

RESEARCH ARTICLE



Asthma severity: the patient's point of view

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ABSTRACT

Objective: Initiated by the Severe Asthma Network Italy (SANI), this study aims to explore asthma patients' perceptions of disease severity, differentiating between mild and severe asthma. The objective is to identify factors influencing tailored treatment strategies for varying disease severities and to provide insights into asthma care in Italy.

Methods: Conducted between November 2020 and January 2021, a survey using Computer-Assisted Personal Interviewing (CAPI) collected data from 308 Italian adults, representing the population. A 25 item multiple choice questionnaire covered asthma diagnosis, symptoms, treatment approaches, associated conditions, and quality of life.

Results: Among participants, 83.8% reported having mild asthma, while 16.2% had severe asthma. Severe asthma patients had longer disease durations, more severe symptoms, frequent exacerbations, and higher hospital/ER visits. Although treatment adherence and symptom profiles generally aligned with international guidelines for self reported severe asthma, 22% of self identified mild asthmatics experienced severe respiratory symptoms. Oral corticosteroid (OCS) use was observed in 50% of severe cases and 22% of mild cases. Adherence was higher in severe asthma patients (76%) versus mild asthma patients (28%). Both groups experienced comorbidities, with 96% of severe asthmatics and 72% of mild asthmatics reporting impaired quality of life.

Conclusion: This study highlights the disparity between clinical categorization and patient perceptions of asthma severity. The prevalence of self reported severe asthma exceeds literature data. The burden of mild asthma remains significant, with treatment approaches not fully aligned, particularly regarding disproportionate OCS use. Addressing this gap requires enhancing patient education, improving diagnostic practices, and promoting adherence.

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Introduction

Asthma is a chronic respiratory condition characterized by the inflammation of the bronchial airways, leading to intermittent or persistent constriction of the bronchi. The symptoms of asthma can be highly variable, ranging from mild discomfort to severe breathing difficulties. They may include shortness of breath, wheezing, coughing, and chest tightness, and these symptoms can change over time [1]. Asthma can restrict daily activities and negatively affect the quality of life for the patients. The symptoms might inhibit normal functioning, leading to a sense of limitation. Asthma exacerbations may require immediate medical care, adding stress and burden to both patients and their families. The challenges of asthma control thus extend beyond physical discomfort, impacting various aspects of life [2,3].

The understanding that patients have of their asthma is a critical factor in the management of the disease, as it directly influences their ability to diligently follow prescribed treatments. Being conscious of the nature of asthma, its triggers, and the importance of consistent treatment can make a significant difference in controlling symptoms. In fact, adherence to treatment represents one of the most substantial obstacles in effectively managing this disease [4,5].

According to the recommendations provided by the Global Initiative on Asthma (GINA), the severity of asthma is categorized based on the necessary treatment to manage and control the disease. If symptoms and

night-time disturbances are either absent or infrequent, and daily activities are only minimally affected through the utilization of Step1 or Step2 GINA treatment (including symptom responsive low dose inhalation of corticosteroids (ICS)formoterol as needed and/or for chronic therapy, or the use of leukotriene receptor antagonists (LTRAs)), asthma is referred to as 'mild.' Conversely, 'severe' asthma is characterized by frequent exacerbations, defined as acute or sub-acute worsening in symptoms and lung function from the patient's usual status, the occasional or constant necessity for oral corticosteroids (OCS) and may be controlled or remain uncontrolled even with the most maximum treatment protocol [6].

While the categorization of asthma's severity is pertinent for healthcare professionals to formulate and standardize the treatment approach, it may hold less importance for the patient suffering from the disease. For the patient, the classification of severity often relies more on personal experience and subjective assessment of symptoms. What physicians view as a clear categorization system may not align with how the patient perceives or experiences their condition. This discrepancy between clinical evaluation and personal perception can influence the patient's engagement with treatment and even affect how they manage and respond to their asthma [7,8]. This study, commissioned by the Severe Asthma Network Italy (SANI), aims to understand how asthma patients perceive the severity of their condition, with a particular focus on the distinctions between mild and severe asthma. By shedding light on these differences in awareness, we aim to elucidate

potential influences on treatment and management strategies tailored to varying disease severity levels. Through an examination of epidemiology, symptoms, and treatment patterns, we attempt to provide a complete picture of asthma care in Italy in order to focus on possible critical areas for future action.

