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COMMUNITY PHARMACY-BASED PROGRAM FOR PATIENTS WITH ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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ABSTRACT

The aim of our study was to develop and implement an education program both for moderate and severe asthma patients and patients suffering from chronic obstructive pulmonary disease (COPD) (all stages) at community pharmacy conditions and to evaluate its influence on the patients' quality of life. A prospective, randomized, controlled trial was carried out in community pharmacies (n = 24) in Sofia and Plovdiv, Bulgaria. Community-dwelling patients with asthma and COPD participated in the study. An asthma and COPD education and monitoring program was implemented. Intervention patients received information about their disease, instruction on the appropriate use of medication, training in the inhaler technique; ADRs during treatment; recognition of early signs of exacerbation, information about the identification and control of asthma/COPD attacks; tobaccoism and efficacy of different methods on smoking cessation; control patients received routine dispensing services.

The parameters assessed at baseline and at 1, 2, and 3 months were health-related quality of life, PEF and FEV_1% levels, inhaler technique, hospitalization rates, and patient satisfaction with the pharmacy services. The health-related quality of life of the intervention patients improved at 3 months (P = 0.044). In the same time period, PEF and FEV_1% significantly improved for intervention patients compared to the control groups (P = 0.009). The inhaler technique improved in the intervention groups (P = 0.021). As a whole, the community-based pharmaceutical care program was appreciated by the participants and had a positive impact on the QoL of patients with chronic lung diseases, their inhaler technique, and PEF and FEV_1% rates.

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Introduction

Asthma is a common chronic disease worldwide and affects about 24 million people only in the USA. It is the most common chronic disease in childhood, affecting approximately 7 million children, and it is a common cause of hospitalization for children. The pharmacologic management of this disease includes the use of relief and control agents. In general, patients should be examined every 1 to 6 months for asthma control (17).

Another common clinical problem is Chronic Obstructive Pulmonary Disease (COPD). COPD is primarily a disease of the adult. The prevalence of COPD is highly variable. For epidemiological assessment, the rounded-off median prevalence rates were assessed as 5 percent for male and 2.7 percent for female subjects of over 30 years of age. The disease is distinctly more common in males. The male to female ratio varies from 1.32:1 to 2.6:1 in different studies with a median ratio of 1.6:1. COPD results from chronic inhalational exposure to various smokes, noxious particles and gases (18).

The goals of therapy in asthma are different from those in COPD (6). The goals of long-term management of asthma should include the following:

1) achievement and maintenance of control of symptoms;

2) prevention of asthma exacerbations;

3) maintenance of pulmonary function as close to normal levels as possible;

4) maintenance of normal activity levels, including exercise;

5) avoidance of adverse effects from asthma medications;

6) prevention of the development of irreversible airflow limitation;

7) prevention of asthma mortality.

The treatment goals for COPD are:

1) prevention of disease progression;

2) relief of symptoms;

3) improvement in exercise tolerance;

4) improvement in health status;

5) prevention and treatment of exacerbations;

6) prevention and treatment of complications;

7) reduction in mortality;

8) minimisation of side-effects from treatment.

The need for patient education about asthma and COPD and the establishment of a partnership between patients and health professionals in the management of the disease was emphasized by EPR-3 (12, 20). The key points of education include the following:

- Patient education should be integrated into every aspect of lung disease care.
- All members of the healthcare team, including nurses, pharmacists, and respiratory therapists, should provide education. Health professionals should teach patients self-management based on basic disease facts, self-monitoring techniques, the role of medications, inhaler use, and environmental control measures (4, 16, 19).
- Treatment goals should be developed for the patient and family.
- A written, individualized, daily self-management plan should be developed.

