

**EVALUATION OF THE IMPACT OF A PHARMACEUTICAL CARE
PROGRAM ON PATIENTS WITH ASTHMA**

**ASTIM HASTALARI ÜZERİNDE “FARMASÖTİK BAKIM” PROGRAMININ
ETKİSİNİN DEĞERLENDİRİLMESİ**

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ABSTRACT

The objective of this study was to evaluate the impact of a pharmaceutical care program on patients with asthma. A broad asthma education and monitoring program that includes basic asthma knowledge, symptoms and accurate evaluation, pharmacotherapy assessment including inhaler technique and quality of life measurement was developed and applied in several pharmacies in the city of Sofia, Bulgaria. Patients (aged 18 - 80) with moderate asthma, visiting regularly the pharmacies for purchasing their drug treatment were allocated to the intervention. These patients were educated on their disease, pharmacotherapy, self-management, and inhalation techniques. The quality of life scale (QLS) version 08/02/2002 was applied at the beginning and in the end of the experiment to assess the quality of life. Spirometry was done every month. There was a significant improvement in the patients that received pharmaceutical care in terms of the individual domains of interpersonal and social work, occupational role functioning and other residual symptoms. There were considerable changes in the spirometric values after the education.

Key words: *Asthma; Pharmaceutical care,; Pharmaceutical education,; Educational program for asthmatic patients; Bulgaria*

ÖZET

Bu araştırmanın amacı astım hastaları üzerinde “Farmasötik bakım” programının etkisinin değerlendirilmesidir. Çalışmada, astım hastalarına yönelik geniş kapsamlı bir eğitim ve izleme programı hazırlandı. Programa hastalıkla ilgili esas bilgiler, hastalığın belirtileri ve bu belirtilerin tam olarak

yorumlanması, farmakoterapi bilgileri, inhalerlerin uygulanması tekniğinin değerlendirilmesi ve program kapsamındaki astım hastalarının yaşam kalitesinin ölçülmesi bilgileri dahil edildi. Program birkaç Sofya eczanesinde uygulandı. Seçilmiş ve belirlenmiş olan eczanelerden ilaçlarını satın alan astım hastaları (18 – 80 yaş arasında) gözlem altına alındı. Bu hastalar, hastalıklarının esası, farmakoterapi, hastalıkla başa çıkma ve doğru inhaler tekniği konusunda eğitim kursuna devam ettiler. Denemenin başında ve sonunda 08/02/2002S versiyonlu yaşam kalitesini değerlendiren bir tablo (QLS) uygulandı. Kişiler arası ve sosyal ilişkiler, mesleki meşguliyet ve diğer ikincil önem taşıyan belirtiler konusunda farmasötik bakım programından yararlanan hastalarda elle tutulur bir iyileşme kaydedilmiştir. Uygulanan eğitimden sonra spirometrik değerlerde oldukça önemli değişiklikler gözlenmiştir.

***Anahtar kelimeler:** Astım, Farmasötik bakım, Eczacılık eğitimi, Astım hastalarına yönelik eğitim programı, Bulgaristan*

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INTRODUCTION

Asthma is a common disease that leads to significant degrees of morbidity and mortality. It is now estimated that as many as 300 million people of all ages, and all ethnic backgrounds, suffer from asthma and the burden of this disease to government, healthcare systems, families, and patients is increasing worldwide. It is estimated that there may be an additional 100 million persons with asthma by 2025. It is estimated that asthma accounts for about 1 in every 250 deaths worldwide. Asthma was the 25th leading cause of disability-adjusted life years (DALYs) lost worldwide in 2001 [1]. It is characterized pathologically by lymphocytic and eosinophilic infiltration of the bronchial tree with associated airway narrowing. Physiologically it is characterized by bronchial hyper-reactivity and, clinically, by variable degrees of chest tightness, wheeze, cough and shortness of breath [2]. Asthma has a considerable impact on domestic, school, and industrial life as well as primary care workload. This, taken together with the variability of the disease, makes it seem logical to involve patients in managing their own care. However, attempts to implement self-management have met with varied success, and the evidence is inconclusive, particularly in primary care, where asthma patients receive most care [3].

The management of asthma involves both pharmacological and non-pharmacological interventions. Non-pharmacological interventions include appropriate management of often-undetected contributing disease, avoidance of known precipitating factors, and specific allergen avoidance. Patient education about the disease is of great importance although, it is often

neglected. The management of asthma depends on the severity of the disease, as well as the nature and frequency of the attacks [4]. Patient education, counseling and compliance checks are fundamental parts of asthma management that should not be forgotten. Studies have demonstrated the importance and benefit in outcome of patient counseling, support and production of written self-medication plans that allows the patients to adjust their medication when necessary [5, 6]. Patients should also be educated on how to use a peak flow meter and to recognize signs or symptoms that indicate deterioration of their asthma.

