

MANAGEMENT AND CONTROL

The level of control of mild asthma in general practice: an observational community-based study

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Abstract

Objective: The aim of the present community-based study was to evaluate the level of asthma control in patients with mild asthma, regularly treated with inhaled steroids (ICS). **Method:** This observational cross-sectional study included patients registered in the general practitioner (GP) database and with at least three prescriptions of ICS in the last 12 months. Patients were asked to refer to the doctor's office for a standardised interview. The level of asthma control was self-measured by the patients using the Asthma Control Test (ACT)TM (Quality Metric, Inc.). **Results:** The study included 950 asthmatic patients, referred by 540 GPs: 54.5% were females, mean age was 51 (±19.1) years; 59.5% were non-smokers, 22.5% were current smokers and 18.0% were former smokers; 81.1% of the patients were on ICS in the last 4 weeks. Only 38.6% of patients had a spirometry in the last 12 months. According to the ACT, 13.7% of the asthmatic patients were totally controlled, 51.0% well controlled, and 35.3% poorly controlled. Smoking habit, older age (>60) and living in Central or Southern Italy were associated with poorer control. In the last 12 months 4.5% of patients had an asthma-related hospitalisation, 5.3% an emergency visit and 18.9% a specialist visit. **Conclusions:** More than one of three patients had poor asthma control, despite being considered by their GPs as mild asthmatics and treated with ICS. Asthmatic patients need to be regularly re-evaluated. Treatment is often inadequate and should be targeted to improve control and reduce asthma morbidity (SAM104964).

Keywords

Asthma control, asthma control test, asthma in general practice, asthma long-term management, inhaled steroids

History

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Introduction

International guidelines highlight that asthma control (defined as prevention of chronic symptoms, minimal use of rescue medication, no exacerbations, no emergency care, and maintenance of normal levels of physical activity) is the major goal in the long-term management and suggest that the level of control should be monitored by both health care professionals and patients themselves at regular intervals [1]. Asthma control test (ACT) is one of the most widely used instruments for the self-assessment of asthma control [2,3].

Despite the advances in therapeutic approaches, and the dissemination of guidelines, several studies have shown that the degree of asthma control in Italy is still not optimal, and does not match guideline targets [4–7]. Furthermore, a high percentage of asthmatic patients in Italy still reports

unscheduled visits, emergency room and hospital admissions, as a consequence of poor asthma control [4]. Mild asthmatics represent a relevant fraction of patients, but their level of asthma control has not yet been specifically investigated. Thus, we designed a community-based study, in the GP setting in Italy, to obtain more detailed information on this aspect.

Methods**Study design**

This study was a multicenter, observational cross-sectional study performed in the offices of 540 Italian GPs, distributed over the entire Italian territory (Figure 1), and representing 1.2% of all Italian GPs. According to the GP databases, patients with mild asthma were identified and their level of control was assessed by ACT at the physician's office. The protocol was approved by the Ethic Committee of the Italian Society of General Medicine (SIMG; www.simg.it). Written informed consent was obtained by each patient before the

