



# Medication use and disease control of asthmatic patients in Flanders: A cross-sectional community pharmacy study

E. Mehuys<sup>a,\*</sup>, L. Van Bortel<sup>b</sup>, L. Annemans<sup>c</sup>, J.P. Remon<sup>a</sup>, I. Van Tongelen<sup>a</sup>, E. Van Ganse<sup>d</sup>, L. Laforest<sup>d</sup>, G. Chamba<sup>e</sup>, G. Brusselle<sup>f</sup>

<sup>a</sup>Pharmaceutical Care Unit Ghent, Faculty of Pharmaceutical Sciences, Ghent University, Harelbekestraat 72, 9000 Ghent, Belgium

<sup>b</sup>Heymans Institute of Pharmacology, Faculty of Medicine and Health Sciences, Ghent University, De Pintelaan 185, 9000 Ghent, Belgium

<sup>c</sup>Department of Public Health, Faculty of Medicine and Health Sciences, Ghent University, De Pintelaan 185, 9000 Ghent, Belgium

<sup>d</sup>Pharmacoepidemiology Unit, University of Lyon, EA 3091 CHU-Lyon, France

<sup>e</sup>Institut des Sciences Pharmaceutiques et Biologiques, University of Lyon, 8 Avenue Rockefeller, 69373 Lyon Cedex 08, France

<sup>f</sup>Department of Respiratory Diseases, Ghent University Hospital, De Pintelaan 185, 9000 Ghent, Belgium

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## KEYWORDS

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**Summary** The aim of this study was to describe medication use and disease management of asthmatic patients and to evaluate the usefulness of the Asthma Control Test (ACT) in community pharmacies. In 54 Flemish community pharmacies 166 asthmatic patients were included in the study. At inclusion, the study persons completed a survey to assess subject characteristics, symptoms and asthma attacks, and peak expiratory flow (PEF) was measured. Furthermore, the actual level of asthma control was assessed by ACT, a clinically validated measure of asthma control. Prescribed medicine data of the patients were 1 year retrospectively analysed from the prescriptions.

Mean age of the sample was 36.8 year, 23% were smokers. As maintenance treatment, 63% of the patients used a combination product containing an inhaled corticosteroid and a long-acting  $\beta_2$ -agonist in a single inhaler. According to ACT, 49.1% of the patients were insufficiently controlled. Only 4.9% of the patients had a maximal ACT score of 25, indicating complete asthma control; 46.0% of the study population obtained an ACT score between 20 and 24, meaning that their asthma is well controlled. In contrast, 30.7% of the patients had a score between

\*Corresponding author. Tel.: ++32 9 2648082; fax.: ++32 9 2228236.  
E-mail address: els.mehuys@ugent.be (E. Mehuys).

15 and 19, indicating uncontrolled asthma. In all, 18.4% obtained ACT scores of less than 15, meaning that their asthma was seriously out of control and necessitating referral to their general practitioner or lung specialist. Importantly, the correlation between the self-perceived level of asthma control and the objective assessment of the asthma control level was poor: 82.3% of the patients believed their asthma to be totally or well controlled, while this was the fact for only 50.9% of the patients. In conclusion, the ACT appears to be a useful tool to determine rapidly and accurately the level of asthma control in patients presenting at community pharmacies.

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## Introduction

Asthma is a chronic inflammatory airway disease characterized by widespread, variable and reversible airflow obstruction associated with airway hyperresponsiveness, leading to recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. Throughout the world, asthma is a major cause of chronic morbidity and economic burden. It is estimated that more than 5% of the world's population suffers from asthma, and its prevalence is still increasing. A full explanation for this increase has not been found, but it is suggested that it is related with the increasing urbanization and adoption of western lifestyles.<sup>1</sup>

The aim of asthma management is to achieve and maintain control of the disease.<sup>2-4</sup> Asthma management guidelines, such as Global Initiative for Asthma (GINA), have been developed to obtain optimal asthma control and to provide effective medical care for asthmatic patients. Despite the improved treatment options and the existence of asthma management guidelines, large-scale telephonic surveys such as the Asthma Insights and Reality (AIR) surveys which were conducted in America, Europe, Asia-Pacific and Japan, have shown that control of asthma is suboptimal for many patients.<sup>5</sup> In order to improve asthma control, asthma management programs are extensively promoted in primary care. Due to their frequent contact with the patient on prescription refill, community pharmacists are well placed to play an important role in the management of asthmatic patients. However, studies investigating asthma management in a community pharmacy setting are rare.

