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Asthma management, focused on the use of oral corticosteroids: the opinions of Italian asthmatic patients

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ABSTRACT

Objective: Patients' perceptions of asthma symptoms, and attitudes regarding diagnosis and management, can affect their ability to reach good asthma control. The aim of the study was to explore patients' perceptions of asthma management, with focus on treatment with oral corticosteroids (OCS).

Methods: A DOXAPHARMA survey was conducted. A questionnaire with 46 multiple choice questions was completed by 50 patients with severe uncontrolled asthma, and 258 with mild–moderate controlled or partly controlled asthma. Participants were representative of Italian asthmatic patients—with medium age, long asthma duration, delayed diagnosis, poor asthma control, and frequent exacerbations.

Results: Many asthmatics reported inadequate pharmacologic treatment. The majority but not all patients regularly used ICS/LABA. Oral treatment was common, mainly with OCS, particularly in severe asthmatics. One-fourth of patients did not regularly use inhaled therapy, and adherence was poor, resulting in frequent OCS use to treat exacerbations, which were common in mild–moderate cases. Patients were fairly satisfied with asthma therapies, but many had concerns about long-term corticosteroid use. Patients complained about poor management of comorbidities associated with asthma and OCS use, but were generally satisfied with their patient/doctor relationships. Many patients failed to achieve optimal health-related quality of life (HRQoL), mainly those with severe asthma who used OCS treatment and emphasized how OCS therapy impacted QoL.

Conclusions: The survey results confirmed many problems related to mild–moderate and severe asthma management in Italy and highlighted the overuse of OCS rather than more effective and safe treatments, which had strong negative effects on HRQoL.

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*Membership of SANI is provided in [Appendix A](#).

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Introduction

Asthma is a heterogeneous disease characterized by chronic airway inflammation (1). Over 300 million people worldwide suffer from asthma, of whom 5–10% have severe asthma. Due to the high socio-economic burden of this disease (especially the severe forms), the main objectives of diagnostic and therapeutic asthma management include preventing exacerbations, improving quality of life, and reducing healthcare costs.

Asthma management is well reported in GINA guidelines (Global Initiative for Asthma), suggesting different steps of the treatment progression, until the control of symptoms and the reduction of the future risk are reached (1). Although historically oral corticosteroids (OCS) were largely used for treating asthma symptoms and exacerbations, GINA recommends that the use of low-dose chronic OCS should be limited only when no other drugs, including biologics, are not able to reach and maintain an acceptable level of global control.

Up to now, OCS are used as short-term therapy in cases of exacerbations and, at low doses, as control therapy in patients with severe asthma. OCS improve symptoms and reduce exacerbations in severe asthma; however, they have many short-term and long-term side effects, which greatly impact quality of life (2–7). Notably, severe asthma is frequently associated with comorbidities, some of which are aggravated by frequent or long-term use of OCS (8). The costs of managing these OCS-related diseases are reportedly much higher than the costs of managing severe asthma without OCS treatment, or mild–moderate asthma (9,10).

In this manuscript, we report the results of a survey conducted in a large population of patients with asthma of different severity. The aim was to focus on the patients' perceptions of their asthma management, and particularly on the use and the risks of oral corticosteroid treatment. To evaluate the therapies, preferences, mode of drug administration, and frequency of OCS use for asthma treatment in Italy, a DOXAPHARMA survey was conducted among a total of 308 patients—including 50 with self-reported severe uncontrolled asthma, and 258 with mild–moderate controlled or partly controlled asthma. DOXAPHARMA is one of the leading service companies in the field of market research for the pharmaceutical and health sector for Italian and international companies. The survey was conducted anonymously by telephone interviews at the homes of the participants from November 2020 to January 2021. The survey was based on the hypothesis that the poor asthma control

and the inadequate pharmacologic treatment are associated with a large use of OCS, which may contribute to the presence of comorbidities and lowest quality of life.

The study protocol was approved by local Ethics Committee of Area Vasta NORD-OVEST Toscana, Italy (Number of Protocol: 73714, December 2016). All the data that supports the results of this study is contained in the article and/or its additional materials.

Methods

The study was conducted according to the method commonly used for marketing research. DOXAPHARMA collected unbiased data using a random sampling technique which involved the following steps: 1) the starting point was a large database including individuals who willingly took part in market research and provided socio-demographic data useful for profiling; 2) within this panel, a random selection was carried out adopting stratification criteria (age, gender, geographical area, etc) in order to ensure a representative sample of the whole population; 3) the selected subjects were asked to fill a questionnaire without revealing the specific purposes of the study, to avoid that such information could influence the decision to take or not the survey; 4) an informed consent was obtained (according to art.13-14 of the European Regulation NO. 679/2016) prior to the digital interview with a series of questions to verify the eligibility requirements, including the doctor diagnosed asthma and the use of asthma treatments (supported by medical evidence and/or drug prescriptions); 5) then, a total number of 308 asthmatic patients were selected.

Some demographic characteristics of the patients included in the sample are reported in [Table 1](#).

