7%)$^{+}$
Correct use of a dry powder inhaler, N (%)	47 (62.7%)	46 (60.5%)

N = number of cases; IC = inhaled corticosteroid; LABA = long-acting β_2-agonist; MDI = metered-dose inhaler. Outcome measures of asthma control analyzed as dichotomous measures: controlled (controlled and partly controlled) and uncontrolled asthma. Chi-square test for categorical variables. *Standard adjusted residual >1.96 or <-1.96 implies significantly different percentages. $^{+}$P < 0.05 compared to controlled group. Percent of correct use of inhaler device calculated by the effective use of the device.

Table 4. Logistic regression for uncontrolled asthma.

Variable	Beta	P	OR	95%CI for OR
GINA severity classification (persistent severe asthma)	1.674	<0.0001	5.33	3.00-9.47
Use of inhaled corticosteroids	1.769	0.030	0.17	0.04-0.84
Mode of acquisition of asthma medications (dispensed by the public health system)	0.678	0.025	1.97	1.09-3.57
Gender (male)	-0.537		0.58	0.30-1.13
Incorrect use of inhaler device	0.387		1.47	0.83-2.61
Marital status (widowed)	0.708		2.03	0.67-6.16
Use of oral corticosteroids	0.938		2.55	0.45-14.60
Age	-0.006		0.99	0.98-1.01
Use of oral xanthine	0.530		1.70	0.18-16.25
Constant	-0.839		0.432	

OR = odds ratio; CI = confidence interval; GINA = Global Initiative for Asthma. Outcome measures of asthma control analyzed as dichotomous measures: controlled (controlled and partly controlled) and uncontrolled asthma.

Discussion

This study showed a high rate of uncontrolled asthma (55.6%) in patients who attended an outpatient asthma clinic in a large tertiary care, university-affiliated hospital in Porto Alegre**,** Brazil. We identified several independent factors associated with the risk of uncontrolled asthma: severity of asthma, access to asthma medications and use of inhaled corticosteroids.

Peters et al. (12) assessed 1812 patients to determine the prevalence of uncontrolled asthma in the United States. Similar to our findings, they demonstrated that 55% of patients had uncontrolled disease. Cazzoletti et al. (5) assessed 1042 adults with asthma in Europe and demonstrated the prevalence of uncontrolled disease in 32% of them.

The goal of asthma management is to achieve and maintain control of the disease without side effects from the therapies used (2). Both national and international asthma management guidelines (2,13-15) are now widely available and provide recommendations for the optimal control of asthma. However, despite the implementation of asthma guidelines around the world and the availability of highly effective medications to treat asthma symptoms and the underlying inflammatory component of the disease, asthma remains poorly controlled (16).

In the past, a number of markers have been separately considered to define the health status of asthmatic subjects (5) and, more recently, to evaluate asthma control (3,5,8,17). In the present study, we used a composite measure of asthma control according to a scheme based on GINA guidelines (2). Although this measure has not yet been validated, it simultaneously takes into account several markers of uncontrolled asthma (5). More recently, several studies have used this measure to evaluate asthma control (3-5,8,17).

Although asthma control and asthma severity are closely related, they distinctly measure different aspects of the disease. Severity is a better reflection of the natural history of the disease and is less likely to vary over the long term, whereas control is an expression of disease activity based on levels of symptoms over a given period. In other words, severity measures the intrinsic components of the disease, while control measures its dynamic aspects (9). In the present study, asthma severity was assessed by the GINA classification system according to daily medication regimen (6). With this approach, effective therapy could control the disease, but would not interfere with the classification of severity.