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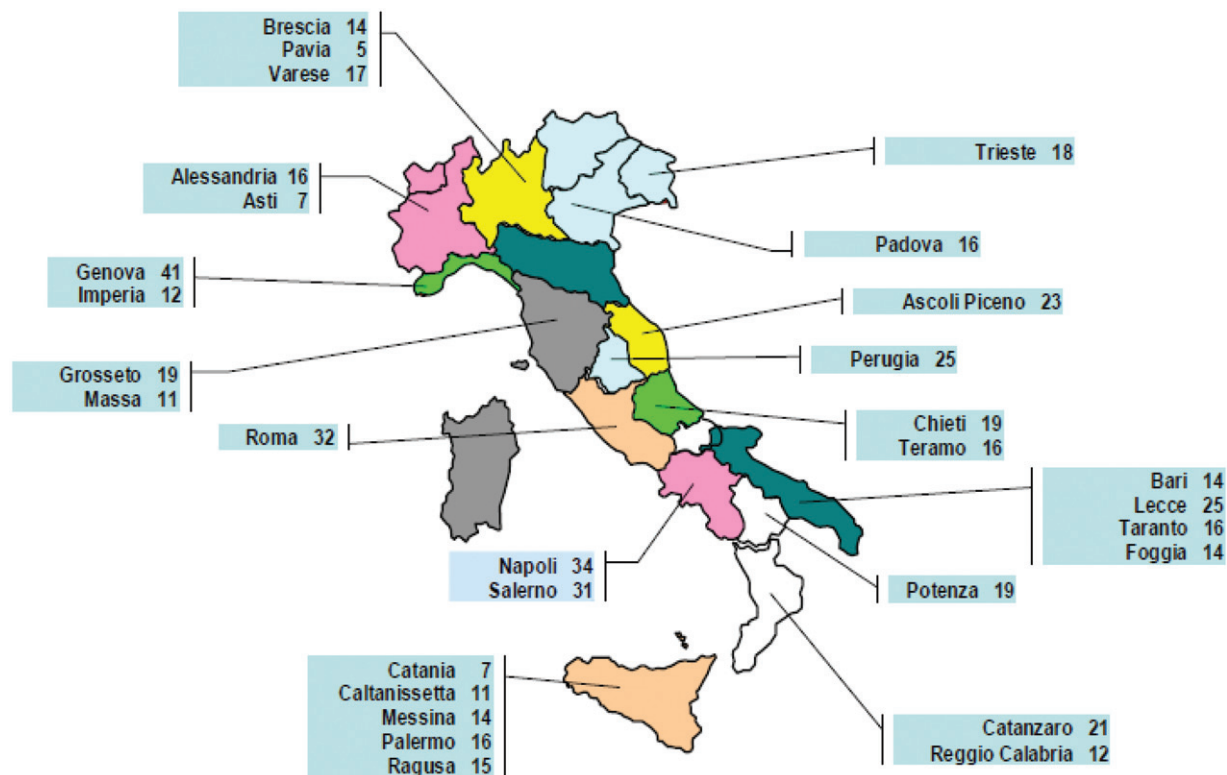


Figure 1. Distribution in Italy of GPs involved in the study.

inclusion into the study. The study was conducted between September 2005 and January 2006.

Selection of the general practitioners

The sample of GPs was selected on the basis of the availability of a computerised patient database in their practice, according to the information stored in the archive of the European School of General Medicine (Scuola Europea di Medicina Generale, SEMG, Firenze, Italy) and of their willingness to participate to the study. The GPs involved in the study were subdivided in groups of 20 investigators, each coordinated by a protocol-trained colleague. Each GP had to select up to 10 patients with mild asthma from his database according to the most recent visits registered in the last 12 months.

Selection of asthmatic patients

The eligible asthmatic patients identified among those registered in the GP data base had to be ≥ 18 -year-old and to be diagnosed with mild persistent asthma according to Pulmonary Function Test criteria and to GINA classification of asthma severity [1]. Moreover, at least 3 accesses to GPs office to renew inhaled steroids (ICS) prescription (with or without inhaled short-acting β_2 agonists) had to be registered for each patient during the past 12 months. It was considered an indirect marker of persistent asthma.

Asthmatic patients with a concomitant prescription of long-acting β_2 agonists and/or theophylline and/or nedocromil or sodium cromoglycate, and/or antileukotrienes, and/or anticholinergics drugs were not included.

The eligible asthmatic patients were invited to fill, without any help from the GP, the Italian version of the ACT.

Statistical analysis

The statistical analysis was performed at the end of the study. To analyse differences in patients characteristics (i.e. asthma control), the χ^2 test (binary variables), Mantel–Haenszel test for trend (categorical variables) or linear regression models (continuous variables) have been used where appropriate. Statistical significance was defined as *p* value two-tailed less than 0.05.

Univariate logistic regression was used to assess the relation between the level of asthma control (poor versus total plus good) and hospitalisations, emergency room visits, specialistic visits. Statistical analyses were performed using STATA 8.0 (STATA Corporation, College Station, TX).

Results

Clinical details of the patients

During the recruitment period, 991 asthmatic patients resulted to be eligible. The level of asthma control could be assessed in 950 patients, since 41 patients (4.1%) did not fill correctly the ACT questionnaire. The clinical data of the 991 asthmatic patients are shown in Table 1. The mean age of the patients was 51 ± 19.1 years. Five hundred and forty patients (54.5%) were females, 59.5% were non-smokers, 22.5% were current smokers and 18.0% were ex smokers. All former smokers had quit since more than 1 year.