Patients were classified as affected by severe uncontrolled asthma (Group 2, called “severe asthma”) if they self-reported all the following characteristics: very serious or serious symptoms, frequent symptoms (e.g. difficulty breathing, dyspnea, wheezing, chest tightness, or dry cough), acute severe asthma attacks, and admission to emergency room and/or hospitalization due to severe asthma attack. The remaining patients were classified as affected by mild–moderate controlled or partly controlled asthma (Group 1, called “mild–moderate asthma”).

The questionnaire included several sections, aiming to collect the patients' opinions regarding different aspects of asthma management (Asthma diagnosis, symptoms, and severity; Prescribed drugs, dose

regimen, and frequency; Patients' attitudes about pharmacologic treatment; Comorbidities of asthma, and prescription of additional medical examinations; Patient satisfaction and the patient-doctor relationship). Additionally, The RhinAsthma Patient Perspective (RAPP) questionnaire (11) was administered to evaluate health-related quality of life (HRQoL). RAPP is the first questionnaire designed to evaluate HRQoL impairment in patients with rhinitis and/or asthma in routine care, it was validated (12) and translated in different languages, including English. It provides a short and simple assessment and has overall psychometric properties (13). The Short Form Health Survey-12 (SF-12) (14) is a generic validated questionnaire that has also been used to assess health status. It comprises 12 questions and provides physical (PCS) and mental health (MCS) component scores, with higher values indicating better health status.

All results are reported in a descriptive way; the only statistical analysis was the comparison between prevalences by chi-square test comparing each Group vs total sample.

Results

Asthma diagnosis, symptoms, and severity

In over half of the patients, asthma was diagnosed by a pulmonologist, mainly in Group 2 (severe asthma, 72%) in comparison with Group 1 (mild-moderate asthma, 45%), while in the other cases asthma was diagnosed by an allergologist and, in a minority of patients, by a general practitioner. The reported diagnosis was confirmed by specific exams (like spirometry, skin prick tests, etc) which had been prescribed by the doctor in 90% of surveyed patients.

About 50% of patients had suffered from asthma for over ten years, while only 5% of patients had been diagnosed with asthma within the last year. Differential

analysis of patients in the two groups indicated that the time from diagnosis did not differ between patients of Group 1 (mild-moderate asthma) versus Group 2 (severe asthma).

When patients were asked for their perspective on the severity of their symptoms, 65% considered their symptoms moderate, and 35% severe. As expected, the patients in Group 2 considered their symptoms to be severe in 66% and very severe in 34%. Conversely, among patients of Group 1, 78% considered their symptoms to be moderate. but in 22% of these patients' symptoms were reported as severe or very severe.

Regarding the types of symptoms reported in the last year (Figure 1), cough was the more frequent symptom both in Group 1 and in Group 2, followed by chest tightness and wheezing. As expected, the combination of all four typical asthma symptoms (cough, wheezing, chest tightness and shortness of breath) was reported in a large percentage of Group 2 patients, while 50% of Group 1 patients reported just one or two among the typical symptoms, and 17% of them did not report any symptom.

Within the last year, 59% of the entire population experienced at least one exacerbation. Every patient in Group 2 experienced at least one exacerbation in the last year. Additionally, 52% of the patients in Group 1 reported one or more acute exacerbation in the past year. Due to asthma exacerbations, all patients with severe asthma required hospitalization and/or emergency room access at least once, while patients with mild-moderate asthma needed hospitalization and/or emergency room admission in only 7% of them.

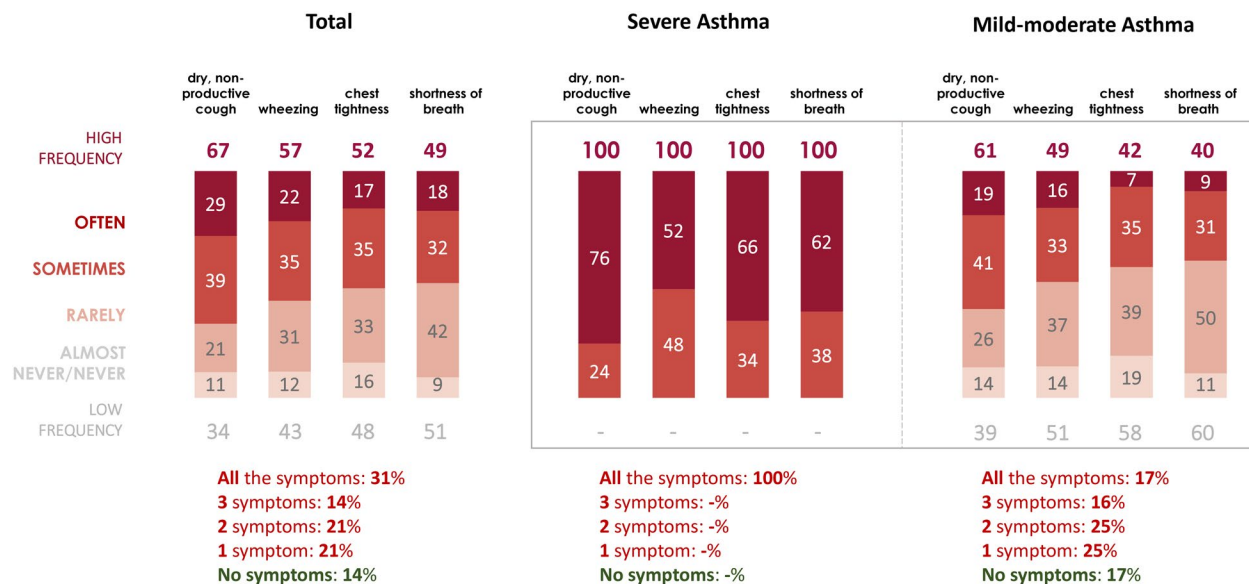
Prescribed drugs, dose regimen, and frequency

The frequency of the use of pharmacologic therapy was different in Group 2 vs Group 1 patients, with 76% of severe patients reporting to use asthma drugs regularly every day versus 72% of mild-moderate patients who used asthma drugs only during exacerbations or as rescue medication. Group 2 patients used more frequently oral treatment, particularly OCS, than Group 1 patients (Figure 2).

