

Prevalence of Uncontrolled Severe Persistent Asthma in Pneumology and Allergy Hospital Units in Spain

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■ Abstract

Background: Severe persistent asthma is often poorly controlled and its prevalence in pneumology and allergy hospital units in Spain is unknown. *Objectives:* To determine the prevalence of uncontrolled severe persistent asthma in hospital units in Spain and to describe the clinical characteristics of this condition.

Methods: An observational, cross-sectional study was conducted in 164 Spanish hospital pneumology and allergology units. A record was made of all patients with asthma and patients with uncontrolled severe asthma (diagnosed on the basis of clinical criteria) seen in these units over 6 months. Information on sociodemographic variables, clinical characteristics, pharmacological asthma treatment, skin prick testing, total serum immunoglobulin E (IgE) levels, pulmonary function (forced expiratory volume in the first second and forced vital capacity), asthma control (Asthma Control Questionnaire [ACQ]), and quality of life (Asthma Quality of Life Questionnaire) was collected.

Results: According to the clinicians' judgement, 1423 out of 36 649 asthma patients (3.9%, 95% confidence interval, 3.7%-4.1%) had uncontrolled severe persistent asthma. These patients had a mean (SD) ACQ score of 3.8 (1.0); 55.8% had a positive skin prick test to common aeroallergens and 54.2% had high levels of total serum IgE. The agreement between the assessment of asthma control based on clinicians' criteria and according to the Global Initiative for Asthma (GINA) guidelines was moderate (63.2%, $\kappa=0.337$), with an underestimation of asthma severity by clinicians; 53.2% of the patients classified as having controlled moderate to severe asthma had uncontrolled severe persistent asthma according to GINA criteria.

Conclusions: There is a low prevalence of uncontrolled severe persistent asthma in patients seen at hospital units in Spain according to clinical criteria, although it should be noted that level of asthma control is overestimated by clinicians.

Key words: Prevalence. Asthma. Uncontrolled. GINA guidelines.

■ Resumen

Antecedentes: Normalmente, el asma persistente grave no está adecuadamente controlada, y su prevalencia en unidades hospitalarias de neumología y alergia en España es desconocida.

Objetivos: Determinar la prevalencia del asma persistente grave no controlada y describir sus características clínicas.

Método: Estudio observacional transversal llevado a cabo en 164 unidades hospitalarias de neumología y alergia en España. Se registraron pacientes con asma y con asma grave no controlado, de acuerdo a criterios clínicos, que acudieran a los servicios en un período de 6 meses. Se recogieron datos sociodemográficos, características clínicas, tratamiento farmacológico del asma, pruebas cutáneas, total IgE en suero, función pulmonar (FEV1, FVC), test de control del asma (ACQ), y cuestionario de calidad de vida relacionada con el asma (AQLQ).

Resultados: Un total de 1.423 (3,9% [CI 95%: 3,7-4,1%]) sobre 36.649 pacientes con asma tenían enfermedad grave persistente no controlada de acuerdo a criterio médico. Los pacientes con asma grave no controlada tenían una puntuación ACQ media de 3,8 (1,0), 55,8% de estos pacientes tenían prueba cutánea positiva a los alérgenos aéreos comunes, y el 54,2% tenían niveles altos de IgE en suero. El acuerdo entre la valoración del médico y las guías GINA fue moderado (63,2%, Kappa=0,337), con una infraestimación de los pacientes no controlados por parte del especialista; 53,2% de los pacientes deberían ser considerados como con asma persistente grave no controlada (de acuerdo con GINA) por sus médicos.

Conclusiones: El asma persistente grave no controlada entre los pacientes con asma que acuden a unidades hospitalarias en España muestra una baja prevalencia de acuerdo a criterio médico. Sin embargo, el nivel de control del asma está sobreestimado por los médicos.

Palabras clave: Prevalencia. Asma. No controlada. Guías GINA.

Introduction

Asthma is one of the most common chronic airway diseases worldwide, with an estimated prevalence of 300 million people [1]. The International Study of Asthma and Allergies in Childhood (ISAAC) has shown that asthma prevalence is similar across Western European Mediterranean countries (8.9%-13.5%), with the exception of Greece, which has one of the lowest prevalence rates (3.7%) [2,3]. According to a phase-III ISAAC study conducted in 2002 and 2003, the prevalence of asthma in Spanish children aged 6 to 7 years is 10.7% for boys and 8.2% for girls; in children aged 13 to 14 years, the respective rates are 9.3% and 9.2% [4]. There are scarce data regarding the prevalence of asthma in adults, and rates vary greatly from one geographical area to the next. It is, however, widely accepted that approximately 5% of the Spanish adult population have asthma [5,6].