Simply promoting access to health care is consistent with a wellness practice. Noting those patients who have difficulty managing their asthma or who persist in self-treatment long after it becomes clear they need professional help and getting them into the health care system may be an easy place to begin.

Assessing the importance of the patient's education, many hospitals have concentrated their patients into specific asthma clinics for some years. Asthma clinics in general practice are best if they work with management guidelines and care plans. In some practices they are run by doctors, but in most cases it is nurses, who have more time to spend with each individual patient to go through inhaler techniques, understanding, and management plans. An interested doctor should be available for consultation and a close liaison should be built up with chest physicians at the local hospital [7]. But still the role of the community pharmacists as consultants for the individual patient is underestimated. The medication administration methods to get drugs to the lungs are complex and rapidly changing. From nebulizers and metered dose aerosol inhalers to breath-actuated dry powder inhalers, the instructions for proper use vary widely. A pharmacist's expertise on proper use of all types of inhalers can be great asset to the patients. When a new prescription is dispensed, it is natural to instruct patients on proper technique. Pharmacists can hold inhaler clinics on a regular basis to reevaluate and reinforce prior teaching on inhalation technique.

Pharmacists can help patients understand how to monitor and manage their asthma through the use of an asthma action plan. Discussing controller versus rescue medications for treatment of asthma can reduce health care utilization and lost productivity. Advocating patient use of asthma action plans by distributing blank copies with a brief explanation is a way to promote wellness.

Pharmacy wellness programs in asthma have been shown to be beneficial. A program in the United States increased the use of appropriate medications and reduced costs [8]. Pharmacists

in Sweden participated in a yearlong national effort to educate both health care professionals and the general public in asthma [9]. The result of their efforts was that 42% of the population received some information about asthma and 49% learned something new about their disease. The number of patients receiving regular steroid therapy doubled and a modest decrease in asthma-related deaths occurred. In many areas of the world people with asthma do not have access to basic asthma medications, education or medical care. Until there is a greater understanding of the factors that cause asthma and new public health and pharmacological measures become available to reduce the prevalence of asthma, the priority is to ensure that cost-effective management approaches which have been proven to reduce morbidity and mortality are available to as many people as possible with asthma worldwide [1]. Unfortunately only a minority of patients receives a proper asthma education in Bulgaria. The reason for that is the educational programs require time, specific training, and communication skills from the healthcare providers. The lack of educational resources for asthma patients in fact is critical in Bulgaria, where the costs of the asthma treatment arise also on account of the disease complications.

The importance of the proper asthma treatment together with the underuse of asthma self-management in Bulgaria stimulated us to develop an educational program, suitable for implementation in the Bulgarian community pharmacies that will enable the pharmacists to apply it easy after a short training period; and to evaluate the effect of this program on the clinical, therapeutic and economic outcomes.

The aim of the study was to assess the health-related quality of life (QoL) outcomes in a group of asthma patients receiving a pharmacy-based asthma management service.

MATERIALS AND METHODS

The educational project continued 5 months (from 01 May 2004 to 30 September 2004). It was designed and adapted to the local conditions of the Bulgarian community pharmacy. It was conducted in 9 community pharmacies in Sofia, Bulgaria. The staff provided patient training in asthma management was from the Department of Social Pharmacy Faculty of Pharmacy, Medical University, Sofia, Bulgaria in coordination with specialists from the community pharmacies.

The education course was presented to 55 ambulatory asthma-diagnosed patients. There were specified the most suitable conditions for both the patients and the pharmacists that allowed good interaction. The educational course included four-months teaching units. Every month

there was an appointment with the patients that consisted of two parts -examination of the acquired knowledge on the previous unit and a new education.

Patient selection.

Inclusion criteria for the participants in the pilot study were that (i) the patients had been diagnosed with asthma at least six months previously; (ii) they did not suffer from other comorbidity. Exclusion criteria were other severe life-limiting illness, inability or unwillingness to participate in the asthma education program. The latter criterion was based on the assumption that other chronic conditions could interfere with health outcomes measured, including patient's QoL and could make it difficult to identify the effect of the education on the asthma management. However, to stimulate real-life situation, it was decided that if a concomitant condition were identified during the study the patient continued participation. The patients were fazed into the study in groups of 5-6 per pharmacy in order to be avoided overwhelming of the pharmacies by large number of patients at one time. All participants communicated in Bulgarian and were able to make reliable measurement of peak expiratory flow (PEF). The individuals who covered the inclusion criteria and agreed to participate were included in the study after providing an informed consent. Specific materials were provided on asthma treatment, etiology, therapies, devices and other. Pharmacists initiated the service by arranging interviews with their patients at monthly intervals.

