

BRONCHIAL ASTHMA AND COPD: IMPACT OF PHARMACEUTICAL CARE ON OUTCOMES AND QUALITY OF LIFE IN EGYPTIAN PATIENTS

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تتناول الدراسة تقييم مدى تأثير الرعاية الصيدلانية على المردود العلاجي (patients' outcomes) وعلى جودة الحياة (quality of life) لمرضى الربو الشعبي ومرض الإنسداد الرئوي المزمن. تم اختيار مريضاً من العيادات الخارجية للأمراض الصدرية لمستشفى الدمرداش كلية الطب جامعة عين شمس. وتم تقسيم المرضى إلى مجموعتين متساويتين كل منهما مريض. تم تطبيق برنامج الرعاية الصيدلانية على المجموعة الأولى من المرضى أما المجموعة الثانية فقد تلقت الرعاية الصحية المعتاد عليها بالمستشفى. وتم قياس الفرق بين المجموعتين من حيث جودة الحياة، المردود العلاجي والتكلفة العلاجية.

أظهرت النتائج اختلافاً ذا مدلول إحصائي بين المجموعتين. حيث أظهر المرضى في مجموعة الرعاية الصيدلانية تحسناً له دلالة إحصائية من حيث المردود العلاجي (أعراض المرض، وظائف الرئة، تكرار تفاقم الأعراض ودخول المستشفى) مما كان له أثر كبير على جودة الحياة بالمقارنة بالمجموعة الثانية التي تلقت الرعاية المعتادة. كذلك فإن المرضى في مجموعة الرعاية الصيدلانية أظهروا إنخفاضاً ملحوظاً ذي دلالة إحصائية في تكلفة العلاج.

مما سبق يمكننا إستنتاج أن الرعاية الصيدلانية للأمراض المزمنة مثل الربو الشعبي ومرض الإنسداد الرئوي المزمن لها تأثير إيجابي على المردود العلاجي والإقتصادي وجودة الحياة.

This work was performed to assess whether a pharmaceutical care program improves outcomes and optimizes quality of life in Egyptian patients with bronchial asthma or chronic obstructive pulmonary disease (COPD). Three hundred and fifty adult patients

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with bronchial asthma or COPD were selected from the out-patient chest clinics, El-Demerdash hospital, Faculty of Medicine, Ain Shams University, Cairo, Egypt; from January 2003 to August 2004. Participants were divided into 175 patients for whom the program was implemented and the remaining 175 patients were considered as control; received the hospital usual care. Patients at the out-patient chest clinics were invited to participate in the pharmaceutical care program. The program consisted of scheduled meetings between the pharmacist and patients to assess drug therapy, plan goals, and intervene through counseling and/or consultation with other health professionals. Three primary parameters were measured monthly. First: health-related quality of life (HRQOL). Second: clinical outcomes including change in peak expiratory flow rate (PEFR), physical findings, numbers of visits to clinics' and emergency department (ED) and hospitalization. Third: the costs. Results showed great statistically significant improvements in HRQOL and the clinical outcome for patients in the intervention group; either asthmatics or patients with COPD, compared with control groups. The monthly average costs were statistically significantly higher for the control group in comparison with either asthmatics or patients with COPD in the intervention group. In conclusion: results from this study provide evidence that through providing structured, co-operative, patient-oriented pharmaceutical care, pharmacists can help patients with reactive airway disease achieve desired health outcomes, optimize health related quality of life in realistic economic parameters. Recommendation: Pharmaceutical care would have maximum impact if its effect on patients' outcomes could be demonstrated in community pharmacies by well trained pharmacist. Community pharmacies have the capacity to rapidly implement programs system-wide. However, for programs to be integrated into these pharmacies, a rigorous change in pharmacy education in Egypt will be necessary.