There are many educational programs for patients with asthma and COPD, provided by different health-care providers (11, 16, 24, 25). Community pharmacists are considered to be in a unique position to support these patients with the management of their chronic illness because of their permanent contact with the patients, their drug knowledge, authority and relevant easy accessibility. Training and experience of the pharmacists can improve patient's drug knowledge, inhaler technique and level of compliance. Pharmacists play an important role in asthmatic and COPD patients treatment focused on the safe and effective use of drugs (15). In the European TOM-studies (Therapeutic Outcome Monitoring) pharmacists improved not only isolated factors such as patients' drug knowledge, inhalator skills, compliance to prescription and self-management, but also the quality of drug therapy, in collaboration with the general practitioner (8, 14, 22, 25). The pharmacist's contribution to patient care through education and monitoring, and through assessing and optimizing the drug therapy leads in general to improvement of patients' quality of life (9, 13, 24).

Materials and Methods

The aim of our study was to develop and implement an education program both for moderate and severe asthma patients and patients suffering from COPD (all stages) at community pharmacy conditions and to evaluate its influence on the patients' quality of life. The study design was a prospective and randomized study with a control group.

Patients were invited to participate in the study during their visit at the pharmacy. The inclusion criteria for the asthmatic patients were diagnosis of bronchial asthma, age over 14 years, and understanding of spoken and written Bulgarian. The inclusion criteria for the COPD patients were: outpatients, diagnosis of COPD, men and women 40 years old or over. Exclusion criteria were presence of other significant pulmonary disease (e.g., carcinoma), presence of any condition that would hinder completion of questionnaires (e.g., poor eyesight or illiteracy), and any mental disease. Sixty asthmatic patients were included; they were diagnosed between 2005 and 2010. Thirty of them were assigned to the educational group; and 30, to the control group. They were assigned based on the principle of random numbers. Twenty-six COPD patients participated in the study; diagnosed between 2000 and 2010. Thirteen were assigned to the educational group; and 13, to the control group, on the principle of random numbers.

All the participants were informed about the essence and aim of the investigation and were asked to sign a basic consent form. The groups were identical with regard to disease severity parameters, inhaler technique and quality of life. Patients' condition and disease severity were assessed by physicians and the information was taken down from their personal medical records. The control groups were treated as usual at the pharmacy, with no additional information, while the educational groups attended educational sessions for a period of 3 months.

The pharmacies were selected from the list of private community pharmacies located in Sofia and Plovdiv, Bulgaria, provided by the Bulgarian Ministry of Health (1134 private pharmacies). The 24 pharmacies with the highest number of patients with asthma and COPD were selected. The education was performed by the authors and by 14 pre-graduating students that had passed their exam in Pharmaceutical care. Patient diaries that included information on the patient's peak flow value, smoking history, disease complications and prescribed drugs were made. Any problems encountered during the treatment were also included in the diary. Patients were kindly asked not to change their pharmacy during the study.

The educational program included information about asthma/COPD, instruction on the appropriate use of medication, training in the inhaler technique; ADRs during treatment; recognition of early signs of exacerbation, information about the identification and control of asthma/COPD attacks; tobaccoism and efficacy of different methods on smoking cessation. All the materials were developed by the authors. They were based on the information provided by the Association of the Bulgarians with Asthma and from the National Asthma Education Program Office of Prevention, Education, and Control National Heart, Lung and Blood Institute, National Institute of Health (23) and Global Initiative for Chronic Obstructive Lung Diseasse (10), American Thoracic Society (1), British Thoracic Society (5) and *COPD – National consensus for Bulgaria (7)*.

The educational leaflets were prepared in the form of a self-study program that includes information on one of the topics. After the educational session they were given to the patients. During the program there were applied:

-43×3 (n = 129) information leaflets on the different education sessions;

-86 patients' health diaries;

-86 QoL assessing questionnaires;

A direct interview during which specific questions were asked on the previous education of subjects was applied in the

beginning of the second, third and final sessions in order to assess the level of the newly achieved knowledge and to clarify any doubt or illegibility (n = 129). The following parameters were assessed at baseline and every month:

- Asthma patients' PEF rate determined with a peak flow meter. COPD patients' FEV_1 rate determined with a peak flow meter. There was appropriate equipment in the pharmacy (MicroPeak peak flow meter).
- Patients' inhaler technique. The patient was observed while using the inhaler and a score (1 = correct, 0 = incorrect) was given for each step according to the standard instructions (3). If a patient forgot a step, such as shaking the inhaler, removing the cap etc., a score of 0 was assigned.
- Patients' self-monitoring. Patients were asked how often they had suffered from any complication – the severity and duration of the crisis, whether they had been admitted at the hospital, and if hospitalized, for what length of hospitalization, and how often they had forgotten to take their prescribed drugs. Patients were also asked about their visits to the doctor. The hospitalizations and GP visits were verified through their medical records.
- Patients' subjective opinions on their health-related quality of life were assessed through adapted disease-specific instrument Asthma Assessment form (2) that was translated into Bulgarian using conventional back translation procedures and adopted for the needs of the study. The questionnaire includes 8 questions on the duration of the disease, severity of the disease, reasons for triggering, application of inhaler during the past 4 weeks, cases of shortness of breath during the past 4 weeks, fully-experienced day at work or at home in the past 4 weeks; frequency of hospitalizations and Urgent Medical Aid calls in the past 4 weeks. This information was obtained in the beginning and end of the study.

PEF rate measurements, FEV_1 inhaler technique assessments and data obtained from quality-of-life instrument were analyzed using repeated-measures analysis of variance (ANOVA). In addition, changes between baseline and 4 months for the various measures were compared within and between the groups of the patients using t-test, and the Mann–Whitney U-test (between-group analysis), as appropriate. A P-value below 0.05 was considered statistically significant. Statistics were performed by SPSS/version 17.0.

Results and Discussion

Eighty-six patients were eligible to participate in the study: 43 in the intervention group (Group 1) – 30 diagnosed with asthma and 13, with COPD; and 43 in the control group (Group 2) – 30 diagnosed with asthma and 13, with COPD. **Table 1** and **Table 2** give demographic information about the patients with asthma and COPD.

TABLE 1

Main characteristics of the population sample for asthmatic patients

Demographics	**Group 1 (n = 30)**	**Group 2 (n = 30)**
Age	37.21 ± 12.4	39.72 ± 17.1
Sex		
Female	13	11
Male	17	19
Female/male ratio	0.76	0.58
Cigarette smoker (%)	6	6
Duration of disease since diagnosis (years)	8.75 ± 4.0	9.04 ± 3.5
Severity of asthma (according to EPR-2)		
Mild intermittent (n)	14	12
Mild persistent (n)	13	14
Moderate persistent (n)	2	3
Severe persistent (n)	1	1

TABLE 2

Main characteristics of the population sample for COPD patients

Demographics	**Group 1 (n = 13)**	**Group 2 (n = 13)**
Age	66.38 ± 10.69	69.12 ± 14.7
Sex		
Female	5	4
Male	8	9
Female/male ratio	0.63	0.44
Cigarette smoker (%)	3	3
Duration of disease since diagnosis (years)	6.45 ± 3.2	8.04 ± 3.5
Severity of COPD (according to FEV_1)		
Mild intermittent (n)	4	4
Moderate persistent (n)	6	7
Severe persistent (n)	2	1
Very severe (n)	1	1

Statistically there was no significant difference between the number of men and women in the intervention and control groups ($P > 0.05$). The intervention groups had a significantly younger mean age compared with the control groups. All the patients had health insurance coverage. Nine patients from the intervention groups (6 with asthma and 3 with COPD) and 9 patients from the control groups (6 with asthma and 3 with COPD) were current cigarette smokers. The duration of the asthma and COPD since diagnosis was comparatively equal in both groups. The severity of asthma and COPD is shown in the tables.

Table 3 represents the influence of the education on the studied parameters: PEF rate, inhaler technique, disease self-monitoring, quality of services provided and patient's quality of life (QoL). It is clear that there were some differences between the two groups at baseline: the hospitalization rate and the frequency of UMA calls were lower in the intervention group than in the control group, while the results for disease (asthma/COPD) self-monitoring, shortness of breath and availability of cough were nearly equal in the two groups. The purpose of the study was to assess whether there was any alteration in the results between the intervention and control groups as a result of the education.

