Allergol Immunopathol (Madr). 2014;42(6):510–517

Allergologia et immunopathologia

Sociedad Española de Inmunología Clínica, Alergología y Asma Pediátrica

www.elsevier.es/ai

ORIGINAL ARTICLE

# Prevalence and clinical profile of difficult-to-control severe asthma in children: Results from pneumology and allergy hospital units in Spain

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Received 20 December 2013; accepted 6 February 2014
Available online 16 June 2014

**KEYWORDS**
Childhood;
Difficult-to-control asthma;
GEMA;
Health-related quality of life;
Severe asthma

**Abstract**
*Background:* Severe asthma is often poorly controlled and its prevalence in Spanish children is unknown. The aim was to determine the prevalence of difficult-to-control severe asthma in children, the agreement of asthma control between physicians and Spanish Guidelines for Asthma Management (GEMA), and the health-related quality of life (HRQoL) for children and parents.
*Methods:* Observational, cross-sectional, two-phase, multicentre study. In the first phase, all children who attended pneumology and allergy units during a three-month period were classified according to physicians' criteria as patients with: asthma, severe asthma, or difficult-to-control severe asthma. Patients aged 6–14 years with severe asthma (difficult-to-control or controlled) were included in the second phase.
*Results:* 12,376 asthmatic children were screened in the first phase. According to physicians' criteria, 8.8% (95% CI 8.3–9.3%) had severe asthma. Of these, 24.2% (95% CI, 21.7–26.8%) had difficult-to-control severe asthma. 207 patients with severe asthma (mean age $10.8 \pm 2.3$ years; 61.4% male; mean of $5.5 \pm 3.4$ years since asthma diagnosis) were included in the second phase. Compared to the patients with controlled asthma, children with difficult-to-control asthma had a higher number of exacerbations, emergency room or unscheduled primary care visits in the previous year ($p < 0.0001$, all) and poor HRQoL ($p < 0.0001$, both children and caregivers). 33.3% of patients with controlled asthma according to physicians' criteria were poorly controlled according to GEMA.

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http://dx.doi.org/10.1016/j.aller.2014.02.003

*Conclusions:* Around one in four asthmatic children with severe disease had difficult-to-control asthma, although one third was underestimated by physicians. Children with difficult-to-control severe asthma had a poor HRQoL that also affected their parents.


## Introduction

Asthma is the most common chronic disease in childhood.[1] It is estimated that in economically developed countries approximately 10% of the paediatric population is affected by this disease.[2] Due to the absence of a concrete and precise definition of asthma, a lack of standardisation, and the disparity of the diagnostic criteria, studies on the prevalence of this disease vary in methodology and consequently are difficult to compare. Considering these limitations, the available data indicate large geographical differences with a prevalence rate varying from 6.6% to 33.5%.[3,4] The International Study of Asthma and Allergies in Childhood (ISAAC Phase III, 2005) reported asthma diagnosis figures in Spain that range from 12.8% in children aged 13–14 years to 10.9% in children aged 6–7 years.[5]

Asthma causes deterioration of health-related quality of life (HRQoL) in children and adolescents due to the limitation of daily activities; physical and recreational activities; interference with sleep, academic performance, truancy; and working absenteeism of parents.[6] Likewise, the economic burden and HRQoL are worsened by those exacerbations requiring unscheduled visits and emergency care and hospital admissions.

After the remarkable progress in reducing infant mortality from asthma, the current challenge is to set new goals to improve the global control of the disease and to encourage early medical intervention in an attempt to change the course of the disease.[7] In this context, the Spanish Guidelines for Asthma Management [GEMA][8] define asthma control as the degree by which its symptoms are absent or by the maximum degree that they can be reduced due to therapeutic interventions and treatment goals met. Some studies estimate that more than half of asthmatics fail to achieve adequate control.[9–11] In this regard, difficult-to-control asthma is defined as asthma which is inadequately or poorly controlled despite an appropriate therapeutic strategy that is adjusted to clinical severity. In general, the factors that contribute to asthma being difficult-to-control are not known, however both genetic and epidemiological factors appear to be involved.[12] The classification of childhood asthma is in accordance with its severity, symptomatology, rescue bronchodilator requirement, and respiratory function test data. Two major patterns have been defined: episodic (occasional or frequent, depending on the number of exacerbations) and persistent asthma, which cannot be treated as if it were a mild disease, but rather as at least moderate or severe.

The aim of this study was to determine the prevalence of severe asthma as well as the prevalence of difficult-to-control severe disease in asthmatic children. Additionally, the clinical characteristics of patients with difficult-to-control severe asthma, the agreement between clinical assessment of asthma control and the 2009 GEMA guidelines, the HRQoL of patients and their caregivers, and predictive factors for difficult-to-control severe asthma were assessed.

## Materials and methods

This was an observational, cross-sectional, two-phase, multicentre study conducted in 30 hospitals in Spain. Simultaneous data from two study phases were collected over a period of three months. In the first phase, a daily record was made of all children who attended the pneumology and allergy units of the participating hospitals. The patients were classified according to the physicians' criteria as patients with: asthma, severe asthma, or difficult-to-control severe asthma. In the second phase, each physician consecutively included six or seven patients with severe asthma (either with difficult-to-control asthma or with controlled asthma). The following inclusion criteria were applied in the second phase: patients of either sex, aged 6–14 years, having a spirometry performed in the previous six months, and diagnosis of severe asthma according to the physicians' criteria.

The clinical profile of the patients included in the second phase was evaluated by assessing the socio-demographic data, medical history (date of diagnosis, number of exacerbations in the previous year, and number of times that systemic corticosteroids where needed in the previous six months), clinical classification of the asthma type (allergic or non-allergic asthma) and the level of asthma control according to the physicians' criteria (controlled or difficult-to-control asthma), number of hospitalisations, emergency room visits, and unscheduled primary care visits due to asthma symptoms in the previous six months, relevant concomitant diseases, data from respiratory and allergy testing available in the previous six months (forced vital capacity [FVC], forced expiratory volume in one second [$FEV_1$], plasma levels of immunoglobulin E [IgE], and skin prick test) and current pharmacologic therapy for asthma.

According to the GEMA guidelines,[8] the assessment of asthma control was performed by means of the Childhood Asthma Control (CAN) questionnaire,[13] the only available questionnaire validated in Spain to estimate the extent to which asthma is controlled in children. This questionnaire has two versions: (1) for children aged 9–14 years, and (2) for parents or legally authorised representatives (children aged 2–8 years). In children aged 6–8 years the questionnaire was completed by the parents or legally authorised representatives. Children/teenagers aged 9–14 years filled out the questionnaire themselves and the parents or legally authorised representatives filled out their own. The questionnaire evaluates nine questions about clinical symptoms in the previous four weeks and scores the results from 0