The aim of this pharmacy-based study was to describe medication use and disease management of asthmatic patients and to assess asthma control via the Asthma Control Test (ACT), a clinically validated measure of asthma control.<sup>6</sup> This work has been presented in part in abstract form.<sup>7</sup>

## Materials and methods

### Study design and methods

This asthma study was carried out as a 1-year retrospective, cross-sectional, multicenter trial (start of the study: January 2004) describing the medication use of asthmatic patients. The anti-asthma medication as well as all other prescription drugs purchased by each patient, during the 12 months before inclusion in the study, was reviewed from the anonymous prescriptions from the pharmacy files. At inclusion of the subjects, their actual level of asthma control (by means of the ACT) and peak expiratory flow (PEF) was assessed. PEF data are the best of three measurements and are expressed as the percentage of the predicted value.<sup>8</sup> Furthermore, the study persons completed a written questionnaire providing personal information, information on asthma symptoms and attacks, occurrence of side effects of the asthma medication, doctor's visits, use of alternative medicine and possession of a written action plan. The same study was conducted simultaneously in community pharmacies in France.<sup>9</sup>

Fifty-four community pharmacies in Flanders (Belgium) were chosen for the study. These pharmacies were selected because they act as a trainee post for the Pharmaceutical Sciences students of Ghent University. The pharmacy trainees were responsible for the study and performed the data collection during the study. The pharmacies were not paid for participation at the project.

Asthmatic patients were identified by means of their medication. In each pharmacy, the first 4 patients purchasing asthma medication in the pharmacy and fulfilling the following criteria were included in the study: patients taking prescribed asthma medication for at least 1 year, having a smoking history of less than 10 pack-years (to focus as much as possible on asthma, not on COPD), aged between 18 and 50 years, being regular visitors of

the pharmacy and willing to participate in the study. All patients provided written informed consent before enrollment into the study. The project was approved by the Ethics Committee of the Ghent University Hospital. The general practitioner of each patient was informed about the project by letter.

The severity of a patient's asthma was classified in four levels (Intermittent, Mild Persistent, Moderate Persistent and Severe Persistent) based on the clinical features present—both symptoms during the day and nighttime symptoms—as well as the PEF measurements (Global Initiative for Asthma (GINA), 1995).

### Level of asthma control

At inclusion, the actual asthma control was assessed by the ACT survey, a clinically validated measure of asthma control.<sup>6</sup> The ACT is a 5-item questionnaire asking the respondent to consider the impact of asthma on everyday functioning, shortness of breath, use of rescue medication, nocturnal asthma symptoms and the patient's rating of asthma control, during the last 4 weeks. For each question five answer possibilities were proposed, classified by decreasing level of asthma control. The ACT score (range, 5–25) for each subject was determined by summing the responses to the 5 items, in which a higher score indicated better asthma control. Patients with an ACT score of at least 20 points were classified as "controlled" (25 = "totally controlled"; 20–24 = "well controlled"), while patients with a score of less than 20 points were considered as "insufficiently controlled".

## Results

### Patient characteristics

Of the 224 asthmatic patients meeting the inclusion criteria, 166 patients (72 men and 94 women) participated in the study. Thirty-three patients refused to participate, the main reasons for refusal were: no time, no interest and violation of privacy. Twenty-five persons dropped out of the study because they did not return their questionnaires to the pharmacy.