INTRODUCTION

Reactive airways (RAW) diseases, including asthma and COPD, are prevalent, morbid and costly long-term conditions.¹⁻⁴ Exacerbations are usually preventable by drug therapy intervention,^{5&6} however, patients often have great difficulty following

prescribed regimens.⁷ Pharmacists may be able to enhance patients' outcomes and adherence to therapy.

In addition to dispensing medications, the pharmacy profession advocates that pharmacists offer pharmaceutical care to improve patients' health. Pharmaceutical care activities include monitoring patients'

symptoms, counseling patients about their medications, helping resolve drug-related problems, facilitating communication with physicians, and performing patient-specific interventions when appropriate.^{8&9} Pharmacists are well suited for these tasks because (1) they have the skills needed to identify and resolve drug-related problems, (2) patients often have several physicians, but frequently patronize a single pharmacy, (3) pharmacists are often the last health professional whom patients see before taking a newly prescribed medication, and (4) pharmacists are trusted by patients.¹⁰

Bronchial asthma and COPD are appropriate focus of pharmaceutical care because (1) they are chronic diseases who require ongoing therapeutic monitoring, (2) the acute exacerbations leading to morbidity, increased cost and death are often preventable and (3) patients usually have drug related-problems.^{5&6} This study was performed to assess whether a pharmaceutical care program improves outcomes and optimizes quality of life in Egyptian patients with bronchial asthma or chronic obstructive pulmonary disease (COPD).

METHODS

Patients selection

The study was conducted on 350 patients, during the period February 2, 2003 – August 12, 2004, in chest out-patient clinics of El-Demerdash Teaching Hospital, Faculty of Medicine Ain-Shams University,

Cairo, and approved by the Hospital review Committee. Eligible subjects were (1) non-illiterate patients with bronchial asthma or COPD, (2) between 18 and 60 year of age, (3) candidates for methylxanthines, inhaled corticosteroids, inhaled or oral sympathomimetics, inhaled parasympathetic antagonists, or inhaled cromolyn sodium, (4) not suffering from any serious disease such as unstable coronary heart disease, heart failure, serious hypertension, diabetes mellitus, kidney or liver failure, or significant impairment in vision, hearing, or speech that precluded participation, (5) permanent residents in the area close to the hospital. Subjects with asthma were to have a forced expiratory volume after one second (FEV₁) equal to or higher than 80% of predicted value¹¹ in stable phase. Furthermore we required a positive reversibility test;¹¹ a documented 20% spontaneous variability (PEFR and FEV₁). A positive reversibility test required at least a 20% increase (FEV₁ or PEFR) after inhalation of 400 µg salbutamol. Subjects with COPD were to have a FEV₁ equal to or higher than 40% and lower than 80% of predicted. Among patients with COPD, 28% were reversible to ipratropium bromide 80 µg and/or salbutamol.^{12&13} Spirometry was performed prior to randomization and at 6 month follow-up by standard methods¹⁴ using a *Jaeger MasterLab Body Box* (Würzburg, Germany). The patients were told to abstain from bronchodilators for 6 hours before

testing. The technical staff did not know whether the patients belonged to the control or to the intervention group. Smoking was measured using standard questions on status, daily number of cigarettes, and duration in years.¹⁵

Study design

We designed a randomized controlled trial in which patients were chosen in two successive days (Saturday and Sunday) per week. According to the criteria described below patients' selection, a total of 350 patients were enrolled in the study and in random were classified as an intervention group and a control group. Intervention group was subjected to the pharmaceutical care program while control group received the hospital usual care. Face to face interviews at base line were conducted for selection, evaluation, grouping and education. Patients in the pharmaceutical care group were asked to visit the clinic monthly in regular manner for check, evaluation, continual education, PEFR measurement and ensuring compliance, and also, immediately on the nearest Saturday or Sunday when there is a problem that is related the plan. Patients in the control group were asked to visit the clinic monthly as usual for check and evaluation.

