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 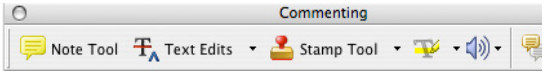

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 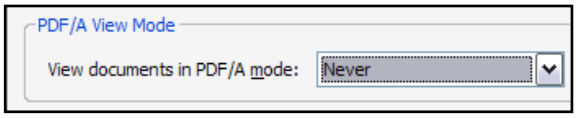

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 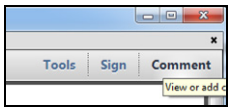

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 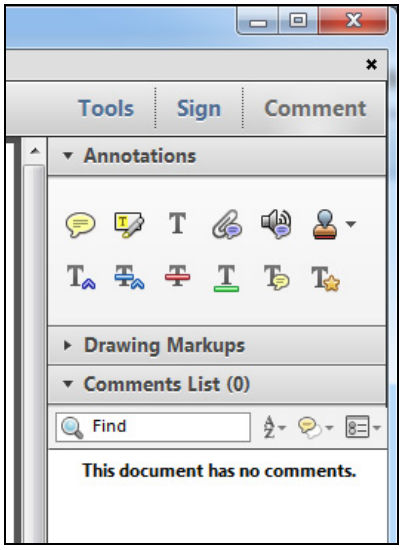
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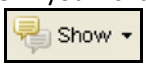
Review	To review your changes, click on the 'Show' button  on the Commenting tool bar. Choose 'Show Comments List'. Navigate by clicking on a correction in the list. Alternatively, double click on any mark-up to open the commenting box.	Your changes will appear automatically in a list below the Comment tool bar. Navigate by clicking on a correction in the list. Alternatively, double click on any mark-up to open the commenting box.
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Review Article

The role of the pharmacy in the management of bronchial asthma
A literature-based evaluation

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ABSTRACT

Objective: Pharmacists play a relevant role in the real-life management of asthma because they are a first-line referral for patients. In fact, the role of pharmacies has been underlined and evidenced also in guidelines. Nonetheless, the true effect of pharmacy-based management of asthma has been assessed in only a few studies. We review the available literature on asthma management in a territorial pharmacy setting.
Data Sources: The literature was searched for the keywords *pharmacy, bronchial asthma, control*, and *management*.
Study Selection: The available studies were subdivided into observational and interventional and described.
Results: Seven observational studies and 14 interventional trials were found, involving approximately 20,000 individuals. Most of those studies were performed in Europe and Australia. A high proportion of patients had poorly controlled asthma in the observational studies. The active involvement of pharmacists, in the interventional trials, consistently led to an improvement of the quality of life, a better inhalation technique, and a reduction of exacerbations.
Conclusion: The literature analysis confirms the relevance of the role of pharmacists in the real-life management of bronchial asthma and underlines the need for a more specific training for those health care professionals.

Introduction

Bronchial asthma is a common chronic respiratory disease; its current prevalence in Western countries ranges from 5% to 15% in the general population.[1] According to the numerous clinical trials performed, the available pharmacologic treatments (bronchodilators, inhaled steroids, leukotriene antagonists) achieve satisfactory control of asthma in most patients.[2] Nonetheless, in real-life, asthma remains only partially controlled or uncontrolled at any step of severity.[3,4] Many factors may account for this fact,[5–8] including the limited time for consultation in the general practitioner (GP) setting and the difficult access to in-hospital follow-up. Actually, most patients undergo no more than 1 visit per year, and spirometry is performed regularly only in a few patients with asthma.[8] Standardized questionnaires represent a practical tool to assess asthma control in every medical setting, but according to a recent Italian survey, the Asthma Control Test (ACT)[9] is routinely used only by 20% of GPs and 42% of specialists because they, surprisingly, consider it time consuming.[8] Although asthma is usually managed by physicians, pharmacists play an important role because they are frequently contacted by the patients for first-line advice or prescription renewal. In particular, adolescents prefer to seek advice in the pharmacies instead of having a long waiting time in the GP's office. In this article, we provide a concise review of the published pharmacy-based studies to better elucidate the active role of pharmacies as coplayers in the management of asthma.