The Global Initiative for Asthma (GINA) guidelines establish 2 classification systems for asthma [7]. One is based on severity (intermittent, mild persistent, moderate persistent, or severe persistent) and the second, more recent, one is based on level of asthma control (controlled, partly controlled, or uncontrolled).

The GINA guidelines were developed to improve the quality of care for patients with asthma and to reduce the public health burden associated with the disease.

However, despite guidelines and new therapeutic approaches many asthmatic patient do not achieve an acceptable asthma control [8,9]. The Real-world Evaluation of Asthma Control and Treatment (REACT) study conducted in the United States among patients with moderate to severe asthma receiving standard asthma medications found a high proportion of patients with uncontrolled asthma (55%) [9]. The Asthma Insights and Reality in Europe (AIRE) study, in turn, also showed suboptimal asthma control in children and adults in Western Europe and reported that only 5.3% of the population surveyed met all the goals established by the GINA guidelines [8,10]. A recent study assessing degree of asthma control in Spain according to the GINA criteria concluded that asthma was poorly controlled and that strategies were needed to improve the management of this disease [11].

Direct and indirect medical costs associated with asthma are very high, and moreover 1 in every 250 deaths worldwide is asthma related [1]. The cost of treating the consequences of poor asthma control accounts for a large proportion of the total cost of asthma. Additionally, while just a small group of patients have uncontrolled severe persistent asthma, they use a disproportionate amount of health care resources (>50% of asthma-related health care resources). It has been estimated that the cost of a patient with severe asthma in Spain is almost 6 times that of a patient with moderate asthma [12].

Moreover, quality-of-life assessments have shown that asthma has a considerable socioeconomic impact [13]. A study of the cost-effectiveness of an intervention based on the GINA recommendations concluded that the implementation of an asthma management program based on these recommendations improved patient quality of life and was cost effective [14].

In view of the important clinical and economic repercussions

of asthma, and the little information available on this condition, and on uncontrolled asthma in particular, we wished to obtain information on the usage of the GINA guidelines and treatment of uncontrolled asthma in Spain and to contribute to characterizing the clinical profile of these patients and the risk factors associated with severe uncontrolled asthma.

The main objective of the study was to determine the prevalence of severe uncontrolled asthma, in asthma patients seen at pneumology and allergology hospital units in Spain. The secondary objectives were 1) to describe the clinical characteristics of patients with moderate to severe asthma and uncontrolled severe asthma; 2) to evaluate the risk factors associated with severe uncontrolled asthma; 3) to determine the agreement between assessment of asthma severity based on clinical criteria and the 2006 GINA guidelines [7]; and 4) to assess the quality of life of patients with moderate to severe asthma or uncontrolled severe asthma.

Material and Methods

Two-hundred-and-one pneumology and allergology researchers at hospital units proportionally distributed throughout Spain were approached to participate in this cross-sectional, observational, epidemiologic study. Of these 201 specialists, 164 agreed to recruit patients.

Simultaneous data were collected over a period of 6 months as follows:

1. A daily record was made of all patients with asthma (regardless of severity or level of control) who attended the pneumology or allergology units at the participating hospitals. Both inpatients and outpatients were included. Prevalence was calculated according to the total number of patients with asthma and the total number of patients diagnosed with uncontrolled severe persistent asthma. Asthma severity was determined by clinicians on the basis of their own criteria.

2. All researchers were asked to recruit 5 consecutive patients with moderate to severe controlled asthma and all patients with uncontrolled severe persistent asthma. Accordingly, no formal sample calculations were performed.

Table 1. Features Used to Define Uncontrolled Asthma

Characteristics	Uncontrolled Asthma	
Daytime symptoms		Daily
Limitations of activities		Yes
Nocturnal symptoms/ awakening	Three or more features	More than once a week or frequently
Need for reliever/rescue treatment		Yes
Lung function (FEV ₁)		<80%
Exacerbations		More than 3 a year

Abbreviation: FEV₁, forced expiratory volume in the first second.

The following inclusion criteria were applied: patients of either sex, an age of over 12 years, clinical history and spirometry performed in the last 6 months, a diagnosis of moderate to severe asthma or uncontrolled severe asthma, and the provision of written informed consent.