Pharmaceutical care program

The intervention group received a specially made 12-page booklet containing essential information about asthma/COPD, medication, compliance, self-care, and self-

management plan. Instructions in the recording of PEFR and symptoms in a diary were given to both asthmatics and patients with COPD. The asthmatics and patients with COPD were educated in separate. The education consisted of 2 hour baseline interview, of 5 to 8 persons, followed by individual sessions.

During the baseline interview, the importance of self-care was emphasized. Patients were given, in simple, a basic introduction to asthma/COPD, concentrating on the airway smooth muscle cramp and inflammatory components of obstruction, which is the target for medical treatment. Prevention of attacks and factors causing exacerbations were emphasized as well as the dangers of smoking. The interview also, included pharmacology of the asthma drugs, how they affect the components of obstruction, and the rationale for their use. Essentials on self-care were reviewed, recording of PEFR and symptoms in a diary was emphasized, and then the model of a stepwise treatment plan at exacerbations was presented in general.

During individual sessions effort was made to establish a partnership with the patient by using open-ended questions, acknowledging concerns and fears about the obstructive lung disease. Each patient received a 20 to 30 minute educational interview. At this interview, the patient was asked to bring all medications (both prescription and over the counter) to the pharmaceutical care session,

which took place in a room or area of privacy. The goals of asthma/COPD treatment were stated and again the components of obstruction were emphasized together with the site of action of individual anti-asthmatic medication. The individual factors causing attacks/exacerbations were discussed. Tobacco weaning was emphasized. Fears of adverse effects of medication was obtained. Inhalation technique was checked and PEFR and symptoms were discussed. The pharmaceutical care intervention also included communication with the patient's physician about drug therapy problems that had been identified by the pharmacist. At the final teaching, the patients received an individual treatment plan on the basis of the acquired personal information. The personal understanding of the treatment plan was discussed and tested. Follow-up meetings with each patient were supposed to occur with each subsequent problem.

Measured parameters

Three primary parameters were measured monthly: health-related quality of life (HRQOL), clinical outcomes, and costs. Measurements of these parameters were based on methods described by Earl S. *et al.* but with little modifications.¹⁶ Measures of HRQOL, clinical outcomes and costs were determined monthly, then the average values of measures, for each patient, in the first 3 months and the second 3 months were calculated to be taken as 2 points of comparison, corresponding

to evaluation after 3 and 6 months, respectively, between control and intervention groups. Average values of the first 3 and second 3 months were calculated for each group to be evaluated and compared.

Health-related quality of life (HRQOL)

Four HRQOL questions were asked to participants: (1) "Would you say that in general your health is: excellent, very good, good, fair, or poor during the past 30 days?"; general health scoring of 5, 4, 3, 2, and 1 was applied for excellent, very good, good, fair, and poor answers, respectively, (2) "Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?", (3) "Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?" and (4) "During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?"

Clinical outcomes

Clinical outcomes' measures included: (1) accurate monthly determination of PEFR, (2) numbers of self limited attacks of symptoms such as cough, sputum production and shortness of breath during the past 30 days, (3) numbers of visits to private clinics (PCs) or out-patient's

clinics (OPCs) of hospitals as a result of attacks of symptoms during the past 30 days, and (4) numbers of emergency room (ER) visits and hospitalization during the past 30 days.

Costs

Costs included medication costs as a result of the reactive airway disease, treating drug adverse effects, PCs, OPCs or ER visits, or hospitalization.

Statistical analysis

All data were managed with Microsoft Excel[®] spreadsheet software. Systat[®] (SYSTAT, Inc., Evanston, IL) was used to generate any additional statistical analysis. Parametric variables were expressed as mean (standard deviation). Differences in means between groups were compared using independent “t” test while absolute changes in mean within groups over the evaluation period were compared using paired “t” test after assessing for normality. Respecting the non-parametric parameters, comparisons between control and intervention groups were tested by the χ^2 test.