Available Literature

We searched the literature (PubMed) for *bronchial asthma* [AND/OR] *management* [AND/OR] *treatment* [AND/OR] *control* [AND/OR] *pharmacy* [AND/OR/] *pharmacist*. The available studies were subdivided into observational/screening and interventional, as detailed below.

Asthma Control Screening

The assessment of asthma control in the pharmacy setting, without an active intervention in the management of the disease itself, was performed in 7 studies,[10–21] 3 of them[10–12] in the setting of a national campaign (Table 1). Asthma control assessment was

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1081-1206/

Table 1
Level of Asthma Control Reported in Studies Performed in a Community Pharmacy Setting

Reference	No. of patients	Country	Questionnaire used	Controlled asthma, %	Uncontrolled asthma, %
Laforest et al[10]	1.559	France	ACT	28	72
Laforest et al[11]	1.048	France	ACT	30	70
Mendes et al[12]	5.551	Portugal	ACT	39	61
Nishiyama and Chrystyn[13]	306	United Kingdom	JMA	50	50
Mehuys et al[14]	166	Belgium	ACT	51	49
Le May et al[15]	354	Australia	PACS	23	77
Lourenco et al[16]	224	Portugal	CARAT	13	87
Armour et al[17]	396	Australia	JMI	21	79
Mehuys et al[18]	201	Belgium	ACT	52	48
Giraud et al[19]	727	France	ACQ	49	51
Armour et al[20]	570	Australia	JMI	23	77
Garcia-Cardenas et al[21]	336	Spain	ACQ	34	66

Abbreviations: ACT, Asthma Control Test; ACQ, Asthma Control Questionnaire; CARAT, ■■■; JMA, ■■■; JMI, Jones Morbidity Index; PACS, ■■■.

mainly based on standardized questionnaires, including the ACT,[9] Asthma Control Questionnaire (ACQ),[22] and Jones Morbidity Index (JMI),[23] the most frequently used. In 2 studies the assessment of pulmonary function test (PFT) was also included.[10,14] Those studies were performed in Europe and Australia and overall involved 12,246 individuals (range, 166–1.555). Only adults with mild to severe asthma were enrolled. The prevalence of controlled asthma ranged from 13% to 54% (Table 1). Of note, in 7 studies, more than 70% of individuals had uncontrolled asthma. The level of asthma control remained unchanged when assessed prospectively 2 years apart in the same populations.[10,11,14,18] In most studies, the population was not stratified according to the severity of asthma; however, in the study by Laforest et al, approximately 3% of patients probably had severe asthma and were repeatedly hospitalized. Failure to self-perceive asthma control was reported in more than 50% of patients, particularly in adults aged 41 to 50 years. When peak expiratory flow (PEF) was measured, forced expiratory volume in 1 second (FEV_1) greater than 80% of predicted was found in 60% of patients.[10]

Interventional Studies

To date, 14 interventional pharmacy-based studies have been published,[18–21,24–33] including 6,526 adults with asthma, with all but 1 performed in Europe and Australia (Table 2). The duration of intervention was 1 to 12 months. Several outcomes directly involved the pharmacists: quality of life, asthma control and severity, PEF measurement, inhalation technique, and awareness of the disease. All the mentioned outcomes were evaluated together in a single study,[33] and asthma control was assessed only in the more recent studies[18,20,21,30–33] after the official guidelines underlined the central role of pharmacies in the management of asthma.[1]

Different interventions were delivered to active groups: posted asthma educational information, indication for seeking GPs advice,[31,32] short training session on inhalation techniqueuntil comprehensive,[18] and organized asthma programs.[21]

According to the available results, pharmacy involvement overall led to an improvement of quality of life,[18,21,25,28–30] better asthma control,[18–21,30,31] and reduction in asthma severity.[18–21,26–29] An improvement in the inhalation technique was also observed.[18–21,28,30] Higher PEF values after intervention were reported in 4 of 6 studies.[24,25,27,28] In 1 study,[28] FEV_1 remained unchanged, although PEF increased.[28]

Most studies documented an improvement in the knowledge of the disease,[20,24,27,29,33] which persisted after the interventional phase.[20,33] Two studies assessed also the socioeconomic effect of pharmacy intervention[27,28] and found a significant reduction in the expenditure for medications and insurance claims.