The mean duration of asthma from start of the asthma treatment was 32 years (± 19.7); 43.5% of the patients were atopic (defined as skin prick test positive to at least one common aeroallergen). The most frequent concomitant diseases were, as expected, ear, nose and throat (ENT) (9.6%),

Table 1. Main characteristics of the asthmatic patients recruited to the study.

	Patients (n = 991)
Mean age, years (SD)	51.0 (19.1)
Mean duration of asthma, years (SD)	32.0 (19.7)
Female, n (%)	540 (54.5)
Smoking habits	
Non-smokers, n (%)	583 (59.5)
Former smokers, n (%)	176 (18.0)
Current smokers, n (%)	221 (22.5)
Smoking history, mean years (SD)	13.5 (10.6)
Concomitant diseases, n (%)	
Cardiovascular	267 (26.9)
Osteoarticular	178 (18.0)
Gastrointestinal	119 (12.0)
Endocrine	98 (9.9)
Ear Nose and Throat	95 (9.6)
Respiratory disease different from asthma	86 (8.9)
Urinary	66 (6.7)
Psychiatric	45 (4.5)
Neurological	27 (2.7)
Skin disease	25 (2.5)
Skin Prick test, positive n (%)	431 (43.5)

Percentage have been calculated taking into account missing data.
Missing data: Sex = 1; Smoking habits = 11.

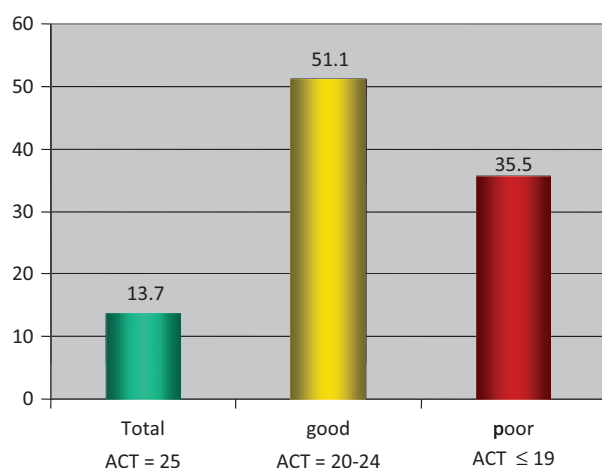


Figure 2. Level of asthma control according to ACT.

gastric disorders (12.0%) cardiovascular (26.9%) and osteoarticular diseases (18.0%) (Table 1).

ICS were delivered using metered dose inhalers (MDI) in 67.1% of cases, nebulas in 37.9%, and dry powder inhalers (DPI) in 5.1% of cases, respectively (not mutually exclusive). Of note, only 38.6% of patients had a spirometry in the last 12 months.

Levels of asthma control

Total control of asthma (ACT score = 25) was observed in 13.7% of all patients, asthma was well controlled (ACT score 20–24) in 51.0% of patients, whereas asthma was poorly controlled in 35.3% of patients (ACT < 20) (Figure 2).

When stratified by geographic area, total control was significantly more frequent in Northern compared to Southern or Central regions of Italy (respectively from 20.7% to 12% and 11%, Table 2).

A significant relationship was also observed between asthma control and age: poor control was more frequent in patients with age >60 (40.4%) than in those with age <40 (30.8%); at variance, total control was more frequent in patients with age <40 with respect to those with age >60 (17.6% versus 9.6%) (Table 2).

The smoking history was also a significant predictor of the level of asthma control: total control of asthma was significantly more frequent in non-smokers as compared to former smokers and current smokers (16.4% versus 11.8% and 8.4%, respectively) (Table 2).

As expected, the patients with total control of their asthma used less rescue short acting beta2 agonists (SABA) in the last 12 months compared with the patients with poor control of their asthma (mean number of MDI SABA 3.0 versus 5.3, $p < 0.0001$) (Table 3).

The duration of asthma (Table 2) and the different delivery systems used for the inhaled drugs (data not shown) did not significantly influence the level of asthma control.