The results of the PEF rate from the patients' diaries show that at baseline, the mean PEF rates of the patients in both groups were comparatively equal (327.45 ± 12.73 L/min for Group 1 vs. 331.12 ± 10.27 L/min for Group 2). After ANOVA analysis with gender and age as covariates (predictors), it was proven that PEF was not significantly different in the two groups ($P > 0.05$). These PEF values are mean for the two groups without taking into consideration the influence of the patients' age and height. The results of FEV_1% rate showed that at baseline, the mean FEV_1% of the patients in both groups were comparatively equal (47 % for Group 1 vs. 49 % for Group 2). It was proven that FEV_1% was not significantly different in the two groups ($P > 0.05$).

After the education process, stable values of the PEF rate were observed for Group 1 (338.64 ± 12.55), while there were still fluctuations in the PEF rate of the patients in Group 2 (333.57 ± 14.00) (**Table 3**). The same situation was observed for the COPD patients: after the education the FEV_1 % values of the intervention group were 57 %, whereas for the control group they were 47 %.

During the study patients' self-monitoring was provided. It included patients' reports about the existence, duration and severity of crises, hospitalization and duration of hospitalization if needed, and compliance with the drug treatment.

The patients reported the frequency of cough, chest tightness and shortness of breath. Over 90 % of the patients in both the control and intervention groups reported that they had experienced these symptoms most of the time. Up to 55 % reported feeling these symptoms 3 to 6 times a week or more frequently. After the education, significantly more patients in the intervention group than in the control group (37 % vs. 9 %) reported no occurrence of these symptoms at all ($P = 0.013$; χ^2 test).

A significant part of the control group (71.7 %) in comparison with the intervention group (40.1 %) was hospitalized due to crisis and the length of hospital stay was from 2 to 5 days. After the education process, there was a decrease in the hospitalization rate in the intervention group. Six patients reported that during the observed period they had been hospitalized only once (13.6 %). The rest of the patients from this group were not hospitalized. While the results in the control group show increase in the rate of the poly hospitalizations to 77.9, the self-reported hospitalization rates were significantly different between the two groups ($P = 0.001$; paired t-test).

A significant decrease in the frequency of Urgent Medical Aid (UMA) calls was observed. In the beginning of the study about 47.3 % from the intervention group patients were not calling for UMA and the rest had needed UMA once (17.4 %) or more than once (27.8 %), while there were only 22.9 % from the control group patients that did not need these services. After the education process there was a decrease in the UMA calling rate in the intervention group. The patients reported that during the observed period they had needed these services only once (18.2 %). The rest of the patients from this group did not have any disease complications that called for UMA intervention. The results in the control group showed decrease in the rate of

TABLE 3

Education effect

Parameters	Baseline		After 4 months	
	Group 1 (*n* = 30/13)	**Group 2 (*n* = 30/13)**	**Group 1 (*n* = 30/13)**	**Group 2 (*n* = 30/13)**
PEF rate (L/min) – asthma	327.45 ± 12.73	331.12 ± 10.27	338.64 ± 12.55	333.57 ± 14.00
FEV_1% – COPD	47 %	49 %	57 %	49 %
Inhaler technique	0.41 ± 0.5	0.46 ± 0.5	0.55 ± 0.51	0.46 ± 0.51
Self-monitoring				
availability of cough, shortness of breath	90.9 %	96.4 %	68.2 %	96.4 %
hospitalization rate	40.1 %	71.7 %	13.6 %	77.9 %
frequency of UMA calls	52.7 %	77.1 %	18.2 %	73.29 %
visit to GP				
- less than 2 or 3 times	63.7 %	17.9 %	86.4 %	21.4 %
- more than 6 times	9.1 %	3.6 %	4.5 %	3.6 %
QoL	3.55 ± 1.335	3.39 ± 0.685	3.77 ± 1.020	3.00 ± 0.903

the calls from 77.1 % to 73.2 %. The difference between the 4-month results and the baseline was not significant in the two groups ($P > 0.05$; Mann–Whitney U-test).