RESULTS

The study population consisted of 350 patients, of whom 100 were randomized to each asthma treatment group and 75 to each COPD treatment group (Table 1). The patients in the intervention and control groups were found to be equal with regard to baseline parameters. There were 46 (23%) men in the

asthma group and 72 (48%) in the COPD group. The asthmatic patients had a mean baseline FEV₁ of 92.2% of expected value, whereas the patients with COPD had a mean baseline of 60.5% of expected. Altogether 61 (30.5%) and 52 (34.7%) of the asthmatics and the patients with COPD, respectively, were current smokers at randomization and 82 (41%) and 98 (65.3%) had a smoking history, respectively. The mean age (SD) in the asthma group was 39.4 (11.3) year and in the COPD group it was 59.2 (15.1) year.

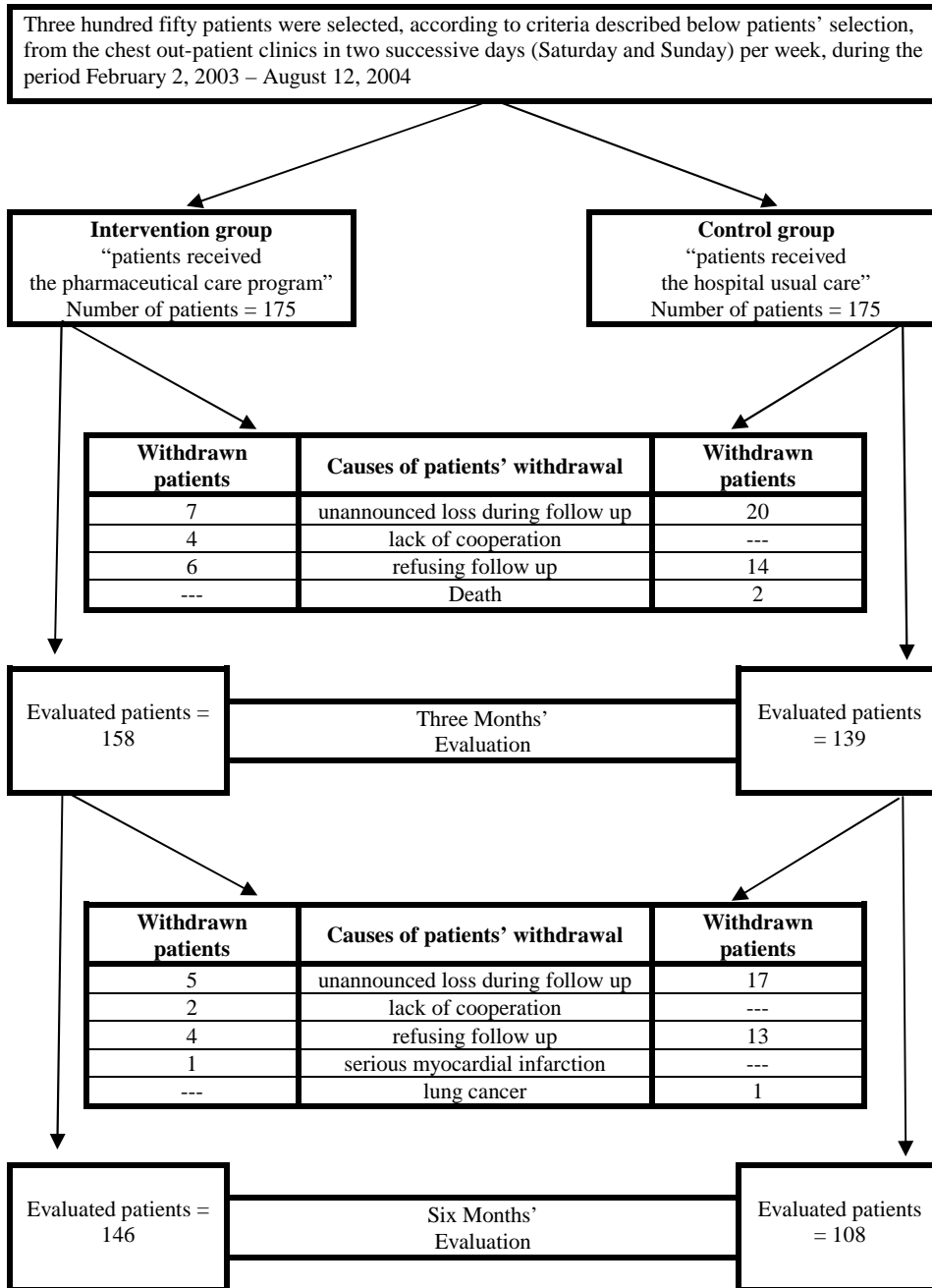
In the intervention group 29 patients did not complete the educational program due to different reasons (Fig. 1); 17 patients during the first three months and 12 patients during the second three months. The reasons for not finishing the program were unannounced loss during follow up (n= 12), lack of cooperation (n= 6), serious myocardial infarction (n= 1), and refusing follow up for unknown reasons (n= 10). This left us with 158 patients (90%) for a 3-months' evaluation and 146 patients (83%) for a 6-months' evaluation. The withdrawn intervention group patients did not -to our knowledge- have any serious deterioration in their obstructive lung disease, and none were hospitalized.