Totally controlled patients performed significantly less spirometries and specialistic visits compared with poorly controlled patients (respectively, 10.8% versus 37.1, $p = 0.076$; 7.8 versus 43.9, $p = 0.005$) (Table 3).

Patients with poorly controlled asthma have also an increased risk of asthma-related unscheduled specialist visits (OR 1.57; 95% CI: 1.12–2.18), emergency room visits (OR 5.49; 95% CI: 2.93–10.2), and hospitalisation (OR 4.94; 95% CI: 2.49–9.79) as compared to patients with good or total control of their asthma (Table 4).

The high concordance between the level of asthma control defined by self-administered ACT score and the GP's subjective perception of the respiratory health status is shown in Table 5. For example, 86.2% of totally controlled patients according to ACT score were considered to have an excellent respiratory health status by their physicians; whereas, only 2.9% of these patients were judged to have a poor respiratory health status by their physicians.

Discussion

This community-based observational cross-sectional study investigated the level of asthma control in patients with mild asthma in Italy, using the Asthma Control Test™, a validated tool. Measurement of the level of asthma control is recommended by GINA guidelines as a key part of the long-term management of the asthmatic patients [1].

One of the most striking results of our study is that 35.3% of patients had poor or no control (score < 20) of their asthma, despite being considered by their general practitioners as mild asthmatics and regularly treated with ICS; total control of asthma was present only in 13.7% of patients.

The results are in keeping with previous studies performed in the Italian general population. For example, a questionnaire-based survey found that only 10% of the asthmatic patients were controlled (neither symptoms nor life impairment), despite 90.2% of them received a pharmacological treatment in the last 12 months [6]. More recently, the European National Health and Wellness Survey (NHWS) estimated a large proportion of uncontrolled asthmatics (around 56%) in five European countries including Italy [7].

Table 2. Demographics and characteristics of asthmatic patients stratified by asthma control.

	Patients N = 950	Total control N = 130, n (%)	Well Control N = 485, n (%)	Poor control N = 335, n (%)	p Value
Geographic area					<0.0001
Northern	208	43 (20.7)	112 (53.8)	53 (25.5)	
Central	211	23 (11.0)	121 (57.3)	67 (31.7)	
Southern	531	64 (12.0)	252 (47.5)	215 (40.5)	
Age ranging, years					0.027
<40	279	49 (17.6)	144 (51.6)	86 (30.8)	
41–60	319	46 (14.4)	161 (50.4)	112 (35.1)	
>60	322	31 (9.6)	161 (50.0)	130 (40.4)	
Duration of asthma, years					0.226
<10	262	40 (15.3)	129 (49.2)	93 (35.5)	
11–20	299	46 (15.4)	160 (53.5)	93 (31.1)	
>20	347	40 (11.5)	172 (49.6)	135 (38.9)	
Smoking habits					0.006
Non smokers	556	91 (16.4)	293 (52.7)	172 (30.9)	
Ex smokers	170	20 (11.8)	74 (43.5)	76 (44.7)	
Smokers	213	18 (8.4)	112 (52.6)	83 (39.0)	

Missing data: Duration of asthma N = 32.

Smoking habit N = 37.

Total control of asthma is when the ACT score = 25; Good control of asthma is defined as an ACT score = 20–24; Poor control of asthma is defined as an ACT score < 20.

Table 3. SABA use, lung function tests and visits of asthmatic patients stratified by asthma control.

	Patients, n = 950	Total control, n = 130, n (%)	Well control, n = 485, n (%)	Poor control n = 335, n (%)	p Value
Spirometry or PEF*	372	40 (10.8)	194 (52.1)	138 (37.1)	0.076
Specialistic visits ^a	180	14 (7.8)	87 (48.3)	79 (43.9)	0.005
SABA packs in the last 12 months Mean (SD)	691	3.0 (3.0)	4.1 (4.0)	5.3 (5.3)	<0.0001

*Not mutually exclusive.

^aAt least once in the last 12 months.

Table 4. Univariate logistic regression on clinical outcomes during the last 12 months of poor asthma control evaluated in the last 4 weeks.

	OR	95% CI
Hospitalisation ^a	4.94	2.49–9.79
Emergency room visits ^a	5.49	2.93–10.2
Specialistic visit ^a	1.57	1.12–2.18

^aAt least once in the last 12 months.