Critical Evaluation

The above described studies, performed in the pharmacy setting, confirm the overall unsatisfactory control of asthma, as already known in the medical setting and cross-sectional studies. To overcome this long-standing problem, some innovative approaches to asthma management have been recently suggested, including the proactive role of various health care professionals, other than physicians. In this perspective, the involvement of pharmacists could represent a step forward in the future of asthma management. Given their knowledge, skills, and expertise, pharmacists could play an important role in supporting the screening of the general population, in identifying at risk patients and referring them to their GP at earlier stages of the disease, and possibly in actively following up patients. The successful involvement of pharmacies has been already documented for other chronic diseases, such as diabetes, hypertension, and dyslipidemia.[34,35] Furthermore, the easy and regular accessibility of pharmacies over the territory remains an essential aspect in most geographic areas. For example, in Australia, where health care facilities are widely dispersed, this approach is considered advantageous, and in fact, many studies were performed in that country. The positive results so far reported and summarized in the present review confirm the positive effect of pharmacy-based interventions on clinical aspects, quality of life, and economic outcomes.

Assessment of Asthma Control

Patients referred to pharmacies are usually able to correctly report their symptoms irrespective of the questionnaire used.[34] This finding confirms that the ACT, ACQ, and JMI are suitable tools in a pharmacy setting, as previously reported in medical settings.[36,37]

The structural bases of questionnaires (ACT, ACQ, and JMI) are equivalent because all include questions on asthma-induced limitations due to breathlessness, sleep and daily activities impairment, and use of rescue medications. The ACT scores patients from 0 to 25, whereas the JMI classifies patients into 3 levels of morbidity (low, medium, high). The ACQ (designed for clinical trials) is slightly more complex because it has separate questions on wheezing and severity of symptoms and requires a lung function assessment. However, independently of the questionnaire used, all studies detected a poor asthma control in approximately 50% of the patients evaluated. In some studies,[18,32,33] the screening questionnaires were mailed to patients but the response rate was low (15%). Therefore, on-site assessment in the pharmacy would be a more suitable opportunity for screening programs. In some studies, PEF measurement was the primary instrument, whereas FEV_1 was regularly evaluated only in 2 studies.[20–28] A regular inclusion of spirometry in the pharmacy setting was recently promoted on the basis of encouraging preliminary results.[38,39] However, whereas the PEF can be measured and correctly interpreted by a trained pharmacist, the evaluation of the lung function needs a robust expertise and a careful quality evaluation of the maneuvers and instruments.[40]

Educational Interventions

Education remains the major unmet need in asthma management, and this can be successfully improved by an appropriate involvement of the pharmacists. Several educational interventions were applied in the studies published so far, from a training on the inhalation technique to printed or mailed information to personalized programs. Most of the reported interventional protocols provided a baseline educational session through individual or