Study design.

In this 20-week, observational study, patients were subjected to a specially designed questionnaire (Quality of Life Scale (QoLS), Version Date 08/02/2002) to ascertain the QoL of asthma patients. This questionnaire contained questions relating to interpersonal and social work, occupational role functioning and other residual symptoms. The questionnaire was pretested and a scoring method was tested. The scores so obtained were analyzed by Statistika Ver., applying the following tests of significance: a) Pearson's Correlation Coefficient; b) descriptive statistics.

At the initial step, pharmacists elicit information on patients' asthma and other relevant history, including their concerns and understanding of their condition and their medication. The pharmacists also perform peak flow measurement by a portable hand held spirometer. The pharmacists provided individualized education to the patient on the disease, drug therapy and usage of medication and demonstrated inhaler technique and the ways to identify and avoid asthma "accelerators".

The first unit acquainted each of the patients with the aim of the educational program, provided general concept about asthma and about self-monitoring and emphasized on the active patient participation in the treatment. The pharmacists elicit information on the patients' asthma and other relevant history, including their concerns and understanding of their condition and their medication. Each of the patients was instructed about their inhaler technique. It was discussed with every patient the effect of obesity on their physical condition and the advantages of weight reduction. An easy approach for meal selection based on pyramid diet was structured. It was emphasized on the fact that some foods can trigger acute asthma attacks, either from IgE mediated food allergy or chemical intolerance and that the regular physical activity helps controlling the weight and from there it may help to manage asthma. Each of the patients was supplied with written materials on proper nourishing and physical activity. They were asked to monitor their peak flow (thrice a week) and to write down the results in their diaries. The main topic discussed during the **second teaching unit** was nicotinism (tobaccoism) and its effect on asthma complications. The educator explained how serious the indoor air pollution can be for asthma patients. Even at relatively low levels, some indoor air, including smoke pollution from tobacco pollutants can cause breathing difficulties. Each of the patients was supplied with written materials on the topic discussed. Those of them that persist smoking were supplied with a 7-day quit smoking plan and were asked to try to stop smoking.

The **third teaching unit** was on the asthma complications. The educator explained how serious it can be if the disease is out of control. It was cleared that uncontrolled asthma can impose serious limitations on daily life, because it is the second most important respiratory condition to cause home confinement for adults. Each year, asthma causes more than 18 million days of restricted activity, and millions of visits to physicians' offices and emergency rooms.

The **fourth educational unit** was based on the possible adverse drug reactions that can arise during the drug treatment. It was cleared that the type of adverse drug reaction that is usually predictable but sometimes unavoidable may occur if a drug dose is too high, if the person is unusually sensitive to the drug or if another drug slows the metabolism of the first drug and thus increases its level in the blood. That is why the patients were told to be strict to the prescribed dose and to turn immediately to their pharmacist or GP when such a reaction is observed. At the end of the session the patients were supplied with written materials on this subject.

During the **fifth unit** after the assessment of the patients' knowledge on the previous topic a patient satisfaction questionnaire was applied again in order to be assessed the changes in the patient's quality of life after the education.

Educational materials.

The following educational materials were applied:

- A set of one-page written materials that illustrate the most important aspects of every educational lecture, provided to the patient after every module;
- Questionnaire cards for distribution among the participants as a standardized procedure for assessment of their knowledge acquired in the previous educational units;
- Individual diaries for recording the self-monitored data (PEF, asthma crisis);
- Patient's satisfaction questionnaires for evaluating patient's QoL;
- Teaching files for the educator as a structured guideline on how to perform each session and what kind of information to supply to the patients.

In the end of the program the clinical data were evaluated. The clinical data included medical history, drug intake, compliance with asthma medication, duration of the disease, sleep disturbances, PEFR.

RESULTS

Of the 55 asthmatic patients recruited, three declined to continue participation after the second month, and seven withdrew for personal reasons and did not complete the education. Forty-five participants, 26 men and 19 women, remained in the program till the end. Demographic characteristics of the 45 patients are shown in Table 1.

The mean age of the study group was 48.95. The mean duration of the asthma was 9.37 years. These numbers show that the patients are well selected. Forty-four of the participants are on asthma medication - mono or combined.