All the patients recruited (ie, diagnosed by clinicians as having either moderate to severe asthma or uncontrolled severe persistent asthma) were then assessed for uncontrolled asthma according to the GINA guidelines [7]. Because this study was designed before the 2006 GINA asthma control classification [7], some considerations were made. Patients with uncontrolled asthma were defined as patients with more than 3 exacerbations per year and/or patients who presented at least 3 of the 5 features listed in Table 1.

The clinical profile of the patients classified as having uncontrolled asthma based on the GINA criteria was evaluated with assessment of socio-demographic data, clinical characteristics, pharmacological asthma treatment, skin prick tests, total serum immunoglobulin (Ig) E, spirometry parameters (forced expiratory volume in the first second and forced vital capacity), asthma control (using the Asthma Control Questionnaire [ACQ]) [15], and quality of life (using the Asthma Quality of Life Questionnaire [AQLQ]) [16].

The study was approved by the ethics committee at Hospital Clinic i Provincial de Barcelona, Spain and duly reported to the Spanish Health Agency (AEMPS).

Statistical Analysis

Statistical analyses were conducted using SAS software (version 9.1.3). Qualitative variables were analyzed by the χ^2 or Fisher exact test, as appropriate, and quantitative variables were analyzed using the *t* test, the Mann-Whitney test, or analysis of variance. Values of $P < .05$ were considered statistically significant. The strength of associations were expressed as odds ratio (ORs) and 95% confidence intervals (CIs).

Agreement between asthma severity determined by clinicians and according to the GINA guidelines was evaluated using Cohen's κ coefficient.

Results

A total of 36 649 asthmatic patients were screened by the 164 participating hospitals during the 6 months of the study. The prevalence of uncontrolled severe persistent asthma diagnosed by clinicians was 3.9% (95% CI, 3.7%-4.1%).

A total of 1131 patients with uncontrolled severe persistent asthma or moderate to severe asthma were recruited. Of these, 120 (10.6%) did not meet the inclusion criteria and were excluded, leaving 1011 patients (89.4%). According to the GINA guidelines, 666 patients (65.9%) had uncontrolled severe persistent asthma and 345 (34.1%) had moderate to

Table 2. Baseline Characteristics of 1011 Patients With Moderate to Severe Asthma (MSA) and Uncontrolled Severe Persistent Asthma (USPA)

Baseline Characteristics	Total	MSA ^a	USPA ^a	<i>P</i>
Patients, No. (%)	1011 (100)	345 (34.1)	666 (65.9)	
Age, mean (SD), y	48.8 (17.3)	48.8 (18.1)	48.9 (16.9)	–
Females, %	65.0	59.1	68.0	.0050
Height, mean (SD), cm	163.0 (9.4)	164.0 (9.5)	162.4 (9.3)	.0107
Weight, mean (SD), kg	72.5 (14.3)	72.0 (13.7)	72.7 (14.6)	–
BMI, mean (SD), kg/m ²	27.3 (5.2)	26.8 (4.7)	27.6 (5.4)	.0214
FVC \leq 80%, %	58.3	47.1	64.0	<.0001
FEV ₁ \leq 80%, %	79.0	72.0	82.5	<.0001
Skin prick test positivity, %	54.2	51.2	55.8	–
Total serum IgE, ^b %	49.7	41.2	54.2	.0006
Sedentarism, % of patients	35.4	26.8	39.9	<.0001
Age of asthma onset, mean (SD), y	29.7 (18.1)	33.4 (19.9)	27.9 (16.8)	<.0021
Exacerbations, ^c mean (SD), No.	3.3 (3.8)	1.5 (1.0)	4.3 (4.3)	<.0001
Oral corticosteroid courses, ^d mean (SD), No.	1.8 (2.6)	0.7 (1.0)	2.4 (3.0)	<.0001
Asthma admissions, ^d mean (SD), No.	0.4 (0.7)	0.1 (0.3)	0.5 (0.8)	<.0001
Emergency visits, ^d mean (SD), No.	1.4 (1.9)	0.6 (1.0)	1.9 (2.1)	<.0001
Unscheduled visits, ^d mean (SD), No.	2.3 (2.6)	1.1 (1.5)	2.9 (2.8)	<.0001
ACQ score, ^e mean (SD)	3.3 (1.2)	2.4 (0.8)	3.8 (1.0)	<.0001
AQLQ score, ^f mean (SD)	4.0 (1.2)	4.8 (1.0)	3.5 (1.1)	<.0001

Abbreviations: ACQ, Asthma Control Questionnaire; AQLQ, Asthma Quality of Life Questionnaire; BM, body mass index; IgE, immunoglobulin E.

^aDiagnosis based on clinicians' criteria.