Also, our results are in keeping with previous studies showing that smoking habit and older age are associated with poor asthma control. Increasing evidence suggests that the efficacy of ICS is reduced in smoking-asthmatics [8]. Furthermore, Silverman et al. have found a high proportion of smokers in patients admitted to emergency department for asthmatic exacerbations [9]. There is some evidence that smoking cessation may at least partially restore steroid responsiveness in asthmatic ex-smokers [10–12].

In line with previous evidences suggesting that older asthmatic patients experience greater morbidity and mortality [13,14] and lower quality of life than younger patients [15], we have found a positive association between poor asthma control and increasing age. A possible explanation is the plausible higher prevalence, in older patients, of factors that

usually make asthma more difficult to manage, such as adult onset [16], poor lung function [17], comorbidities.

Our observation that a poor asthma control is more frequent in the central and southern regions of Italy compared with the northern part of Italy requires to be confirmed in larger epidemiological studies and may be related to the potential influence of climate on asthma, for example through the type and level of allergen exposure [18–20].

In our study, GP perception of patient respiratory health is quite in accordance with the patient evaluation of control by ACT score. On the contrary, by comparing patient perception of control with objective parameters of evaluation the level of concordance may be low, since patients tend to overestimate their asthma control [21].

The prevalence of atopy in our study population is similar to those reported in other studies [22].

A major strength of our study is the large sample representative of all regions of Italy, the use of data already recorded in a GPs database, and the availability of 12-month retrospective data on the asthma-related outcomes.

Data about the ICS doses actually prescribed and about patient's adherence to the treatment have not been analysed, even if they certainly affect asthma control. The correlation between the treatment dosage and the level of asthma control actually lies outside the aim of our study. According to our inclusion criteria selected patients suffered from mild

Table 5. GP perception of the respiratory health of the asthmatic patients stratified by the level of asthma control.

GP perception on patient respiratory health	Patients, <i>n</i> = 944	Total control, <i>n</i> = 130		Good control, <i>n</i> = 485		Poor control, <i>n</i> = 335	
		<i>n</i> (%)	95% IC	<i>n</i> (%)	95% IC	<i>n</i> (%)	95% IC
Excellent	29	25 (86.2)	12.8–27.0	4 (13.8)	0.2–2.0	–	–
Very good	169	45 (26.6)	26.4–43.4	109 (64.5)	18.8–26.4	15 (8.9)	2.5–7.2
Good	395	49 (12.4)	29.3–46.6	249 (63.0)	46.8–55.8	97 (24.6)	24.1–34.1
Not so good	285	9 (3.1)	3.2–12.7	113 (39.6)	19.6–27.3	163 (57.2)	43.1–54.1
Poor	66	1 (1.5)	0.01–4.2	6 (9.1)	0.4–2.6	59 (89.4)	13.6–22.1

Missing GP perception data *n* = 6.

persistent asthma and were treated in conformity with the proper treatment step recommended by GINA guidelines [1]. A potential limitation of our study concerns adherence assessment, since numerous tools are available to evaluate it. On the other hand, it should be noted that a single tool does not reflect the reality of the situation and the lack of standardisation in adherence assessing leads to different estimations in published reports [23]. In other words, currently, there is no easy and pragmatic way to assess adherence in daily clinical practice. However, a structured follow-up plan shared by patients and GPs (and/or specialists) could certainly improve adherence [23].

Another potential limitation is represented by the criteria used to identify the patients with mild persistent asthma. In our study, we selected all the asthmatic patients recorded in the GP database with a diagnosis of asthma and at least three prescriptions of ICS in the last 12 months, and we asked them to refer to the surgery for study recruitment and disease evaluation. These criteria could be considered a reasonable marker of persistent asthma, as previous authors [24,25] reported that adherence to regular ICS treatment is usually less than 50%.

In conclusion, the use of ACT is feasible in the office of the general practitioners and allows an objective recognition of patients with poor control of their asthma so that education and pharmacological efforts may be properly addressed. Even mild patients should be regularly reevaluated. Treatment is often inadequate and should be targeted to improve long-term control and reduce asthma morbidity.

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Declaration of interest

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