The mean age of the patients was  $36.8 \pm 10.8$  year (Table 1). The prevalence of current smokers among these asthmatic patients was high (23%) and more than half of these smoked at least 10 cigarettes per day (Table 1). The mean age at

**Table 1** Patient characteristics.

Age (yr) (SD)	36.8 (10.8)
Sex, % female	56.6%
Age at asthma diagnosis	16.0 (13.3)
<i>Body Mass Index</i>	
Men (SD)	25.6 (4.8)
Women (SD)	24.6 (5.6)
<i>Smoking</i>	
Non-smokers	77.6%
Current smokers	22.4%
1–9 cigarettes/day	10.9%
10–20 cigarettes/day	8.5%
> 20 cigarettes/day	3.0%

diagnosis of asthma was  $16.0 \pm 13.3$  years. The mean PEF of the study population was  $78.5 \pm 21.8\%$  of the predicted value. The frequency of daily asthma crises was less than once a week for the majority of the patients (75.9%), while 17.7% of the patients reported to have several crises per week. Nocturnal asthma symptoms were absent for 64.0% of the study persons; nocturnal awakening due to asthma occurred more than twice a month for 20.1% and more than once a week for 12.2%. During the last 2 weeks, a minority of the study persons reported to have been hindered by asthma symptoms such as wheezing, chest tightness or cough (Table 2). Using the symptom-based GINA classification method of asthma severity (GINA 1995), 30% of the patients were classified as intermittent, 38% as mild persistent, 12% as moderate persistent and 20% as severe persistent.

### Assessment of asthma control by the ACT

According to the ACT, 49.1% of the patients were insufficiently controlled during the last 4 weeks showing symptoms of dyspnoea (during day and night), lifestyle restrictions and regular need of short-acting bronchodilators (Table 3). The correlation between the self-perceived level of asthma control and the objective assessment of level of asthma control—as assessed by the ACT—was poor. In all, 82.3% of the patients believed their asthma to be totally or well controlled, while this was the fact for only 50.9% of the patients. The ACT scores according to the asthma severity class are shown in Fig. 1.

The survey also questioned on factors provoking an asthma-attack. The most cited provoking factor was a respiratory infection; other frequently

**Table 2** Asthma-attacks and symptoms.

<i>Frequency of daytime asthma crises</i>	
≤1 × /week	75.9%
Several times/week	17.7%
≥1 × /day	6.4%
<i>Frequency of nocturnal asthma crises</i>	
Never	64.0%
≥2 × /month	20.1%
≥1 × /week	12.3%
Almost every night	3.6%
<i>Wheezing</i>	
Never/very rarely	35.4%
Rarely/sometimes	45.1%
Quite often	8.5%
Almost always/always	11.0%
<i>Chest tightness</i>	
Never/very rarely	53.6%
Rarely/sometimes	36.7%
Quite often	4.8%
Almost always/always	4.9%
<i>Cough</i>	
Never/very rarely	56.6%
Rarely/sometimes	31.3%
Quite often	6.6%
Almost always/always	5.5%

reported factors were physical effort, tobacco, stress/emotions, air pollution and allergens of animal and vegetable origin. An increased use of rescue medication was for the majority of the patients the most important sign of worsening of their asthma.

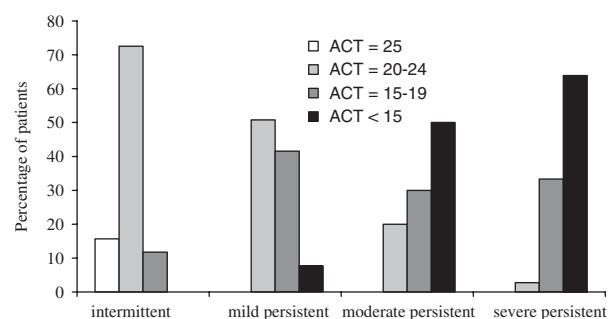
## Asthma treatment

The majority of the patients consulted a general practitioner for their asthma on a 1–3 monthly basis and visited a pneumologist once or twice a year. Only 6.2% of the patients had been admitted to a hospital due to asthma during the last 12 months. A remarkable fact was that quite a large proportion of the patients (29.3%) had recourse to alternative medicine, especially homeopathy (22.3%).