After participating in the education program there were observed metabolic and behavioral changes that are summarized in Table 2.

Table 1. Demographic characteristics of the patients.

Characteristics	Values
Subjects (n)	45
Sex	
Male (%)	58
Female (%)	42
Age	48.95 ± 4.91
Duration of asthma since diagnosis (years)	9.37 ± 1.30
Asthma medication previous 30 days	
No medications	1
Short-acting Bronchodilators alone	9
Inhaled steroids + Short-acting Bronchodilators	28
Long-acting Bronchodilators + Inhaled steroids + Short-acting Bronchodilators	7

Data are presented as n, % or means +SD(standard deviation).

Table 2. Patients' metabolic and behavioral parameters after the education process

Variable	0	Time interval		
		1 month	3 month	5 month
PEFR (Peak Expiratory Flow Rate)				
Male	0.68 ± 0.077	0.72 ± 0.077	0.75 ± 0.065	0.81 ± 0.084
Female	0.69 ± 0.076	0.75 ± 0.055	0.75 ± 0.073	0.81 ± 0.075
Frequency of hospital admission	29	16	12	0
Sleep disturbances	58	36	18	2
Correct inhaler use	53%	67%	71%	93%
QL- Interpersonal and Social Work Scale: 0 to 6	35.6 ± 6.64	-	-	39.64 ± 5.13
QL - Occupational role functioning Scale: 0 to 6	8.93 ± 3.42	-	-	10.22 ± 2.89
QL-Other residual symptoms Scale: 0 to 6	26.33 ± 11.96	-	-	33.62 ± 6.75

Data are % and means +SD. QL - "quality of life".

The Peak Expiratory Flow Rate percentage in the beginning and at the end of the education shows significant increase. The PEFV mean values increased with about 13% for the males and with 12% for the females. The second control parameter also decreased and at the end of the study the frequency of the hospital admission became 0 per cent according to the patients' records. The same situation is observed with the third control parameter "Sleep disturbances" - at the end of the 5-month period only 1 patient declared that he still has such problems. Thanks to the education and to the inhaler demonstration in the pharmacies, there was improvement in its correct application - from 24 patients in the beginning; at the end 42 easy and correctly applied their inhalers. These facts can be explained mainly with the strict self-monitoring of the observed patients.

Descriptive statistics for the quality of life results is provided. The mean change in QoL score was significantly higher for the three sections of the twice-applied patient's satisfaction questionnaire, higher for the section "Other residual symptoms" and lowest for the section "Occupational role functioning". It could be considered that the educational process affects both the physical and the psychological well-being and thus it is beneficial for the global patient's quality of life.

DISCUSSION and CONCLUSION

Asthma is the most common chronic respiratory disorder among all age groups. International efforts to decrease asthma morbidity and mortality have focused on improving patient education and self-management behavior [10-12]. Many clinical trials have examined the relation between the education process and the health outcomes and it was shown that these programs generally reduce the use of health services [13]. In this study it was found that asthma education reduces to 0 the hospital admissions during the 5-months period of time.

Furthermore, this study provided data that motivated and well-trained pharmacists can influence on the QoL of the asthma patients by providing pharmaceutical care. The results show that asthmatic patients did not have sufficient information about their disease and the provided education increased their asthma knowledge and increased correct inhaler use. In the beginning of the education only half of the patients were with proper inhaler skill and the provided education in the pharmacy increased significantly their number. Correct and on-time use of the inhaler is important for achieving full benefit from the drug treatment. Patient education in the proper use of the inhalers is an important part of asthma treatment [14]. The results of many studies have shown that education could have a large impact on the percentage of patients

who use their inhaler correctly [15-17]. From other side simple interventions like education on proper inhaler technique can lead to improvement in patients' QoL [18]. The applied QoL questionnaire reflected improvement in the patients' general behavioral parameters. The obtained results confirm the need of a constant patients' education, using variety of educational models, as an essential part of the asthma care that will result in decrease of the chronic complications.

The results show that such an approach has the potential to improve the quality of life of patients with asthma reported elsewhere [19].

The pharmacist's position in the healthcare system has changed and there are new opportunities for him. The implementation of such an educational approach in the community pharmacy practice will help pharmacists to gain their place as a competent and qualified healthcare provider, performing pharmaceutical care. The results from this study indicated that asthma education has a positive influence on patients' knowledge of asthma and also provided evidence that through well-structured patient-oriented pharmaceutical care, pharmacists can help asthma patients to achieve better health outcomes [20].

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