Methods

Under the directive of SANI and the Italian Society of Allergy Asthma and Clinical Immunology (SIAAIC), an ad hoc survey was conducted by DOXAPHARMA, a research institute based in Milan, according to the method commonly used for marketing. DOXAPHARMA was responsible for selecting participants from a large database of individuals who willingly took part in market research and provided demographics (including gender, age, region, and socioeconomic status) useful for profiling and stratifying them to ensure a representative sample of the the Italian adult population (aged 18–85). A telephone interview was carried out at the participants' homes in order to verify the eligibility requirements, including the doctor diagnosed asthma. In terms of ethical aspects, the survey was approved by the SIAAIC internal committee and subsequently commissioned to DOXAPHARMA. An informed consent was administered by the interviewer to each patient prior to the interview, according to art.13-14 of the European Regulation NO. 679/2016. In the case the consent was not obtained the interview didn't take place.

The specific purposes of the study was not detailed, in order to avoid that such information could influence their decision to take or not the survey. The patients were invited to a free interview, no fee or other kind of compensation was offered.

A total number of 308 asthmatic patients was selected for filling a 25 item multiple choice questionnaire that was formulated by SANI experts, focusing on various aspects of asthma such as diagnosis, symptoms, treatment approaches, associated conditions, and quality of life. The survey, spanning from November 2020 to January 2021 and taking roughly 15 minutes each, were conducted with the assistance of a Computer Assisted Personal Interviewing (CAPI) system, using a laptop computer.

The full report of the survey is currently accepted for the publication in a peer review journal [9].

The questionnaire is available as Appendix 1 attached to the present paper.

Results

Study population

Demographic and clinical data regarding the entire study population and the comparison between the two groups, selfdefined having mild and severe asthma are shown in Table 1.

Out of the total pool of 370 potential subjects contacted for the research, 308 individuals (83% of the sample) agreed to participate. Among these 308 respondents, there was an equal representation of genders, with 50% being men and 50% women. The age range of the participants varied from 18 to 84 years. The participants were geographically distributed uniformly across Italy. Specifically, 27% of the respondents came from North-West regions, 25% from North-East regions, 24% from Central regions, and another 24% from Southern regions and the islands.

The main findings of the study are summarized in Figure 1.

Diagnosis

In the study's participant cohort, 83.8% (258 patients) reported experiencing mild asthma, while 16.2% (50 subjects) acknowledged having severe asthma (as shown in Table 1).

Among the healthcare specialists involved, pneumologists were the predominant group responsible for diagnosing asthma in the participants. Furthermore, it was noted that individuals with severe asthma had a longer duration of the disease compared to those with mild asthma. In particular, 82% of patients with severe asthma had been diagnosed for at least 5 years, while among patients with mild asthma, the percentage was 69%.

Symptoms severity

Every participant with severe asthma in the study reported experiencing severe symptoms, whereas only 22% of subjects with mild asthma acknowledged similar symptoms. In addition, all patients with severe asthma experienced typical asthma symptoms, including dry cough, wheezing and dyspnea. In contrast, only 17% of patients with mild asthma reported experiencing all these symptoms. Among the individuals with mild asthma, 52% stated that they experienced at least one exacerbation per year, and 24% reported experiencing more than one exacerbation within the same time-frame. On the other hand, all patients with severe

Table 1. Demographic and clinical characteristics of the study population, stratified by asthma severity.