As maintenance treatment the majority of the patients used a combination product containing an inhaled corticosteroid and a long-acting  $\beta_2$ -agonist in a single inhaler (Seretide<sup>®</sup> or Symbicort<sup>®</sup>) (Table 4). Alternatives to these combination products are the separate use of inhalation corticosteroids plus a long-acting inhaled  $\beta_2$ -agonist or oral sustained release theophylline. Rescue medication consisted mainly of rapid-acting inhaled  $\beta_2$ -agonists

**Table 3** Asthma control level assessed by means of the Asthma Control Test.

<i>Hinder in daily activities</i>	
Never	12.7%
Rarely	30.7%
Sometimes	43.4%
Most of the time	10.2%
All of the time	3.0%
<i>Shortness of breath</i>	
Never	37.0%
1–2 times/week	38.3%
3–6 times/week	8.6%
Once a day	5.6%
More than once a day	10.5%
<i>Night wakening</i>	
Never	37.0%
Once or twice	36.4%
Once a week	9.3%
2–3 nights/week	9.9%
4 or more nights/week	7.4%
<i>Use of short-acting bronchodilators</i>	
Never	29.7%
Once a week or less	26.7%
A few times a week	16.3%
1 or 2 times per day	16.4%
3 or more times per day	10.9%
<i>Patients' perception of their asthma control</i>	
Completely controlled	39.0%
Well controlled	43.3%
Somewhat controlled	11.6%
Poorly controlled	4.9%
Not controlled at all	1.2%
<i>ACT score =</i>	
25	4.9%
20–24	46.0%
15–19	30.7%
< 15	18.4%

**Figure 1** ACT scores according to the asthma severity class (GINA 1995).

(47.8%) and combination products containing inhaled anticholinergics and rapid-acting inhaled  $\beta_2$ -agonists (26.4%). More than half of the study

**Table 4** Overview of the anti-asthma medication use of the study population.

<i>Daily controller medication</i>	
Inhaled corticosteroids	40.9%
Long-acting beta-agonists	19.5%
Combination products (Seretide <sup>®</sup> or Symbicort <sup>®</sup> )	62.9%
Oral xanthines	18.9%
Leukotriene modifiers	27.0%
<i>Relief medication</i>	
Short-acting beta-agonists (SABA)	47.8%
Inhaled short-acting anticholinergics	5.7%
Inhaled short-acting anticholinergics+SABA	26.4%

persons reported side effects of the asthma medication: palpitations (24.7%), hoarse voice (16.9%), fatigue (16.3%), irritated throat (13.3%), insomnia (10.8%), excitation (10.2%) and headache (9.0%) were the most reported side effects.

More than half of the patients (53.5%) had used antibiotics during the last year. Also oral corticosteroids (22.6%), muco-regulators (22.6%) and anti-tussiva (29.6%) were frequently delivered to the asthmatic patients. Furthermore, 12.4% of the patients consumed nasal corticosteroids in monotherapy, 22.5% antihistaminics in monotherapy and 17.8% combined nasal corticosteroids and antihistaminics. More than half of the patients thus had used antihistaminics or nasal corticosteroids, suggesting co-morbidity of allergic rhinitis.

### Asthma management instructions and information

Asthma management not only encompasses the prescription of anti-asthma medication, but also patient education, instruction of the proper use of inhaler devices, and the administration of asthma action plans. Written asthma action plans inform patients how to adjust the asthma medication and how to manage an asthma attack. Interestingly, only 35% of the patients possessed a detailed asthma action plan in case of an asthma crisis. The proportion of patients having an asthma action plan varied from 22.0% for the patients consulting only a general practitioner to 41.3% for those visiting only a pneumologist and 41.7% for those patients visiting both a general practitioner and a pneumologist.

The questionnaire also asked the patients who gave them the instruction on how to use the inhaler devices. Most of them (74.8%) learned it only from their doctor (general practitioner or pneumolo-

gist), 6.7% only from the pharmacist and 16.0% from both doctor and pharmacist. In 2.5% of the cases, nobody explained the inhaler technique.