^bElevated IgE values.

^cExacerbations over the last 12 months.

^dVisits or admissions over the last 6 months.

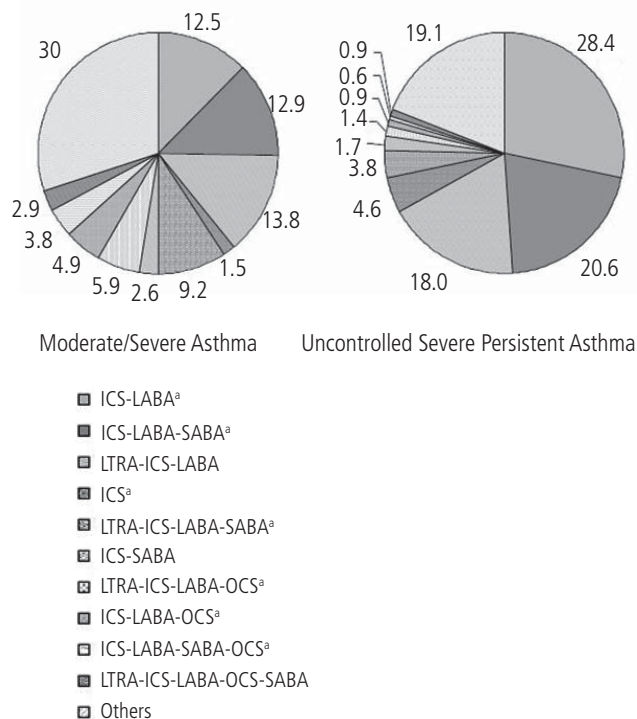
^eTotal possible score, 0-6, with lower scores indicating improved asthma control.

^fTotal possible score, 1-7, with lower scores indicating poorer quality of life.

severe controlled asthma. The demographic and clinical characteristics of these patients are shown in Table 2. Compared to the moderate to severe asthma group, in the uncontrolled severe persistent asthma group, there was a significantly higher proportion of women, sedentary patients, and patients with elevated total serum IgE levels; this group also had a significantly higher body mass index (BMI) and earlier onset of asthma. They also had significantly higher rates of health care use in terms of asthma admissions, emergency room visits, and unscheduled visits. Finally, they had higher ACQ scores and lower AQLQ scores, indicating poorer asthma control and worse quality of life, respectively.

No significant differences were found between the 2 groups for age, geographic area, place of residence (rural vs urban), exposure to animals, smoking habit, or skin prick test results (data not shown).

Of the 861 patients with positive skin prick tests, 467 (54.2%) were sensitized to at least 1 aeroallergen; 52.9% were sensitized to mites, 44.8% to pollen, 29.6% to animal epithelia, and 12% to fungi (*Alternaria* or *Aspergillus*). No statistical differences were observed between patients with moderate to severe asthma and those with uncontrolled severe persistent asthma.



^aP<.05 (statistical differences between both groups of patients)

Figure 1. Pharmacological asthma treatment for patients with moderate to severe asthma (n=345) and patients with uncontrolled severe persistent asthma (n=666). ICSs indicates, inhaled corticosteroids; LABAs, long-acting beta-agonists; SABAs, short-acting beta-agonists; LTRAs, leukotriene receptor antagonists; OCSs, oral steroids. The "others" category includes anticholinergics, xanthines, immunotherapy, chromones, mucolytics, antihistamines, anti-immunoglobulin E therapy, and combined therapies with low frequency.

The risk factors significantly associated with uncontrolled severe persistent asthma were female sex (OR 1.5; 95% CI, 1.1-1.9; P=.0051), and high BMI (OR 1.0; 95% CI 1.0-1.1; P=.0218).

The most common pharmacological treatments overall were inhaled corticosteroids (ICSs) (97.5%), long-acting β -agonists (LABAs) (90.0%), and leukotriene receptor antagonists (LTRAs) (44.3%). Patients with uncontrolled severe persistent asthma had a significantly higher use of the following treatments compared to patients with moderate to severe asthma: LTRAs (49.5% vs 34.0%), short-acting β -agonists (SABAs) (45.1% vs 35.2%), oral corticosteroids (OCSs) (28.5% vs 4.5%), anticholinergics (20.8% vs 9.3%), and xanthines (9.6% vs 1.8%). It should be noted that patients may have been receiving more than 1 treatment.

The analysis of pharmacological treatments by monotherapy or combined therapy showed that the most common treatments were ICSs-LABAs, ICSs-LABAs-SABAs, and LTRAs-ICSs-LABAs in both groups. The statistical analysis of these data showed significant differences in some treatments (Figure 1).