The most frequently prescribed drugs were ICS and LABA in both the mild-moderate and severe asthma patient groups (Figure 3). Interestingly, ICS were not prescribed for all asthmatics, particularly among more severe asthmatics, and a high percentage of patients were prescribed short-acting beta2 agonists. As expected, severe patients reported frequent use of OCS, which were also prescribed for 22% of patients with mild asthma. Anticholinergic drugs were very

Table 1. Main demographic characteristics of the patients enrolled in the survey.

Age	12–34 yrs	15%
	34–54 yrs	37%
	55–74 yrs	44%
	75–84 yrs	4%
Gender	Male	50%
	Female	50%
Geographical area	North West Italy	27%
	North East Italy	25%
	Central Italy	24%
	South Italy and Islands	24%
Level of education	Low	23%
	Medium	57%
	High	20%
Work status	Employed	59%
	Unemployed	41%



Total respondents, n= 308; Severe Asthma, n=50; Mild-moderate Asthma, n=258 – values %

Figure 1. Type and frequency of respiratory symptoms.

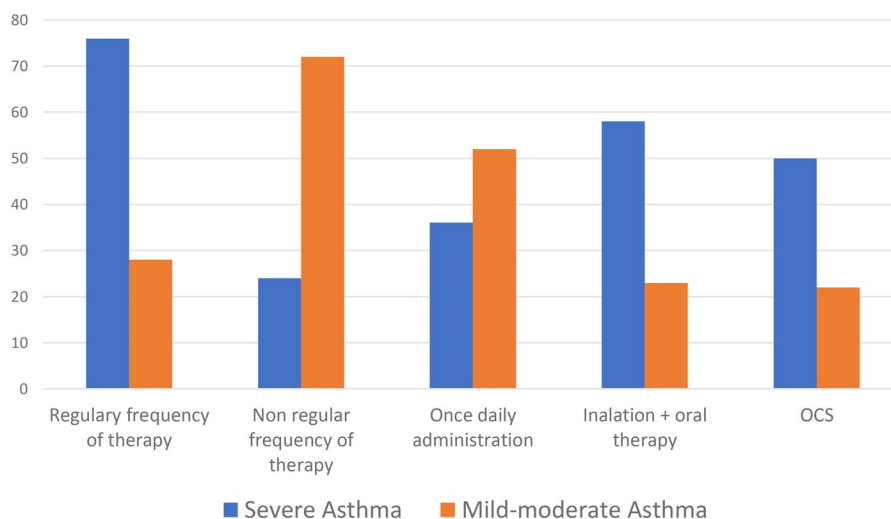


Figure 2. Frequency of the use of pharmacologic therapy.

seldom prescribed, also in severe patients. On the other hand, only a minority of patients (2%) were prescribed therapy with a biological agent.

Patients' attitudes about pharmacologic treatment

The difficulty of taking therapy was generally perceived as not bothersome by the surveyed asthmatics. About 80% of patients reported that it was “little or not at all difficult” to take the drugs, with a negligible difference among the patients with different disease severity. Patients considered the need for chronic treatment to be the most relevant drawback, with

some feeling “addicted” to the drug, and viewing recovery as highly unusual or impossible. Interestingly, independently from disease severity, most patients (83%) slightly preferred the inhalation route compared to the oral route (79%), which is usually the gold standard in terms of adherence.

Overall, about 91% of the patients were satisfied with their asthma therapy (Figure 4). The most appreciated and positive aspects reported by the patients were the relief of dyspnea and the fast action of the drugs, which were more appreciated by patients with mild-moderate asthma. Disadvantages of the therapy were its chronicity, and the potential side effects (especially related to OCS). The data from

Multiple choices:

Q. no. 7 Could you please specify which of the following types of DRUGS have been prescribed for asthma treatment? It's possible to provide multiple answers in the case of different medications

