Asthma Control According to the Community Pharmacists: Evidence and Potential Implications from an Italian Cross-Sectional Study

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Abstract

**Background.** Asthma control and monitoring still represents a challenge worldwide. Although the international guidelines suggest the interplay with primary care as an effective strategy, the community pharmacies’ are rarely involved in asthma management. The present cross-sectional study aimed at providing a picture of the relationship between asthma severity and control according to the community pharmacies’ perspective of the health district of Verona (North-Eastern Italy).

**Methods.** A call for participation was launched through the Pharmacists’ Association of Verona. Patients referring to the participating pharmacies with an anti-asthmatic drug medical prescription and an asthma exemption code were asked to complete the Asthma Control Test and a brief questionnaire collecting information on their age, sex, smoking status, aerobic physical exercise and usual asthma therapy, which also defined the severity level of asthma. A multinomial logistic regression model was fitted to investigate the risk of uncontrolled as well as poorly controlled vs. controlled asthma (base). Results were expressed as relative risk ratios (RRR) with 95% confidence interval (95%CI).

**Results.** 57 community pharmacies accepted to participate and 584 asthmatic patients (54% females; mean-age: 51 ± 19 years) were recruited. According to the ACT score 50.5% patients had a controlled asthma, 22.3% a poorly controlled and 27.2% uncontrolled. A variable proportion patients with uncontrolled asthma was observed at every level of severity, although more frequently in mild persistent form of disease. Most patients (92%) reported regular compliance with therapy. At multinomial regression analysis, patients under regular asthma treatment course (RRR=0.33; 95%CI: 0.15; 0.77) were less likely to have an ACT<16 compared to those not taking medications regularly.

**Conclusions.** Overall, our findings highlighted an unsatisfactory asthma control from the pharmacists’ perspective, independently of the asthma severity level. The relevance of community pharmacies as a first line interface suggest their involvement in an effective asthma management plan, from disease control and treatment compliance assessment to referral of asthmatic patients to medical consultancies.
Background

Asthma is one of the most common chronic disorders on a global scale, with a prevalence in the general population ranging from 1–18% [1-3].

The burden of asthma includes considerable financial impact in terms of direct (health care services, medications) and indirect (sickness absence from work, disability, other) costs [1, 2, 4].

The most striking contradiction in asthma is a general lack of its control [5-8], even for milder cases, despite the availability of very effective drugs which have been proven to be effective in most patients, if regularly taken [9].

Several countries have been adopting national plans to manage asthma, with the aim to improve its control and contain its impact, yet with unsatisfactory health outcomes [1, 12-14]. Since they frequently represent the first point of contact for patients affected by chronic conditions, the involvement of primary care services in asthma management has been suggested as a successful strategy to improve the control of the disease [1, 15]. In particular, in several countries the involvement of community pharmacies has already proven to offer an efficient support for the management of chronic conditions such as diabetes, hypertension and, with more limited evidence, asthma [16]. Nonetheless, community pharmacies are still largely underused to promote health in the general population in high-income countries [17].

Usually patients have good relationships with their local pharmacists, they rely on them and are more comfortable in that health care setting than in a medical environment. Moreover, pharmacists are more easily accessible for patients, also because an appointment is not required. As a result, local pharmacies may be extremely relevant in promoting behavioural changes aimed at improving healthy life-styles and treatment adherence to medications for various conditions, which considerably impacts on health care costs for the national health services (NHS) [17]. Furthermore, pharmacists can contribute to disease control assessment and medical referral if need be. In the case of asthma, easy to use and accurate tools for at a glance disease control evaluation are currently available. For instance, the asthma control test (ACT) is a standardized and validated five-item questionnaire...
measuring asthma control [10]. Although being easy-to-use, ACT is still underused by general practitioners (GPs) and medical consultants [11].

**Aim of the study**
In view of the above, the present cross-sectional study aimed at assessing the role of community pharmacists in the assessment and control of asthma within the health district of Verona (North-Eastern Italy).

**Methods**

**Ethical approval**
The Ethic Committee of the Pharmacists’ Association of Verona Health District approved the study protocol. Written informed consent was obtained from all study participants.

**a. Community pharmacies**
By expanding a previous pilot study [18], a call for participation was launched through the local Pharmacists’ Association, which includes all the community pharmacies in the Verona health district.

Before the study start, pharmacists attended a two-sessions seminar on bronchial asthma, its management, study design and study tools. The study lasted six months, from the 1st of January 2018 to 30th of June 2018.