According to the GINA guidelines, 345 patients had moderate to severe asthma, corresponding to an agreement level of 94.8% with the clinicians' diagnosis. In other words, 5.2% of patients with moderate to severe asthma were diagnosed with uncontrolled severe persistent asthma by clinicians. A total of 666 patients were classified as having uncontrolled severe persistent asthma according to the GINA guidelines, yet 53.2% of these were diagnosed with moderate to severe controlled asthma by clinicians. The level of agreement in this case was 63.2% ($\kappa=0.3372$) (Figure 2).

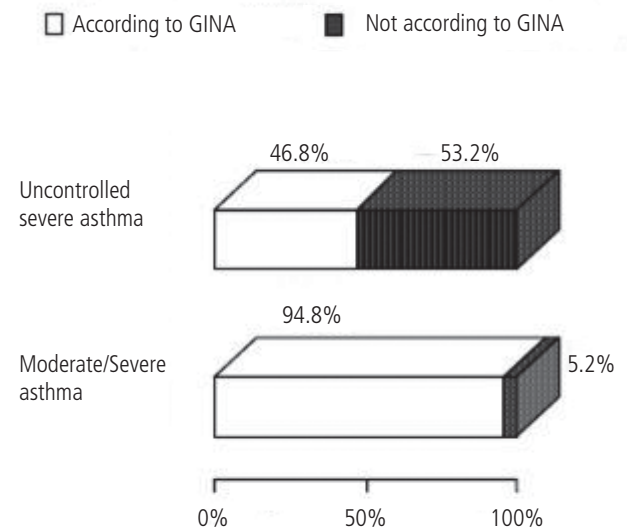


Figure 2. Agreement between diagnosis based on GINA guidelines and clinicians' criteria.

Discussion

Asthma is a major public health problem, and uncontrolled asthma has considerable social and economic impacts [13].

However, some studies have demonstrated that physicians underestimate asthma severity, contributing to poor adherence to guidelines [17]. This is reflected by the poor level of asthma control observed in other studies [8-10, 18-19]. To our knowledge, ours is the first study to assess the prevalence of uncontrolled severe persistent asthma based on clinical criteria in patients attending hospital units in Spain.

The results show a low prevalence of uncontrolled severe persistent asthma (3.9%). The AIRE study showed that just 5.3% of all patients in European countries met all the GINA criteria for asthma control [10], while a study conducted by the ESCASE Group in Spain showed a high number of patients with inadequate asthma control, with slightly higher figures in winter than in spring (74.4% vs 71%) [20]. Another study conducted in Spain reported a similar rate of uncontrolled asthma (71.6%) [21]. These studies, however, included patients with mild and moderate disease. Furthermore, they defined uncontrolled asthma according to GINA guidelines, in combination with the ACQ or the Asthma Control Test [7,14,22], contrasting with our study, in which level of control was determined according to clinical criteria.

Some of the differences between our results and those reported by the above-mentioned studies might be due to the fact that our study included patients who attended hospital allergy or pneumology hospital units on a regular basis, while the others included patients who were not regularly visited by physicians and who were seen even less by specialists.

Our analysis of the agreement between a diagnosis of uncontrolled severe persistent asthma based on GINA guidelines and clinicians' criteria showed that more than half of the patients (53.2%) originally classified as having moderate to severe asthma actually had uncontrolled severe persistent asthma according to the GINA guidelines, indicating a considerable underestimation of disease severity by clinical specialists. These data highlight the importance of following the GINA guidelines in order to achieve good asthma control.

Our results also show that uncontrolled severe persistent asthma was associated with significantly higher rates of health care use than moderate to severe asthma, supporting results recently published by Peters et al [9].

In agreement with reports of more asthma symptoms and poorer quality of life in female patients [23], our study found that female sex was a risk factor for uncontrolled disease. In contrast, Peters et al [9] observed an association between male sex and uncontrolled asthma (OR 1.59; 95% CI, 1.19-2.13) [9].

BMI was also found to be a risk factor for uncontrolled disease, concurring with reports by Mosen et al [24], who found that higher BMI was associated with poor asthma control (OR 2.7; 95% CI, 1.7-4.3). Higher BMI and obesity have also been proposed as potential behavioral factors related to worse asthma control [25].

Our survey shows that uncontrolled asthma is largely underdiagnosed by clinicians, underlining the need to encourage physicians to implement GINA recommendations in order to achieve good asthma control.

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