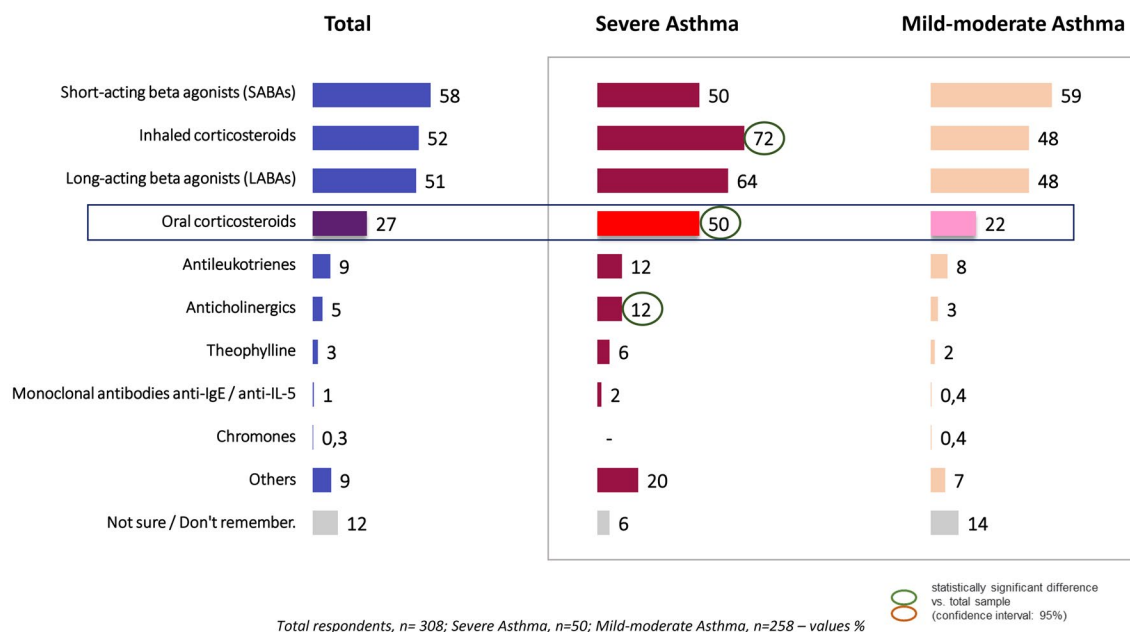


Figure 3. Categories of drugs prescribed for asthma treatment.

this survey showed that 66% of the patients realized that ICS is an important component of asthma therapy. However, the interviewed patients reported equal concerns regarding the use of both ICS and OCS. About 20% of patients in this survey believed that both type of corticosteroids may lead to weight gain.

Comorbidities of asthma, and prescription of additional medical examinations

The prevalence of concomitant diseases was similar in patients affected by mild versus severe asthma (55% and 60%, respectively) (Figure 5). The most frequent comorbidities were hypertension, sleep disorders, gastroesophageal reflux, obesity, hypercholesterolemia, osteoporosis, cardiovascular diseases, type 2 diabetes, and cataract.

Comorbidities appeared to be associated with higher use of OCS. We pointed out a clear trend of increased rates of some comorbidities (e.g. sleep disturbances, GERD, and type 2 diabetes) with increased use of OCS (Figure 6). Overall, among asthmatic patients suffering from systemic or local comorbidities, 73% regularly used OCS. On the other hand, 63% of all asthma patients did not regularly use OCS.

Nevertheless, patients are not regularly assessed for the presence of concomitant conditions that may impact asthma control. In fact, 52% of patients reported that their physician prescribed no further exams to explore comorbidities, with no difference between group 1 and Group 2 patients. Notably,

despite the high proportion of patients who regularly used OCS, physicians rarely investigated for potential OCS side effects—for example, bone metabolism assessment was rarely prescribed (Figure 7).

Patient satisfaction and the patient/doctor relationship

Patients considered their GPs to be very/sufficiently professional, careful, and conscientious in 93% of cases, and reassuring in 92% (Figure 8). Similarly, satisfaction with the doctor/patient relationship was reported to be good (very/enough satisfied) among 93% and 94% of patients managed by a GP and allergist, respectively, and by 100% of participants managed by a pulmonologist (Very 55%, Enough 45%).

Patient-perceived quality of life

In our survey, RAPP was assessed among 308 subjects with asthma and rhinitis. The scores range from 8 to 40, with higher scores indicating greater impact on HRQoL. A cutoff of 14 showed the best sensitivity and specificity for discriminating achievement of an optimal HRQoL. The goal of optimal HRQoL was achieved by 4% of patients with severe asthma, and 28% of patients with mild-moderate asthma. Optimal HRQoL was achieved by 12% of patients using OCS, compared to 28% of patients who did not require frequent or continuous treatment with OCS (Figure

Single answer:

Q. no. 11 Overall, how SATISFIED are you with the prescribed asthma treatment?

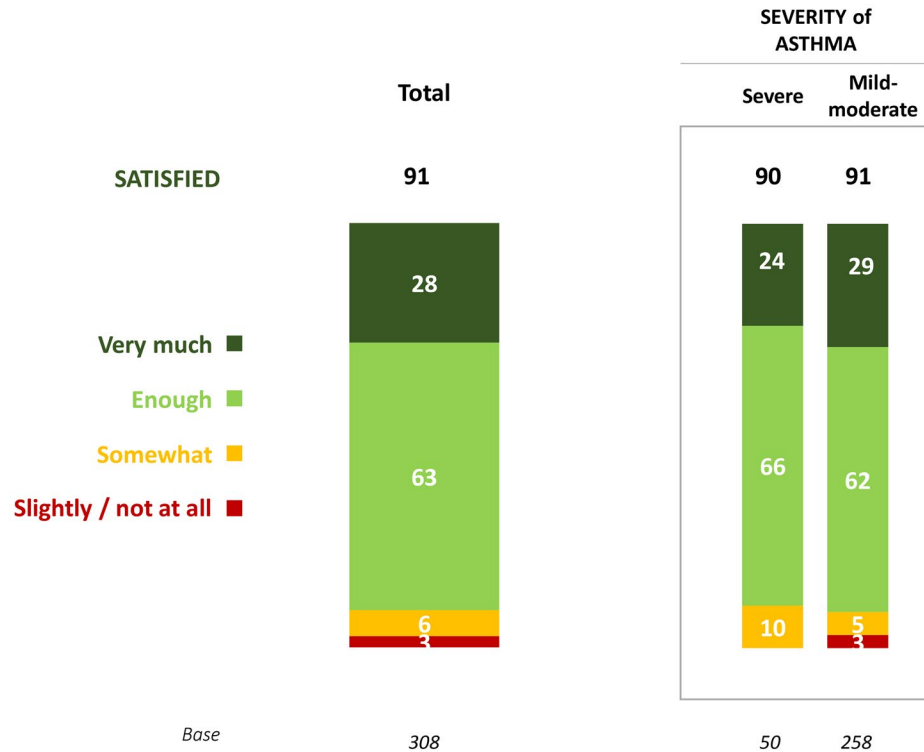
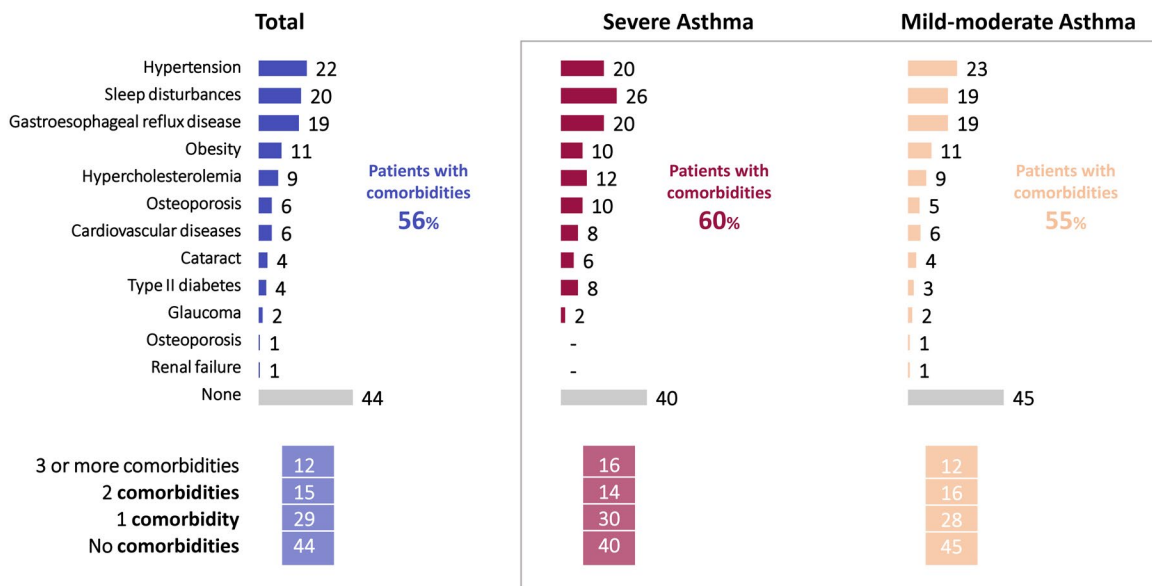


Figure 4. Patients' satisfaction with the prescribed therapy.

Q. no. 19 Do you have any of the following conditions or disease (in addition to asthma)?



Total respondents, n= 308; Severe Asthma, n=50; Mild-moderate Asthma, n=258 – values %

Figure 5. Reported frequencies of comorbidities among asthmatic patients.

9). Moreover, optimal HRQoL was experienced by 16% of asthmatics with other diseases compared to 30% of asthmatics without comorbidities.

As regards the Short Form Health Survey-12 (SF-12), the physical component score (PCS) was lower among subjects with severe asthma compared to those with