The patients' need of information about asthma was also assessed. More than half of the patients searched for information about asthma themselves. The patients are primarily informed about their disease by their doctor. Other sources of information were the pharmacist (30.1%), the patient information sheet (27.7%), press and internet (22.9%), and radio/television (11.5%). The vast majority (88.5%) of the study persons felt sufficiently informed about their disease as well as about their treatment.

### Psychological impact of asthma

Asthma had a moderate psychological impact on the studied population: 42.2% of the patients declared to consider their disease as a handicap or an important concern. Furthermore, almost 1 patient on 6 purchased psychotropic drugs. During the last 2 weeks, almost 15% of the patients declared to be worried at least 'quite often' due to their asthma. Furthermore, a substantial portion of the patients felt frustrated (13.5%) at least 'quite often' or was afraid not to have their asthma medication nearby (18.5%). More than a quarter of the patients was hindered at least 'quite often' by tobacco smoke, while 17% was bothered by dust.

### Discussion

This study showed that despite the availability of effective therapies, asthma control is bad or suboptimal for half of the studied population of adult patients with persistent asthma, but a majority is not aware of that. Recently, the Gaining Optimal Asthma Control Study (GOAL)—a 1-year prospective trial comparing salmeterol/fluticasone propionate with fluticasone propionate monotherapy in patients with asthma—demonstrated that guideline-derived asthma control can be achieved in a majority of the asthmatic patients.<sup>10</sup> A possible drawback of the GOAL study is that it was carried out as a prospective trial implying careful patient recruitment, possibly generating a selection bias, and close follow-up of the patients, resulting in an unrealistic high compliance of 89%.

Asthma is a variable disorder, due to spontaneous and therapy-induced variations in severity, thus regular follow-up of asthmatic patients is required. In order to improve asthma control asthma management programs are extensively promoted in primary



care. GINA (2002) describes a recommended asthma management program, consisting of six interrelated parts: patient education, assessment and monitoring of asthma severity, avoidance of risk factors, individual medication plans, individual management plans for exacerbations and regular follow-up care.<sup>2</sup> These guidelines recommend greater participation of both patients and caregivers in the management of asthma. Since community pharmacists have recently expanded their role to giving health care advice for patients with acute and chronic illness, they can play an important role in the management of asthmatic patients. Furthermore, the community pharmacist has frequent contacts with the patient on account of their frequent visits to the pharmacy to obtain their medication. Therapeutic outcomes monitoring is a model for increasing pharmacists' role in primary health care. It is based on the concept of pharmaceutical care, a way to optimize drug therapy, minimize drug-related problems, and improve self-management and quality of life.<sup>11-13</sup>

Pharmacists could help in the management of asthma in several ways. Firstly, the pharmacist could assess the level of control of the asthmatic patient. Recently, Nathan et al. (2004) introduced the ACT, a brief and easy-to-administer procedure to assess asthma control,<sup>6</sup> which has been proven to detect clinically meaningful changes in asthma control and FEV<sub>1</sub>.<sup>14</sup> Our study evaluated the usefulness of ACT in community pharmacies and showed that it is a simple and pragmatic method for quantifying asthma control by both health care professionals and patients. However, drawback of the test is that 1 of the 5 items of the ACT questions the patient for the self-perceived level of control, which generally results in an overestimation of the ACT score since many patients overestimate their level of asthma control. The use of ACT in community pharmacies could be an efficient tool to improve asthma control, whereby the pharmacist's advice could depend on the patient's ACT score. An ACT score of 20-25 indicates good or complete asthma control, so for these patients no specific advice is needed. For patients having an ACT score of 15-19, indicating uncontrolled asthma, the pharmacist could improve the patient's inhalation technique and point the patient at the importance of adherence to the maintenance treatment. In case of an ACT score below 15, the pharmacist should refer the patient immediately to the GP or lung specialist since these patients are at risk for severe asthma attacks.