After the education there was no significant difference in the results of the control group about the frequency of GP visits: 3.6 % stated that they had visited their physician more then 6 times and 21.4 %, less than 2 or 3 times. While there were significant differences in the intervention group (86.4 % had visited their physician less than 2 or 3 times), only 4.5 % had done so more than 6 times for the last 4 weeks ($P = 0.018$; χ^2 test).

Analysis of the Asthma Assessment form showed no significant differences in the patients' QoL over the 4-month period. About 29.2 % of the intervention group and only 9.1 % of the control group said that they had a fully-experienced day most of the time and their disease did not interfere in their daily routine. After the education there was no significant change in the answers: about 27.0 % of the intervention group and 4.2 % of the control group answered that they had had fully experienced days most of the time for the last 4 weeks (**Table 3**).

Data regarding patient satisfaction with the services provided by pharmacists were collected by means of interviews. They were carried out at the beginning of the project and after the education process. The patients' responses were based on the services provided by the private community pharmacists in the pharmacies included in the project.

At baseline, the two groups classified the provided pharmacy service as poor (54.5 % for the intervention group vs. 71.4 % for the control group). After the education, the responses obtained from the intervention group showed a positive increase: 72.7 % of the patients assessed the services as satisfactory, while the patients from the control group were still assessing the pharmacy services as poor (75.0 %). The difference between the 4-month results and the baseline was significantly higher in the intervention group than in the control group ($P = 0.011$; paired *t*-test).

When assessing the necessity for additional information, nearly all patients at baseline declared that they needed additional information from their pharmacist about their disease or their prescribed drugs (81.8 % of the intervention group patients vs. 64.3 % of control group ones). After the 4-month assessment period, control patients (71.4 %) rated this need as great, whereas intervention patients were more satisfied of the provided contact regarding their condition and its management (54.5 %, $P < 0.017$; paired *t*-test).

Although asthma and COPD share similar characteristics, they are two very different diseases in terms of frequency of symptoms and reversibility of airway obstruction. For asthma patients, removing the triggers like stress, weather, specific allergens, environmental pollutants or even perfume, will oftentimes relieve the symptoms. It is quite the opposite for COPD; for example, quitting smoking may slow the rate of lung decline that occurs with the disease, but does little for improving COPD symptoms. Obstructive lung diseases such as asthma and COPD constitute a serious public health issue with significant financial and resource burdens on the health care system. The goals of treatment include reduction of symptoms, improvement in physiologic function, limitation of complications, and arresting exacerbations of the diseases (26).

These two diseases are treated similarly, i.e. they can both be managed by means of pharmacologic and nonpharmacologic strategies focused on treating bronchoconstriction and airway inflammation. Pharmacy practice in lung diseases management can be assessed as a relatively new approach that integrates disease and drug management (21). The results from our study confirm previous reports that education of patients with asthma and COPD can be effective and beneficial. It proved that pharmaceutical care provision is well received by both asthmatic and COPD patients (8). We keep in mind the fact that the studied patient group was small is size and we cannot generalize about all the asthmatic and COPD patients in Bulgaria. However, our aim was to assess any alteration in the patients' results and the study showed some positive trends in the intervention group. At the end of the study, the education group showed significant differences when compared with the control group (education/control [mean values]) with respect to: improvement in the PEF rate 338.64/327.45 ($P < 0.05$), and in the FEV_1% 57 %/47 % ($P < 0.05$).

Improvements were also observed in the inhaler technique, quality of life, and satisfaction with pharmacy services and information obtained and while these were not statistically significant, it must be taken into account that the education process was for only 4 months long. The value of the inhaler training is evident from the results and it coincides with other studies. The better results of the intervention group suggest that the education in proper application of inhalers at pharmacy conditions is beneficial (8).

Conclusions

It can be concluded that the educational program in pharmacy conditions is easy to be performed and can significantly improve asthma and COPD morbidity. The obtained results confirm the need of constant education for these patients (9, 15). The results show that such an approach has the potential to improve the quality of life of the patients and that it can be implemented in the daily pharmacy routine.

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