Q. no. 19 Do you have any of the following conditions or disease (in addition to asthma)?

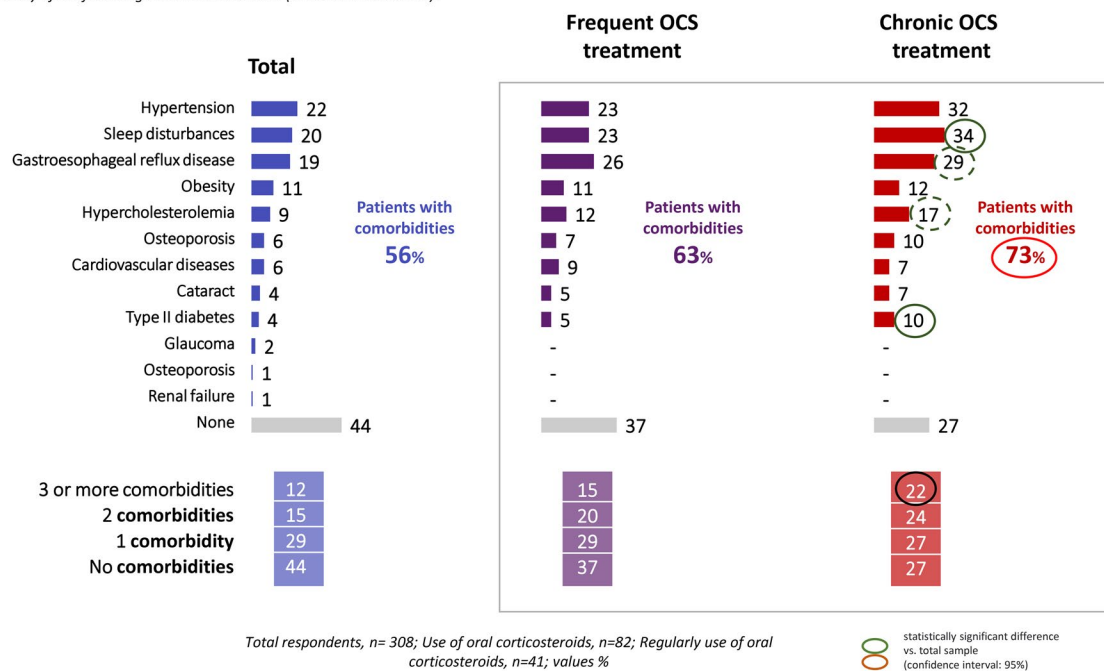


Figure 6. Reported frequencies of asthma comorbidities according to frequent/regular use of OCS.

Q. no. 18bis What kind of tests and investigations have been prescribed to detect the possible onset of other diseases?

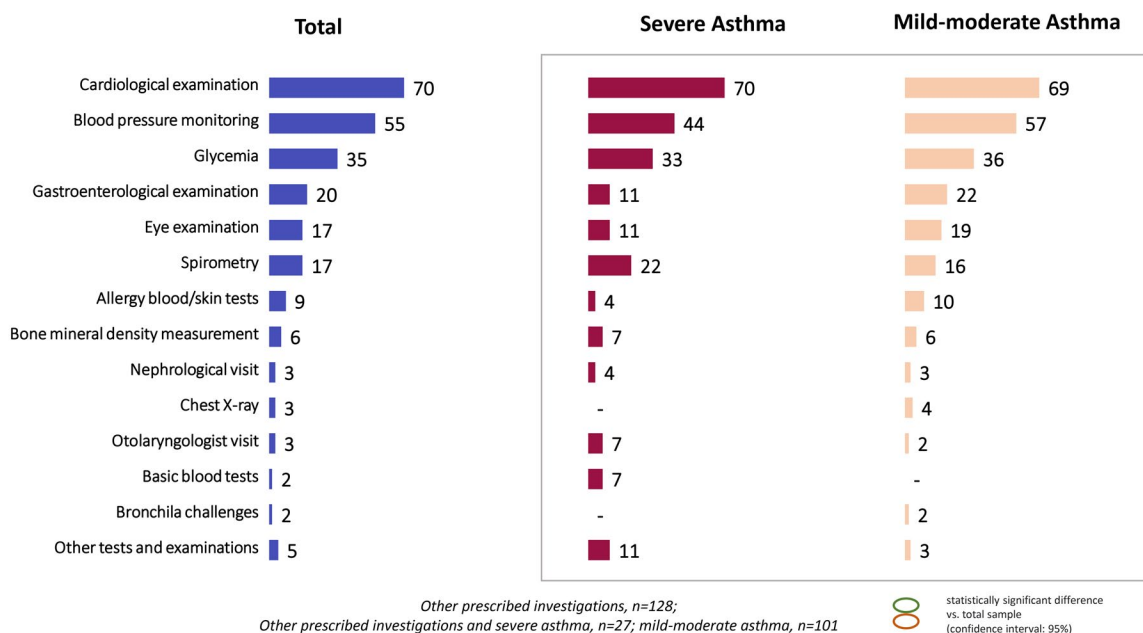


Figure 7. Reported frequencies of prescribed investigations for comorbidities.

mild-moderate asthma (40 vs. 49). The mental health component score (MCS) was 46 in severe asthmatics, and 48 in mild-moderate asthmatics.