Table 2
Interventional Pharmacy-Based Studies in Asthma Management

Reference	Duration, mo	No. of patients	Intervention	Method	PEF	Asthma severity	Asthma control	QoL	Disease knowledge	Inhalation tecnique
Schulz et al[24]	12	242	Educational training and inhalation technique	Prospective observational study. Group meetings (every 6 weeks for 1 year). At 6 and 12 months, QoL and self-efficacy questionnaires.	↑	NA	NA	↑	↑	↑
Weinberger et al[25]	12	947	Educational training and inhalation technique	Randomized clinical trial. Distribution of educational material at baseline. Monthly telephone interviews provided by pharmacists for 1 year.	↑	NA	NA	↔	NA	NA
Barbanel et al[26]	3	24	Educational training and telephone calls	Randomized clinical trial. Individual education sessions (45–60 minutes) at baseline and weekly telephones for 3 months.	NA	↓	NA	NA	NA	NA
Saini et al[27]	6	102	Educational training and follow-up	Randomized clinical trial. Four individual visits: baseline and at 1, 3, and 6 months.	↑	↓	NA	↑	↑	NA
Mangiapane et al[28]	12	183	Educational training and inhalation technique	Randomized clinical trial. Three individual visits: baseline and at 4 and 6 months.	↑	↓	NA	↑	NA	↑
Armour et al[29]	6	351	Regular follow-up and counseling	Randomized clinical trial. Four individual visits: baseline and at 1, 3 (discretionary), and 6 months.	↔	↓	NA	↑	↑	NA
Basheti et al[30]	3	97	Inhalation technique	Randomized clinical trial. Five individual visits: baseline and at 1, 2, 3, and 6 months.	NA	NA	↑	NA	NA	↑
Bereznicki et al[31]	6	1.551	Computer educational training	Randomized clinical trial. Educational material provided at baseline via mail. During the 6-month postintervention period, dispensed asthma medications were monitored.	NA	NA	Increased used of inhaled steroids	NA	NA	NA
Bereznicki et al[32]	6	1.133	Computer educational training	Randomized clinical trial. Educational material provided at baseline via mail. Six months later, self-questionnaires were delivered via mail.	NA	NA	NA	↑	↔	NA
Mehuys et al[18]	6	201	Educational training and inhalation technique	Randomized clinical trial. Four individual visits: baseline and at 1, 3, and 6 months.	↔	↓	↑	↔	↔	↑
Giraud et al[19]	1	727	Educational training and inhalation technique	Prospective observational study. Individual visit at baseline. One month later a self-questionnaire was returned by post.	NA	↓	↑	NA	NA	↑
Saini et al[33]	6	570	Educational training and follow-up	Prospective observational study. Three or 4 individual visits during a 6-month period. First follow-up assessment (mailed questionnaires or visit) 6 months later. Second follow-up assessment (mailed questionnaires) after 6 months.	NA	NA	NA	NA	↑ (sustained effect up to 12 mo)	NA
Armour et al[20]	6	398	Educational training and inhalation technique	Randomized clinical trial. Individual visit at baseline and 1 to 3 follow-up visits at 1, 3, and 6 months.	NA	↓	↑	↑	↑ (sustained effect up to 12 mo)	↑
Garcia-Cardenas et al[21]	6	336	Educational training and inhalation technique	Randomized clinical trial. Individual visit at baseline and 2 follow-up visits at 3 and 6 months. Additional counseling visits were provided if needed.	NA	↓	↑	NA	NA	↑

Abbreviations: ↑, improved; ↓, worsened; ↔, unchanged; NA, not assessed; PEF, peak expiratory flow; QoL, quality of life.

group meetings, focused on disease knowledge and inhaler technique.[18–21,24,26–30,33] In a few studies, educational materials were directly delivered to patients via mail.[25,31,32] Overall, the results revealed an encouraging improvement in inhalation technique after very short education sessions.[30] However, these studies did not assess the persistence of the achieved improvement.

Currently, the availability of generic drugs is increasing in many countries, usually according to local regulations, because they are in general cheaper than brand name drugs. Generic inhaled drugs, although equivalent to the brand name products, may differ in formulation and inhalation device. For economic reasons, patients often switch to different devices so that the educational intervention delivered by pharmacies or physicians are lost.[41] Most studies have found a significant increase of the disease knowledge after diversified pharmacy interventions. However, this improvement should be quantified through the identification of some sensitive outcomes. Up to now, only 2 studies found an increased adherence to the treatment and a larger use of inhaled corticosteroids (ICSs).[20,31]