Secondly, it is believed that asthma control can be optimized if patients regularly monitor their asthma.<sup>2</sup> Self-management includes detection of changes in their condition, making timely adjustments to

their asthma medication and knowing when to seek medical care. The community pharmacist could help to improve self-management of asthma by assisting patients in monitoring their lung function and symptoms. PEF monitoring is an important clinical tool providing an objective measure of lung function and can be used in pharmacy and at home. Active involvement of community pharmacists in promoting self-management by PEF measurement and use of ACT may help to optimize asthma control.

Thirdly, the GINA management program recommends patient education as a means to achieve and maintain asthma control. Therapeutic failure of asthma treatment is often the result of poor adherence to the medication, especially with respect to the maintenance treatment. Most important reasons for poor adherence include lack of immediate benefit from anti-inflammatory therapy, side-effect fears, poor education and resentment about the need for therapy.<sup>15</sup> Medication adherence can be improved by patient education and self-management programs.<sup>3</sup> The pharmacist, who is trained as an expert in drugs and who is the last health care professional to come into contact with the patient, can provide the patient with clear information on the drug, frequency of administration, important side effects and correct use of the inhaler devices. In this survey, 2.5% of the patients mentioned never have been demonstrated the inhaler technique. Attention should also be given to prevention, since asthma exacerbations may be caused by a variety of triggers including allergens, pollutants, tobacco smoke, food, and drugs. Prevention aims to reduce the exposure to these triggers in order to improve the control of asthma and reduce medication needs.<sup>2</sup>

Finally, another GINA recommendation is the possession of a written asthma action plan for the home management of exacerbations. Recently, a Cochrane review showed that patients having an asthma action plan visited less the emergency department, were less hospitalized and had a better lung function than patients without an action plan.<sup>16</sup> However, the current study demonstrated that the spread of action plans under Flemish asthmatic patients is still insufficient. The community pharmacist may point the patient at the usefulness of an action plan.

Some studies have already been performed evaluating the effectiveness of pharmaceutical care in community pharmacies for patients with asthma.<sup>17</sup> Schulz et al.<sup>18</sup> studied 178 patients (101 in the intervention group, 63 in the control group) in Germany and obtained higher peak flow rates at 6 months in the intervention group, but not at 12 months. However, medication knowledge, inhaler

technique and quality of life were greater in the intervention group at 12 months. Weinberger et al.<sup>19</sup> evaluated 1113 patients (447 in a pharmaceutical care program, 363 in a PEF rate monitoring control group, 303 in usual care) in the USA. Significantly higher PEF rates were noticed in the pharmaceutical care group, compared with the usual care group, but not in the PEF monitoring group. Stergachis et al.<sup>20</sup> studied 330 children in 32 community and clinic pharmacists (14 in intervention, 18 in usual care) in the USA. Pharmacists' interventions resulted in no significant effect on asthma outcomes. McLean et al.<sup>21</sup> studied 631 patients (191 in enhanced care, 214 in usual care, 226 in a control group) in the USA. Patients in the pharmaceutical care program had significantly decreased symptoms, increased PEF rates, decreased  $\beta$ -agonist use, improved quality of life scores, increased knowledge levels, decreased doctor's visits, emergency department visits and days of sickness. Future studies should also address the cost-effectiveness of a pharmaceutical care intervention.

Other significant findings of this study were the high prevalence of smokers in the sample, and the high consumption of antihistaminics and/or nasal corticosteroids, which is an indication for the important comorbidity of allergic rhinitis and asthma.<sup>22,23</sup> These data suggest that 52.7% of the study population suffers from allergic rhinitis. This percentage may even be an underestimation of the prevalence of allergic rhinitis among asthmatics since antihistaminics can also be purchased over-the-counter and this study only registered prescription drugs.

## Conclusions

Asthma control of Flemish adult asthmatic patients was suboptimal for half of the studied population. The Asthma Control Test (ACT) appears to be ideally suited to determine the level of asthma control in patients presenting at community pharmacies. Pharmaceutical care performed by pharmacists may improve clinical and humanistic outcomes in asthmatic patients. The next step will be to evaluate the effectiveness and cost-effectiveness of community pharmacy-based interventions on symptom severity and health-related quality of life of asthmatic patients in a controlled prospective study.

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