	Total	Mild asthma	Severe asthma
Population	308	258 (83,8%)	50 (16,2%)
Gender (F)	50%		
Age (years)	18-84		
Who made the diagnosis	<ul style="list-style-type: none"> • Pneumologist: 50% • General Practitioner: 27% • Allergist: 22% • Other: 1% 	<ul style="list-style-type: none"> • Pneumologist: 45% • General Practitioner: 31% • Allergist: 24% • Other: 1% 	<ul style="list-style-type: none"> • Pneumologist: 76% • General Practitioner: 6% • Allergist: 16% • Other: 2%
Disease duration (years)	<ul style="list-style-type: none"> • > 10 years: 50% • 5-10 years: 21% • < 5 years: 29% 	<ul style="list-style-type: none"> • > 10 years: 50% • 5-10 years: 19% • < 5 years: 31% 	<ul style="list-style-type: none"> • > 10 years: 46% • 5-10 years: 36% • < 5 years: 18%
Severe symptoms	35%	22%	100%
Symptoms	<ul style="list-style-type: none"> • Dry cough: 67% • Wheezing: 57% • Chest tightness: 52% • Dyspnea: 49% 	<ul style="list-style-type: none"> • Dry cough: 61% • Wheezing: 49% • Chest tightness: 42% • Dyspnea: 40% 	<ul style="list-style-type: none"> • Dry cough: 100% • Wheezing: 100% • Chest tightness: 100% • Dyspnea: 100%
At least 1 asthma exacerbation per year	59%	52%	100%
Multiple asthma exacerbations per year	35%	24%	94%
At least 1 ER visit or hospitalization in the past year	22%	7%	100%
Treatment	<ul style="list-style-type: none"> • As needed: 57% • Continuous: 27% • Both: 17% 	<ul style="list-style-type: none"> • As needed: 66% • Continuous: 20% • Both: 14% 	<ul style="list-style-type: none"> • As needed: 8% • Continuous: 60% • Both: 32%
Adherence to treatment	<ul style="list-style-type: none"> • Regular: 36% 	<ul style="list-style-type: none"> • Regular: 28% 	<ul style="list-style-type: none"> • Regular: 76%
Mode of administration	<ul style="list-style-type: none"> • Inhaled: 58% • Oral: 11% • Both: 29% 	<ul style="list-style-type: none"> • Inhaled: 64% • Oral: 11% • Both: 23% 	<ul style="list-style-type: none"> • Inhaled: 30% • Oral: 10% • Both: 58%
Oral corticosteroids	27%	22%	50%
Antileukotrienes	9%	8%	12%
Frequency of comorbidities	56%	55%	60%
Most common comorbidities	<ul style="list-style-type: none"> • Hypertension: 22% • Sleep disorders: 20% • Digestive disorders: 19% • Obesity: 11% • Hypercholesterolemia: 9% 	<ul style="list-style-type: none"> • Hypertension: 23% • Sleep disorders: 19% • Digestive disorders: 19% • Obesity: 11% • Hypercholesterolemia: 9% 	<ul style="list-style-type: none"> • Hypertension: 20% • Sleep disorders: 26% • Digestive disorders: 20% • Obesity: 10% • Hypercholesterolemia: 12%
Poor Quality of Life	76%	72%	96%

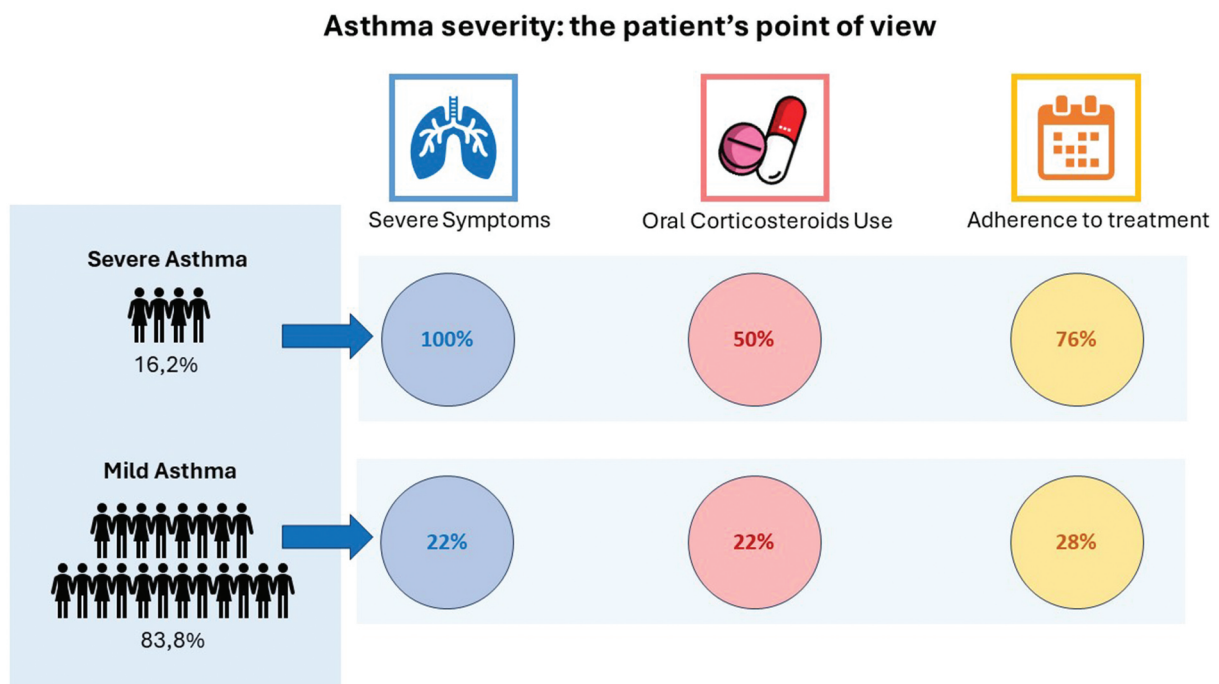


Figure 1. Overview of the main study findings, in terms of symptoms, oral steroids use and adherence to the treatment by asthma severity grade.

asthma reported having at least one exacerbation per year (94%), with 28% experiencing more than one exacerbation within the previous 12 months. Furthermore, 7% of the surveyed patients with mild asthma stated that they had been admitted to the hospital or the emergency room (ER) due to an acute asthma attack at least once in the last year. Of those with severe asthma, 52% indicated a single hospital or ER visit, 44% mentioned a few occasions, and 4% noted numerous admissions.