Another aspect that could be addressed by pharmacists is the overuse or misuse of rescue medications, which is a substantial hallmark of uncontrolled asthma. The screening was particularly relevant in Australia and the United Kingdom, where short-acting bronchodilators are sold over the counter. Furthermore, community pharmacies may easily identify patients with asthma who receive frequent bursts of oral steroids as in need of medical evaluation. The educational message delivered by pharmacies should also reinforce the critical role of ICSs in the long-term treatment of asthma, emphasizing their anti-inflammatory action and the minimal risk of systemic adverse effects.[42] In addition, the evaluation of adherence to treatment and the monitoring of adverse effects caused by the treatment are potential additional benefits of the pharmacy involvement. Adolescents represent a special population because they usually prefer to go to pharmacies instead of having a long waiting time in the GP's office.[43]

Training of Pharmacists

One of the major obstacles to the active role of pharmacists in the management of asthma is their nonoptimal training and education.[44–46] Time constraints and the lack of specific training have been identified as important barriers to the implementation of care within community pharmacy practice in Europe. For these reasons, appropriate training on asthma and its management should be regularly offered to pharmacists. The time spent to attend educational courses is expected to be balanced by sparing on possible work-time lost. Probably, short and frequently repeated sessions remain the most suitable choice, although the theoretical knowledge of asthma and the skill in demonstrating inhaler use seem to be increased among pharmacists over the years.[47] Educational programs for pharmacists should be agreed among pharmacists themselves, GPs, and specialists.

Methodologic Aspects

According to the articles retrieved in the literature, there is increasing interest in this topic; the number of specific publications more than doubled from 2009 to 2014. On the contrary, the short duration of the available studies and their methodologic limitations overall weaken the findings and the nonrandomized or observational design. In fact, only 3 of 14 trials lasted at least 1 year, but asthma can be influenced by many variables in longer periods (viral infections, adherence, comorbidities). In addition, only 5 studies included a control group. More well-designed trials are needed to evaluate the sustainability of pharmacy-based interventions over time and to promote the pharmacists' involvement on a wider scale. In addition, of note, in the retrieved studies, there was no mention of a structured cooperation with the general practitioner, which would have been be a major point of strength. Finally, although no conflict of interest was declared by pharmacists, it is reasonable to think that such studies should be free of any financial interest.

Conclusion

Pharmacists can robustly support the role of physicians in asthma management because they represent a first-line health care service much more accessible for the patient compared with medical services. For this reason, the community pharmacy should be involved in screening and follow-up of patients with asthma by increasing the knowledge of the disease, assessing asthma control, and improving the inhalation technique. Thus, the role of pharmacists has been highlighted in many documents, but an experimental evaluation of the role of pharmacies has been performed in only a few on-field studies. Furthermore, the published interventional studies cannot be easily compared because they follow different experimental designs, target different populations, and analyze a large variety of outcomes, including different measures of asthma control, asthma severity, pulmonary function, and asthma symptoms. For this reason, although each published study has revealed a positive effect of the proposed interventional strategy, it remains difficult to define which kind of intervention should be finally managed by community pharmacies to effectively support medical actions. In addition, the sustainability of the pharmacists' active role should be evaluated in the light of the peculiar health care setting in each country or geographic area. As a matter of fact, most of the interventional studies that involve pharmacies were performed in Australia; therefore, the results cannot be immediately transferred to other countries where, as in Europe, health care facilities are easily accessible and the organization of the health service is different. Thus, the involvement of community pharmacies should be differentiated and adapted to the different countries.

However, the available data consistently suggest a positive contribution of pharmacists in the management of asthma in the presence of a large heterogeneity in study designs, duration, and outcomes. Some additional aspects need to be further investigated. The referenced studies included only adults; therefore, the potential effect of pharmacists in pediatric asthma still needs to be investigated. Furthermore, it is true that web-based medicine is expanding also in the field of respiratory diseases, and it will probably imply a critical revision of the role of pharmacists and general practitioners.[48]

In conclusion, the community pharmacy could play a significant complementary role in asthma control and diagnosis, but physicians (GPs or specialists) continue to guide asthma management and be responsible for prescriptions. The high prevalence of the disease requires new approaches and country-tailored networks, which involve different health care professionals, but easy access to pharmacies should not become a shortcut to avoid regular medical follow-up.

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