In the control group, 67 patients were withdrawn; 36 patients during the first three months and 31 patients during the second three months. Patients were withdrawn because of unannounced loss during follow up

Table 1: Baseline characteristics of patients included in the study.

Studied variables	Asthma		COPD	
	Control Group (n = 100)	Intervention Group (n = 100)	Control Group (n = 75)	Intervention Group (n = 75)
Sex, men (%)	22 (22)	24 (24)	37 (49.3)	35 (46.7)
Age, yr, mean (SD)	38.3 (10.2)	40.42 (12.4)	59.7 (15.3)	58.6 (14.8)
Weight, kg, mean (SD)	77.5 (8.3)	78.2 (7.7)	74.6 (8.2)	73.9 (9.1)
Height, cm, mean (SD)	172.8 (14.1)	174.3 (17.4)	176.2 (22.2)	178.6 (20.8)
Smoking habits				
• Current smokers (%)	(32)	(29)	27(36)	25(33.3)
• Ex-smokers (%)	(42)	(40)	48(64)	50(66.3)
• Never-smokers (%)	(26)	(31)	-----	-----
Duration* of symptoms, median** (yr)	5	6	12	14
FEV ₁				
• Mean (SD), L	2.8 (0.8)	2.9 (0.9)	1.8 (0.59)	1.7 (0.61)
• % predicted, mean (SD)	90.3 (25.8)	93.5 (29.1)	61 (19.7)	60 (21.2)
FVC				
• Mean (SD), L	3.9 (1.1)	4.0 (1.2)	3.1(1.0)	3.0 (1.1)
• % predicted, mean (SD)	92.1 (25.9)	92.3 (27.7)	75 (24.2)	74.7 (27.5)
(FEV ₁ /FVC) × 100, mean (SD)	71.8 (20.5)	72.5 (21.7)	58.1 (18.7)	56.7 (19.2)
PEFR				
• Mean (SD), L/min	401.8 (56.4)	410.6 (58.9)	275.4 (41.9)	281.8 (44.3)
• % predicted, mean (SD)	71.4 (10.4)	70.8 (12.1)	50.3 (8.5)	51.2 (8.6)
FEV ₁ : Forced expiratory volume after one second, FVC: Forced vital capacity, PEFR: peak expiratory flow rate				
*Based on the question: How long have you had asthma/COPD symptoms?				
** Median values are employed for non-normally distributed data.				
Comparisons between control and intervention groups were tested by student “t” test (for parametric parameters) and chi ² test (for non-parametric parameters)				

Fig. 1: Patients' enrollment and withdrawal.