**b. Patients**
Within the study time frame, consenting patients referring to the participating pharmacies with an anti-asthmatic drug medical prescription and an asthma exemption code were consecutively recruited. The asthma exemption code (007-493) enables patients to access free health care and medications related to their asthma condition and is released by the Italian NHS to individuals with a confirmed diagnosis of bronchial asthma, based on clinical history and lung function tests. The asthma exemption code therefore allows to accurately identify asthmatic patients.

Participating study subjects were asked to complete the Asthma Control Test (ACT, see below) and a brief questionnaire collecting information on their age, sex, smoking status, aerobic physical exercise and habitual asthma therapy, which also defines the severity of asthma according to Global Initiative for Asthma (GINA) recommendations [20].

**c. Asthma Control assessment**
Asthma control was assessed through ACT, a validated 5 item questionnaire which provides a snapshot on the degree of asthma control achieved over the past four weeks [19]. The overall ACT score attained by answering each of the five questions classifies asthma control as follows:

- 20-25: well controlled;
- 16 -19: partially controlled;
- ≤ 16: uncontrolled

In the presence of a score < 16 the patient was recommended to refer to his GP/medical consultant as soon as possible.

**d. Statistical analysis**

Numbers and percentages of each variable (age, sex, smoking status, aerobic physical exercise, ACT, asthma level, habitual asthma therapy) were estimated. Furthermore, the mean, standard deviation, median and range were calculated for age and ACT. A multinomial logistic regression model was fitted to investigate the risk of uncontrolled (ACT 16-19) as well as poorly controlled (ACT<16) asthma compared to controlled asthma (Base=ACT 20+), adjusting for sex, age, asthma treatment regimen (regular vs. non-regular) and asthma level (coded from 1 to 5). Results were expressed as relative risk ratios (RRR) with 95% confidence interval (95%CI).

Asthma coded as “unclassified” was classified as missing. All missing data were excluded, and complete case analysis was performed.

Analysis was carried out with Stata 14 (Stata Corporation, College Station, Texas, USA).

**Results**

Overall 57 community pharmacies (41% out of all pharmacies within the catchment area of Verona health district) participated to the study, with 671 asthma patients consecutively recruited. Complete data were available for 584 out of 671 patients enrolled. Patients’ demographic information can be seen in Table 1. Study subjects were predominantly females (54%) and had a mean age of 51±19 years, with 53% of them being older than 50. The mean age of female patients (52.1 years) was slightly higher than males’ (48.6 years). Most study subjects were non-smokers (54.4%), 19.2% were current smokers, and 26.4% ex-smokers. Although the majority of female patients were never-smokers (60.0% females vs. 48.3% males), the proportion of ex-smokers was higher among males.
(30.8% males vs. 22.8% females).

### Table 1

Distribution of variables by sex of patients. Number (N), column percentage (column %); mean ± standard deviation (SD); median, range. M = missing values.

| FACTORS                      | STRATA               | TOTAL  | MALES  | FEMALES |
|------------------------------|----------------------|--------|--------|---------|
| N. pharmacies                | 57                   |        |        |         |
| Sex (M: 87)                  | Female               | 316 (54.1) |        |         |
|                              | Male                 | 268 (45.9) |        |         |
| Age (years) (M: 86)          | Mean ± SD            | 51 ± 19.9 | 48.6 ± 20.7 | 53.1 ± 19.0 |
|                              | Median (range)       | 53 (4-92) | 48.5 (7-92) | 55 (4-90)  |
|                              | < 36                 | 144 (24.6) | 80 (29.9) | 63 (19.9)  |
|                              | 36-50                | 128 (21.9) | 63 (23.5) | 65 (20.6)  |
|                              | 51-65                | 144 (24.6) | 54 (20.2) | 90 (28.5)  |
|                              | 66+                  | 169 (28.9) | 71 (26.5) | 98 (31.0)  |
| Smoking status (M: 145)      | No                   | 286 (54.4) | 113 (48.3) | 171 (60.0) |
|                              | Yes                  | 101 (19.2) | 49 (20.9) | 49 (17.2)  |
|                              | Ex                   | 139 (26.4) | 72 (30.8) | 65 (22.8)  |
| Aerobic exercise (M: 192)    | No                   | 183 (38.2) | 70 (35.7) | 92 (38.2)  |
|                              | Yes                  | 292 (61.0) | 125 (63.8) | 146 (60.6) |
|                              | Unclassified         | 4       | 1 (0.5) | 3 (1.2)  |
| ACT (M: 6)                   | Mean ± SD            | 18.5 ± 5.2 | 18.7 ± 4.8 | 18.9 ± 4.8 |
|                              | Median (range)       | 20 (5-25) | 20 (5-25) | 20 (5-25)  |
|                              | 16-19 (uncontrolled) | 148 (22.3) | 67 (25.3) | 65 (20.7)  |
|                              | < 16 (poorly controlled) | 181 (27.2) | 61 (23.0) | 78 (24.8)  |
| Asthma Level (M: 96)         | 1 (intermittent)     | 76 (13.2) | 31 (12.7) | 44 (14.9) |
|                              | 2 (mild)             | 129 (22.4) | 50 (20.5) | 79 (26.7) |
|                              | 3 (moderate persistent) | 219 (38.1) | 109 (44.7) | 108 (34.7) |
|                              | 4 (sever persistent) | 86 (15.0) | 34 (13.9) | 32 (10.8) |
|                              | 5 (severe difficult asthma) | 17 (3.0) | 1 (0.4) | 5 (1.7) |
|                              | Unclassified         | 48 (8.4) | 19 (7.8) | 28 (9.5) |
| Regular therapy (M: 148)     | No                   | 42 (8.0) | 16 (7.3) | 26 (9.6)  |
|                              | Yes                  | 481 (92.0) | 204 (92.7) | 246 (90.4) |