Discussion

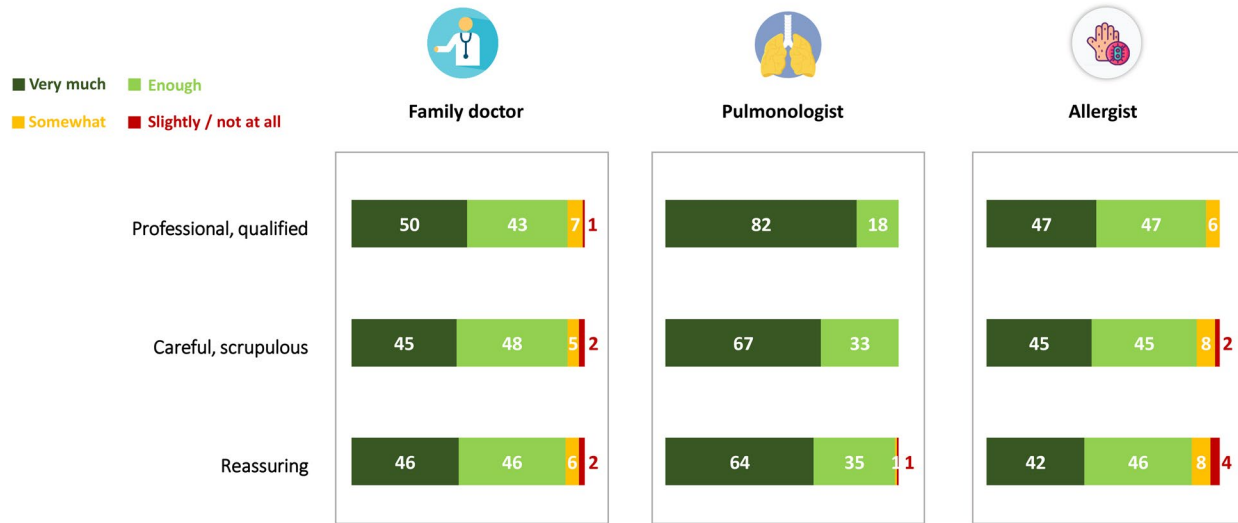
The results of the present DOXAPHARMA survey provide interesting insights into how a large group of

asthmatic subjects perceive their disease and its management.

The investigated sample corresponds well to the characteristics of the general population of asthmatic patients, with most having mild-moderate controlled or poorly controlled asthma, and a minority affected by severe uncontrolled asthma. Asthma severity was defined based only on the referred frequency and

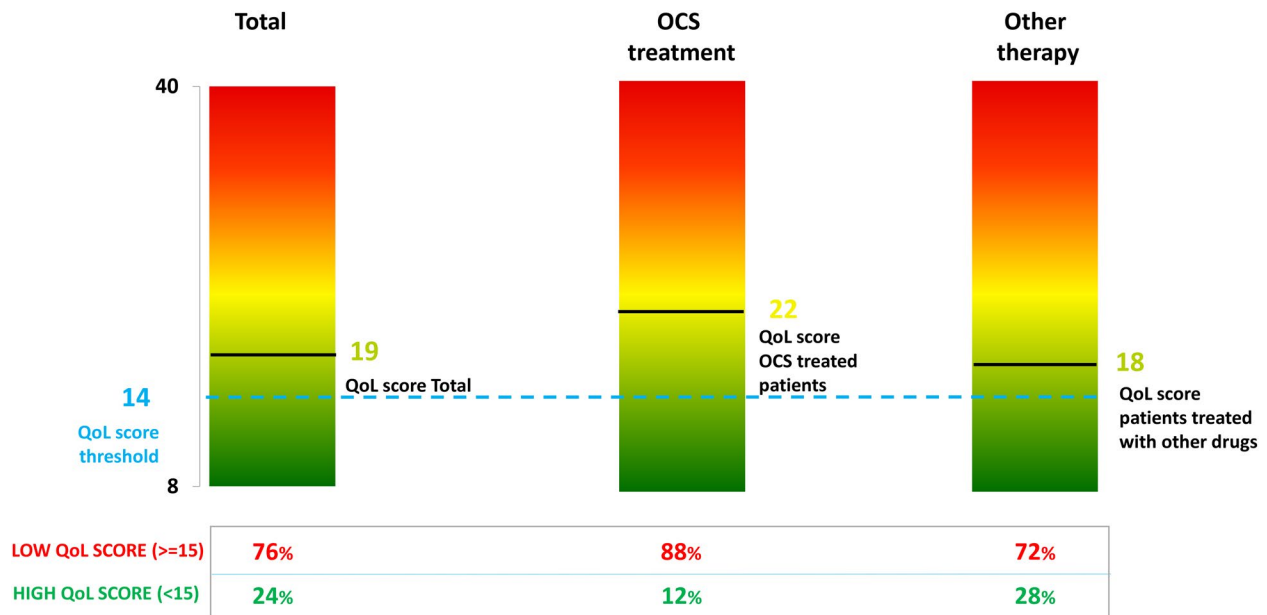
Single answer per item:

Q. no. 16 If you were to give an EVALUATION of the doctor who follows you for the treatment of asthma, how would you define it?



Patients' contact reference: Family doctor, n= 123; Pulmonologist, n=129; Allergist, n=51 values %

Figure 8. Evaluation of the professional characteristics of the physician responsible for asthma management.



Patients taking oral corticosteroids, n=82; Patients not taking oral corticosteroids, n=226

Figure 9. Quality of life among asthmatic patients, subdivided according to regular or frequent use of oral corticosteroids (OCS).

severity of the perceived symptoms, and not also on objective assessment of asthma control and adherence to appropriate pharmacologic treatment. However, we can assume the correct categorization of cases as mild-moderate or severe asthma, also in consideration of the type of symptoms reported, and the frequency and severity of exacerbations. As regards the asthma

diagnosis, we are quite confident in its reliability, considering that in most cases it was made by a pulmonologist/allergologist, and that it was supported by functional evaluation in a large part of patients. The surveyed patients had a long history of asthma, with about half suffering from asthma for over ten years. Notably, many of these patients reported a delay in

diagnosis, as has also been well documented in many prior studies (15).