Treatment

It was observed that 66% of patients with mild asthma relied on an as-needed treatment, while only 20% adhered to a regular treatment schedule. A significant contrast was found in patients with severe asthma, where 92% were consistently on a regular treatment regimen.

Analyzing patients' attitude towards prescribed treatment, 28% of participants with mild asthma stated they consistently adhered to their physician's instructions, while 72% followed the treatment intermittently. In comparison, patients with severe asthma showed better adherence, with 76% consistently following their prescribed treatment.

Considering the type of therapy that was prescribed, 64% of patients with mild asthma used inhaler medications, while 11% opted for oral treatment and 23% used both. Only 2% were treated with subcutaneous or sublingual therapy. Regarding patients with severe asthma, 30% of them utilized inhaler therapy, 10% oral treatment, and 58% both. In this group, the percentage that used other therapies, namely subcutaneous and sublingual, was higher at 12%.

The use of OCS was more frequent among patients with severe asthma (50%) compared to those with mild asthma (22%). Among the asthma patients using OCS, 50% used systemic steroids as needed during asthma exacerbations, 23% used them on a regular basis, and 27% reported increasing the dose of daily intake when experiencing worsening symptoms.

Quality of life

A significant proportion of patients in both groups experienced a decline in their quality of life. Specifically, 96% of individuals with severe asthma and 72% of those with mild asthma reported this impairment.

Comorbidities

Both groups, comprising severe and mild asthma patients, showed a prevalence of concomitant

comorbidities, with rates of 60% and 55%, respectively. The most commonly reported comorbidities included hypertension, sleep disruption, gastrointestinal disorders, obesity and hypercholesterolemia.

Patient assessment and follow-up

Only 22% of patients with severe asthma and 16% mild asthma reported they underwent spirometry during every physical examination. A substantial number of patients reported that during asthma-related medical examinations, a cardiologic examination (cardiac auscultation) was conducted in 70% of severe asthma and 69% mild asthma cases, blood pressure assessment in 44% of severe and 57% of mild asthma, and blood glucose level checks in 33% of severe and 36% of mild asthma patients. It is worth noting that follow up visits for asthma patients were primarily conducted by General Practitioners (GPs).

Discussion

The study provides an overview of asthma management and diagnosis in Italy, focusing mainly on the perception and reality of asthma severity. At the core of this research lies the distinction between 'mild' and 'severe' asthma, as understood clinically and as perceived by the patient.

The percentage of patients with severe asthma within the asthma population is estimated at between 3 and 10% [6]. For instance, in a study that examined the asthmatic population of the Veneto region in north-eastern Italy, the prevalence of severe asthma was reported to be only 3.2% [10]. A study conducted in the Netherlands estimated that around 3.7% of asthma patients had severe asthma [11], whereas in an Israeli study, the prevalence of severe asthma was found to be slightly less than 5% of all asthmatics [12]. In contrast, in our studied population, the proportion of patients with severe asthma was 16.2%, which is notably higher compared to findings from other studies. However, it is known that the true prevalence of severe asthma can be distorted by factors such as poor treatment adherence, untreated comorbidities, or misdiagnoses [13]. In this study, among patients with severe asthma, only 76% reported adherence to prescribed therapy. Adequate adherence to treatment is essential to accurately determine the severity of asthma, especially in severe asthma where biologics are being considered. Verification of adherence to inhaled therapy is a crucial part of the prescription process [14]. In an Italian study, fewer than 50% of patients with severe asthma demonstrate an adherence rate exceeding 80%

when it comes to using inhaled treatments just before and during biologic therapy [15].