Regular aerobic exercise was reported by 62% participants, with equal distribution by sex. Most participants (92%) declared to assume anti-asthmatic treatment on a regular basis, with a rather homogeneous distribution between females and males.

When considering the ACT score, asthma was controlled in 50.5% patients (51.7% males vs. 54.5% females), partially controlled in 22.3% of them (25.3% males vs. 20.7% females) and uncontrolled in the remaining 27.2% patients (23% males vs. 24.8% females).

The stratification of patients by asthma severity was as follows (Table 1):

- **Intermittent**: 76 patients (13.2%);
- **Mild persistent**: 129 patients (22.4%);
- **Moderate persistent**: 219 patients (38.1%);
- **Severe persistent**: 86 patients (15%);
- **Severe difficult asthma**: 17 patients (3%).
- Unclassified: 48 patients (8.4%).

The proportion of patients with mild asthma was higher among females (26.7%) than males (20.5%), whereas the prevalence of moderate (44.7% vs. 34.7%) and severe persistent disease (13.9% vs. 10.8%) was higher among males.

Table 2 and Figure 1 report the level of asthma control by severity of the disease. The mean ACT score was rather consistent across the various categories of disease severity, being lower only for severe asthma (level 5). By contrast, whilst the pattern of mean ACT was homogeneous among females, it increased by disease severity in males (Table 2).

| FACTORS          | STRATA            | ACT Mean ± SD | 20+ | 16-19 |
|------------------|-------------------|---------------|-----|-------|
| ALL PATIENTS     |                   |               |     |       |
| Age              | <50 years         | 19.2 ± 4.8    | 7 (2.7) | 114 (43.9) |
|                  | 50+ years         | 18.7 ± 4.0    | 16 (5.0) | 135 (2.2) |
| Smoking status   | Non-smoker        | 18.9 ± 4.6    | 9 (3.2) | 123 (43.8) |
|                  | Smoker            | 19.6 ± 4.6    | 3 (1.0) | 37 (37.0) |
|                  | Ex-smoker         | 19.6 ± 4.4    | 3 (1.0) | 56 (40.3) |
| Asthma Level     | 1                 | 19.0 ± 5.1    | 36 (47.4) | 16 (21.1) |
|                  | 2                 | 19.6 ± 4.3    | 76 (59.4) | 31 (24.2) |
|                  | 3                 | 19.3 ± 5.5    | 123 (56.4) | 47 (21.6) |
|                  | 4                 | 19.3 ± 4.7    | 47 (55.3) | 17 (20.0) |
|                  | 5                 | 16.2 ± 5.8    | 6 (35.3) | 3 (17.7) |
|                  | Unclassified      | 18.8 ± 4.3    | 21 (46.7) | 14 (31.1) |
| FEMALES          |                   |               |     |       |
| Asthma Level     | 1                 | 18.1 ± 5.1    | 23 (52.3) | 6 (13.6) |
|                  | 2                 | 19.9 ± 4.2    | 50 (64.1) | 15 (19.2) |
|                  | 3                 | 19.5 ± 4.3    | 59 (55.1) | 27 (25.3) |
|                  | 4                 | 19.2 ± 5.3    | 19 (59.4) | 4 (12.5) |
|                  | 5                 | 17.2 ± 3.9    | 2 (40.0) | 2 (40.0) |
|                  | Unclassified      | 18.7 ± 4.7    | 13 (46.4) | 8 (28.6) |