Shortness of breath was undoubtedly among the symptoms least tolerated by the patients, while cough was the more frequently reported symptom. Most patients judged their symptoms to be severe or moderate. This probably reflects that most patients were aware that asthma could have potential negative consequences on their health status and quality of life. Asthma exacerbations negatively influence patients' lives, leading to job absences and depression, and are associated with progressive decline in pulmonary function (16). While frequent exacerbations within the last year were reported by all patients with severe asthma, these were also reported by about half of patients with mild–moderate asthma. These data probably reflect several unmet needs in these patients' treatment, suggesting that this clinical outcome is not appropriately considered in the definition of severity and in the management of asthma.

The analysis of the results concerning prescribed drugs, dosages, and frequency, that the majority of Group 1 patients take medications only during exacerbations or as rescue medication, while Group 2 patients do a regular daily treatment. It is not possible to establish whether this is due to the lack of adherence of the patients or to the doctors' suggestions. In any case, these data demonstrate an inadequate control of the disease, and they are in line with previous reports in the literature, showing that guideline recommendation is poorly followed by physicians and that poor adherence is associated with poor asthma control and risk of exacerbations (17,18). Notably, evidence suggests that about 20% of patients with asthma underuse asthma controller medications. Several factors are generally associated with poor treatment adherence, such as long disease duration, fears about side effects of medication, and issues with devices (18). Importantly, treatment adherence may increase if physicians allocate more time to asthma patients, to inform them about the beneficial effects and safety profile of ICS (19).

Inhaled corticosteroids (ICS) are the most commonly used anti-inflammatory drugs for asthma treatment. Despite minimal systemic adverse effects, patients are often hesitant to use ICS due to corticosteroid phobia (corticophobia). Our survey revealed a high use of OCS, particularly but not only in cases of severe asthma. This finding is in line with previous reports of high OCS use among asthmatic patients, without adequate focus on optimizing regular inhaled therapy or the potential use of new biologics, which may enable reduction of the high rate of OCS

treatment (20). Recent national surveys both in Europe and the US confirm an inappropriate pattern of OCS use among asthmatic patients (21,22). Another important finding, in contrast to the GINA recommendations, was the persistent underutilization of anticholinergic inhaler medication in severe asthma. This has been also demonstrated in other studies of severe asthmatics (23).

Among the categories of prescribed drugs, OCS were found to be excessively used, both continuously and as frequent bursts, not only in severe asthma but also in mild asthma. Despite the existence of clear guidelines for establishing asthma therapy and the availability of various drugs for asthma treatment, the lack of control often derives from a poor assessment of asthma signs and symptoms, and from an incorrect and excessive use of OCS without investigating the underlying phenotype or endotype of asthma. It must be remembered that the GINA report strongly recommends that all implemented strategies aim to minimize both continuous and intermittent OCS use (1).

Severe asthma is commonly considered as a systemic condition, characterized by a complex interaction between bronchial inflammation and various comorbidities, which can account for the difficulty of asthma control (8,24,25). However, the similar proportion of comorbidities in both mild and severe asthma cases suggests that systematic evaluation should be recommended even in milder phenotypes. Independent of asthma severity, the patients reported an overall poor attention paid to concomitant conditions in asthmatic individuals, even though the presence of comorbidities seems to be associated with higher OCS intake and poor quality of life (8). This suggestion should be highly considered in daily clinical practice when managing asthmatic patients of any severity level. Many recent studies confirm the high risk of frequent OCS use, in terms of comorbidities, economic costs, and mortality (26,27).

Despite the poor asthma control and the limitation in the use of regular appropriate treatment in contrast with the abnormal large use of OCS, the results revealed a high rate of satisfaction among patients for their patient/doctor relationship, particularly in those with severe asthma who are often treated in specialized centers. A good patient/doctor relationship is a pivotal factor in asthma management, particularly in cases that are difficult to treat, and it is the basis for achieving good asthma treatment adherence and asthma control (28).

We found that high percentages of patients were failing to achieve the goal of optimal HRQoL at all asthma severity levels, with a particularly negative

impact in cases of severe asthma, and especially for patients with severe asthma who were treated with OCS, emphasizing how OCS therapy also impacts quality of life. These findings are in line with other reports (29,30), suggesting that appropriate and correct asthma management, particularly in more severe asthmatics, with greater use of new biologic drugs, may allow minimization of OCS use and improvement of quality of life (31).

The study has some limitation, especially the selection of the patients enrolled in the survey may represent a criticism; however, DOXAPHARMA methodology is usually adopted in many market investigations, and the patient stratification may blunt the bias. The definition of asthma severity was self-reported by the patients according to the frequency and the severity of symptoms; even if a specific medical examination was not available, the severity of asthma in Group 2 patients was confirmed by the high rate of regular treatment with ICS/LABA combination, the large use of OCS and the number of exacerbations.

Conclusions

The results of this survey confirm the existence of many problems related to asthma management among both mild-moderate and severe asthmatics in Italy, including poor asthma control, frequent exacerbations, and insufficient use of traditional and new biologic drugs. This is in line with previous observations conducted in Italy (17,18,28).

The high overuse of OCS rather than use of the more effective and safe treatments appears to carry a high risk of negative effects on comorbidities and quality of life among these patients.




Declaration of interest

The authors have no conflict of interest to declare.

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Appendix A

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