Poor adherence is a significant factor leading to uncontrolled asthma, irrespective of its level of severity [16]. In our population, only 28% of those with mild asthma consistently followed the doctor's recommendations. These patients were diagnosed with mild asthma, yet the symptoms they experienced, and the related quality of life decline, underscore the spectrum's vast heterogeneity. In fact, 22% of patients with mild asthma report having severe symptoms, suggesting a discrepancy between the subjective understanding of severity and clinical classifications. Furthermore, 7% of patients with mild asthma report having been admitted to hospital or an ER at least once in the last year. This percentage is not to be underestimated considering that they were classified as 'mild' asthmatics and suggests that the disease is definitely not well controlled. This mismatch between the patient's perception and clinical symptoms underlines the latent risk they may be underestimating. The importance of patient education becomes evident, ensuring that even individuals with milder symptoms recognize the significance of consistent treatment [4].

In the management of mild asthma, the extensive use of short acting beta2 agonists is often linked to the belief that asthma is an intermittent condition, requiring intervention only during symptomatic periods. However, this view has been reevaluated because of the risks involved in such a treatment strategy, potentially culminating in severe or even fatal asthma attacks [17–20]. Moreover, this strategy may lead to inadequate management of asthma, which may result from patients' misconceptions or underestimation of the severity of their condition. These discrepancies between the perception of the disease and its real intensity may cause inappropriate treatment and, consequently, the inability to effectively control asthma [18,21]. In this study, the issue becomes evident when we consider the percentage of patients with mild asthma who use oral corticosteroids. Specifically, 22% of patients with mild asthma reported using OCS. This percentage is remarkable and underlines how inadequate management of patients' chronic care can result in emergency use of OCS during exacerbations. According to the international guidelines set by GINA [6], the criteria for mild asthma do not encompass the utilization of OCS for exacerbation management, experiencing a minimum of one exacerbation annually, or requiring emergency room admissions. Among patients with severe asthma, the usage rate of OCS is 50%. Each

OCS prescription may lead to a cumulative health burden, regardless of the dose and duration [22], underscoring the importance of OCS-sparing strategies to improve patient outcomes [23].

Comorbidities were equally represented in both groups, and they may also be associated with OCS therapy, such as hypertension or sleep disorders [24]. This highlights the systemic impact of asthma and potential wider health implications. This interconnection between asthma and other diseases may justify a more integrated approach to treatment [25]. The impaired quality of life reported by the majority of subjects, particularly among those with severe asthma, underlines the sociopsychological burden of the disease, which requires more comprehensive management strategies [26].

The longterm assessment component sheds light on an area requiring attention, the consistency and comprehensiveness of clinical follow ups. Despite the availability of various diagnostic tools, spirometry remains underutilized, emphasizing a potential gap in routine asthma assessment. The prominence of GPs in conducting follow up visits reinforces their pivotal role in primary asthma care. Given their frequent contact with asthma patients, GPs may benefit from increased resources or targeted training to enhance asthma care further [27,28]. Addressing the main challenges in asthma control requires a personalized medicine approach, considering patient specific factors beyond drugs and biomarkers. Increasing awareness of asthma phenotypes and treatment options is crucial for both patients and physicians [29].

Strengths and limitations

A key strength of the study is its representative sample, ensuring a broad and inclusive understanding of asthma management across different regions and demographics. Additionally, the use of a structured questionnaire and rigorous data collection methods enhances the reliability of the findings.

However, the study has some limitations. The population characteristics are not separately available for mild and severe subgroups, precluding the possibility to compare the two samples in terms of gender and age. The self reported nature of the data may introduce bias, as participants' perceptions and recall can affect accuracy. The simplification to only two severity categories may limit the accuracy of the analysis and comparability with other studies that use more detailed classifications. Despite these limitations, the study underscores the importance of aligning clinical

assessments with patient experiences to improve asthma management and outcomes.

Conclusion

This study underscores the complexities of asthma management in Italy, highlighting the significant differences between clinical classifications and patient perceptions of disease severity. These findings reveal that many patients with mild asthma experience severe symptoms, suggesting potential underestimation of their condition. The high prevalence of comorbidities and the impact on quality of life further emphasize the need for comprehensive management strategies. Additionally, the study highlights issues related to treatment adherence, with a substantial proportion of patients not consistently following prescribed therapies.

The differences between clinical categorization and patient understanding shed lights on critical areas for targeted intervention, education, and support. Comprehensive care should address not only the physiological aspects of asthma, but also the sociopsychological components. Future interventions should prioritize improving diagnostic practices, including comorbidity evaluation, and assessing medication regularity before prescribing biologics for severe asthma. Furthermore, promoting better adherence to treatment and prioritizing patient education to equip individuals with the knowledge and tools for effective asthma management is crucial. This study accentuates the importance of these measures in optimizing asthma care, regardless of its severity.

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Data availability statement

The full dataset supporting the reported results is available upon request to the corresponding author.

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