A lower proportion of patients with poorly controlled asthma (ACT<16) was found among those affected by mild disease (16.4%), with similar pattern between females and males. Among patients with uncontrolled asthma (ACT=16-19), the proportion with moderate persistent disease was higher in females (25.3%) than males (16.5%), whereas the percentage of patients with severe persistent disease was higher among males (21.2%) than females (12.5%). Among patients with poorly controlled asthma (ACT<16) the percentage with moderate persistent disease was higher among males (24.8%) than females (19.6%), whereas more females had severe persistent asthma (29.2% females...
Table 3 shows the results of the multinomial logistic regression analysis investigating the risk of uncontrolled (ACT 16-19) and poorly controlled (ACT <16) vs. controlled asthma (base), after removing the effect of sex, age, treatment adherence and asthma level. As can be seen, patients under regular asthma treatment course (RRR=0.33; 95%CI: 0.15; 0.77) were less likely to have an ACT<16 compared to those not taking medications regularly.

| FACTORS      | STRATA | ACT 20+ (Base) | ACT 16-19 | RRR (95%CI) | ACT < 16 | RRR (95%CI) |
|--------------|--------|----------------|-----------|-------------|----------|-------------|
|              |        | N (%)          | N (%)     | N (%)       | RRR (%)  | N (%)       | RRR (%)     |
| Regular therapy | No     | 17 (40.5)      | 11 (26.2) | Reference   | 14 (33.3)| reference   |             |
|              | Yes    | 103 (21.6)     | 98 (20.6) | 0.45 (0.20; 1.22) | 276 (57.9)| 0.33 (0.15; 0.77) | |
| Asthma level | 1      | 36 (47.4)      | 16 (21.1) | reference   | 24 (31.6)| reference   |             |
|              | 2      | 76 (59.4)      | 31 (24.2) | 1.44 (0.56; 3.72) | 21 (16.4)| 0.46 (0.21; 1.00) | |
|              | 3      | 123 (55.3)     | 47 (21.6) | 1.48 (0.60; 3.68) | 48 (22.0)| 0.58 (0.29; 1.16) | |
|              | 4      | 47 (55.3)      | 17 (20.0) | 1.10 (0.38; 3.24) | 21 (24.7)| 0.58 (0.25; 1.18) | |
|              | 5      | 6 (35.3)       | 3 (17.7)  | 4.16 (0.49; 35.65) | 8 (47.1)| 1.63 (0.21; 13.0) | |

Discussion

Our study explored the disease control of asthmatic patients in a community pharmacy setting. According to the ACT score, 50.5% patients were controlled, 22.3% poorly controlled and 27.2% uncontrolled. A variable proportion of patients with uncontrolled asthma was observed at every level of severity, although more frequently in those affected by mild persistent asthma. Most patients (92%) reported regular compliance with prescribed treatment. Treatment adherence was the only significant determinant for disease control, after removing the effect of all other factors.

Asthma control still represents a challenge worldwide [7,8] and the community pharmacies have been identified as a relevant partner in sharing this challenge with physicians [16]. Pharmacists can offer a first point of contact with the health care services to patients, easy to access for disease counselling and symptom relief. In his way, community pharmacies somehow compensate the difficult access of patients to hospital care as well as the limited time for consultations dedicated in GPs [16,18]. Although the involvement of primary care (particularly pharmacists) in asthma control is recommended by current international guidelines [20], only a few studies have been conducted on
this topic and none has been carried out in Italy [21-24]

According to our results the level of asthma control assessed by ACT was overall higher in comparison with studies using the same tool but conducted in a medical setting in Italy [5-8] or in community pharmacies of other European countries [21-24]. Some reasons may account for this discrepancy. The mean age of our study population is >50 years, whilst in previous studies reporting a worse asthma control, a higher proportion of younger patients were recruited. It has been previously reported that the prevalence of uncontrolled asthma is higher among young adults and adolescents [25]. The older age of our patients raises issues of differential diagnosis with other chronic respiratory conditions, particularly chronic obstructive pulmonary disease (COPD); in which case, the ACT may provide an unreliable score as it is not a validated instrument for obstructive syndromes other than asthma. However, the inclusion of the exemption code (007-493) among patients’ selection criteria allowed us to overcome this confounding factor. On the other side, it is well known that patients’ reported outcomes do not always tally with objective measurable indicators [26,27].

Overall, our findings highlight an unsatisfactory asthma control from the pharmacists’ perspective, independently of the asthma severity level. The main determinant of asthma control was treatment adherence and not the disease severity or other patient-related features.