In the State of Rio Grande do Sul, the public health system provides ambulatory, hospital, and emergency care free of charge, but not all asthma medications for treatment of ambulatory patients. Beclomethasone dipropionate and short-acting β_2-agonists MDI are available at primary care public outlets in several cities, but a long-acting β_2-agonist (formoterol or salmeterol) and the combination therapy of a long-acting β_2-agonist with an inhaled corticosteroid are freely available only for a small percentage of patients. As a consequence, only 54.2% of the patients in this study were using a long-acting β_2-agonist and only 46.9% were using it as a combined therapy with an inhaled corticosteroid, despite appropriate prescription according to asthma severity. Logistic regression analysis showed that provision of asthma medications was significantly associated with asthma control (OR = 1.97). Patients who depend on the public health system for the acquisition of asthma medications had lower rates of controlled asthma. This finding can be explained by the fact that asthma medications were not always regularly dispensed by the public health system and when lack of needed medications occurs patients have to pay for their drug therapy. Availability of and accessibility to medications are determinants of adequate treatment and, consequently, of adequate asthma control (6).

In the present study, the regular use of inhaled corticosteroids was associated with a protective effect against uncontrolled asthma (OR = 0.17). Of 275 patients included in the study, 28 (18.8%) reported that they did not use inhaled corticosteroids despite medical prescription of this medication. Similar to our findings, Schatz et al. (1) reported regular use of inhaled corticosteroids as independently associated with better asthma control. Inhaled corticosteroids are the cornerstone of modern asthma treatment. They control the underlying airway inflammation in asthma by inhibiting many aspects of the inflammatory process (16). The delayed clinical impact of inhaled corticosteroids compared with the immediate relief obtained with bronchodilator drugs may be a factor of noncompliance (18). These data support the explanation that the poor control of asthma is due at least in part to inadequate treatment. Education has been shown to increase compliance (18). Thus, these patients should be considered to be the most important target for asthma education.

In our study, correct use of inhaled corticosteroid through an MDI was significantly lower in the uncontrolled group (22.7%) than in the controlled group (44.2%). Conversely, correct use of inhaled corticosteroid with a DPI was similar in the two groups (60.5 *vs* 62.7%). The effectiveness of inhaler therapy also depends on the inhaler technique, which is highly dependent on the type of device used. Cochrane et al. (18) showed that patients using a DPI such as the Turbuhaler and the Diskhaler had lower rates of inadequate technique. DPIs have the intrinsic advantage of a natural coordination between generation of the aerosol cloud and inspiration (19). Several studies have shown that education can have a great impact on the percentage of patients who correctly use an inhaler (20,21).

One or more comorbidities identified in our study were in 40.3% of patients with mean age of 51 years. There was no significant association between the level of asthma control and the number of comorbidities, and a possible

explanation for this finding was that these patients were under adequate treatment so that this common marker did not influence the asthma control status. Chen et al. (22) analyzed asthma control, severity and quality of life in 987 asthmatic adults and identified one or more comorbidities in 21% of patients with a mean age of 52.8 years. Similar to our findings, there was no association between the level of asthma control and the number of comorbidities. In contrast, Peters et al. (12) reported comorbidities significantly associated with uncontrolled asthma.

The present study has some potential limitations. It is a cross-sectional study, and therefore it is not possible to establish the temporal sequence between the factors studied and asthma control. It is worth noting that our institution provides free care for patients covered by the public health system. As a consequence, our study population is made up of people with lower income and education. Asthma is more prevalent and severe in lower socioeconomic groups (23), and our patient sample is biased toward the socially disadvantaged. However, the present study did not show any association between asthma control and socioeconomic status or educational level. Also, the study population was selected from patients referred to a reference center and was probably biased toward the more severe disease. Furthermore, Brazil is a country of continental dimensions and Rio Grande do Sul, a Southern State, cannot be used as an example representative of other regions of Brazil.

The present study showed a high rate of uncontrolled asthma among patients who attended at an outpatient asthma clinic in Porto Alegre, Brazil. Severity of asthma, access to asthma medications and use of inhaled corticosteroids were associated with the level of control. It is hoped that better education of patients and equal accessibility to medications will improve the asthma control level.

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