The present study addressed two relevant points:
the assessment of asthma control in the general population; and the potential role of community pharmacies in managing the disease.

Regarding the first issue, our main finding was that a low treatment adherence was the only determinant of poor asthma control (ACT<16). Although this result may be intuitive, it highlights the importance of the local pharmacies in monitoring treatment compliance for asthma, a critical aspect to control the disease.

Patients recruited in the present study showed a surprisingly high treatment adherence (92%), which seems unreliable, as typically patients tend to overvalue their compliance to therapy [26]. Further, this finding is in contrast with actual data from the Italian regulatory agency [27]. Nonetheless, the prevalence of patients with moderate and severe persistent asthma in our population may account for higher treatment adherence due to the severity of their disease. Moreover, since adult or elderly
patients are more familiar and comfortable with the local pharmacists, they receive more frequent advice on the need of regular asthma therapy.

On the other hand, in the present study the lack of asthma control was more common among patients with mild persistent asthma. This finding is not surprising, as in our previous pilot study we reported a 31% prevalence of uncontrolled asthma in a GP setting [8]. It is plausible that the presence of intermittent symptoms led these patients to a treatment on demand, with a consequent overuse of beta-2 short agonists and underuse of inhaled steroids. Moreover, these patients prefer self-medication than regular follow-up by their GPs or by medical consultants. However, the risk of fatal asthma is still possible with mild persistent disease, as recently reported [28].

Our study confirmed the potential role of local pharmacies in the management of asthma, giving patients the opportunity to be counselled on disease control outside medical settings. However, whilst the positive results of this study suggest feasibility of asthma control at a local pharmacy level in real life, an overall inclusion of community pharmacist is a challenging target, as not all of them may be interested in being involved in a similar health plan, rating it demanding and time consuming, particularly in periods of the year of high morbidity with intense access to pharmacies [29]. Therefore, in addition to careful selection of well-trained, motivated community pharmacists, within a structured health plan, value-based incentives (VBI) programs may also be considered. Similar to other health care settings (e.g. GP practices), financial incentives could be granted to pharmacies to accomplish quality health outcomes in patients [17]. Beside assessment of asthma control, trained pharmacists have also the opportunity to teach patients about the disease and the proper use of medical devices, thus facilitating patients’ engagement [30]. Moreover, the local pharmacy could also be an optimal setting to deliver spirometry tests for a fee. However, despite charging patients for spirometry could motivate the participation of pharmacists in asthma control plans, similar measures are still open to debate, since the interpretation of spirometry entails specific competences that should be limited to trained and certified pharmacies [31]. Finally, community pharmacies should be encouraged to provide counselling on smoking cessation, as in our study population one out of five asthmatic patients was a smoker.
Conclusions
The community pharmacy is an underuse yet widely accessible primary care setting potentially useful to promote the health of the general population [17]. Due to the high prevalence of asthma, the inclusion of other allied healthcare professionals, such as the community pharmacists may represent a step forward to be considered with the view of improving the control of the disease. The main determinant for asthma control would appear to be compliance with therapy. Patients with chronic conditions may face barriers to access burdened healthcare services in high income countries. Allied health professionals as local pharmacies may provide critical cost-effective support to screen patients for their risk of asthma, increase their knowledge of the disease, assess asthma control, improve inhalation techniques and follow up their treatment compliance.

Abbreviations
ACT
Asthma Control Test
CI
Confidence Interval
COPD
Chronic Obstructive Pulmonary Disease
GINA
Global Initiative for Asthma
GP
General practitioner
NHS
National Health Service
RRR
Relative Risk Ratio
VBI
Value-Based Incentive

Declarations
Conflict of Interest
LC is Associate Editor of BMC Public Health. All other authors declare that they have no competing interests.

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Authors’ contributions:
GS and MC designed the study, coordinated the data collection; interpreted the data and wrote the original draft; LC analysed/interpreted the data and wrote the original draft; MB & NS coordinated the data collection and contributed to draft the manuscript; AD, CB, BO, FB provided technical clinical advise and contributed to draft the manuscript.

Ethics approval and consent to participate
The Ethical Committee of the Pharmacists’ Association of Verona Health District approved the study protocol. Written informed consent was obtained from all study participants.

Consent for publication
Not Applicable.

Availability of data and material
The datasets generated and analysed during the current study are not publicly available, since they were purposively collected by the authors for the present study, but are available from the corresponding author on reasonable request.

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Figures
Figure 1

Distribution of patients by asthma control test (ACT) and severity of asthma.