(n= 37), diagnosis of lung cancer (n= 1), death (2) and refusing follow up for unknown reasons (n= 27). Five of the withdrawn control group patients were hospitalized, at the time of the 6th month's evaluation, for exacerbations of their COPD. This left us with 139 patients (79%) for a 3-months' evaluation and 108 patients (62%) for a 6-months' evaluation.

Patients in the intervention groups; either asthmatics (Table 2) or patients with COPD (Table 3), showed great statistically significant differences in HRQOL compared with control groups. Better scores for all four HRQOL measures were observed for both intervention groups when compared with control groups either in three or six months' evaluation. General health scores for the intervention groups; either asthmatics or patients with COPD, were significantly higher compared with the control groups. Comparing results of 3-months' and 6-months' evaluations, a statistically significant improvement was found in general health for the intervention group in six months' evaluation. Physically unhealthy days, mentally unhealthy days and days of activity limitation were significantly lower for intervention groups; either asthmatics or patients with COPD, when compared with control in both of 3-months' and 6-months' evaluations. Six months' evaluation showed statistically significant improvement in the intervention groups; asthmatics or patients with COPD, compared with 3-months' evaluation.

A statistically significant differences in patients' clinical

outcome were observed between intervention and control groups for asthmatics (Table 4) and patients with COPD (Table 5). Compared with baseline values, PEFr in both the 3-months' and 6-months' evaluations, significantly increased ($p < 0.001$) in the asthma intervention group, whereas it insignificantly changed in the asthma control groups (Figs. 2 & 3). Likewise, PEFr in the 6-months' evaluation, significantly increased ($p < 0.001$) in the asthma intervention group when compared with the 3-months' evaluation. In the patients with COPD no statistically significant improvements were noted for the intervention group or the control group (Figs. 2 & 3). Numbers of self-limited attacks of symptoms, PCs, OPCs visits or ER visits and hospitalization were significantly lowered in both asthma and COPD intervention groups when they were compared with control groups. Patients in both asthma and COPD intervention groups in the six months' evaluation showed statistically significant improvement when they were compared with 3-months' evaluation.

Table 6 provides a proof that monthly average costs are statistically significantly higher for control groups in comparison with both asthma and COPD intervention groups. Comparison between six months' and 3-months' evaluation showed a statistically significant decrease in the monthly average costs for the six months' evaluation of the intervention groups; either asthma or COPD.

Table 2: Effect of pharmaceutical care on HRQOL in the included asthmatic patients.

Several Measures of HRQOL	Three Months' Evaluation				Six Months' Evaluation			
	Control Group (n = 81)	CV %	Intervention Group (n = 94)	CV %	Control Group (n = 67)	CV %	Intervention Group (n = 85)	CV %
General health	2.7 (1.0)	36	3.1 (0.5) ^{a,b}	16	2.5 (0.9)	36	4.1 (0.7) ^{a,b,c}	17
Unhealthy days (physically)	7.1 (2.7)	38	4.9 (1.2) ^{a,b}	24	7.7 (2.3)	29	3.6 (0.8) ^{a,b,c}	22
Unhealthy days (mentally)	6.4 (1.9)	30	5.8 (1.1) ^{a,b}	19	6.8 (2.3)	33	4.5 (0.9) ^{a,b,c}	20
Days of activity limitation	9.4 (3.3)	35	6.4 (1.7) ^{a,b}	27	10.2 (3.7)	36	4.3 (0.8) ^{a,b,c}	18
Values are expressed as mean (SD)								
HRQOL: Health related quality of life, CV%: Coefficient of variation percent								
Three months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the first 3 months								
Six months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the second 3 months								
Differences and changes were tested by student "t" tests								
a: Significant difference when compared with control; in the 3 months' evaluation point								
b: Significant difference when compared with control; in the 6 months' evaluation point								
c: Significant difference when compared with intervention group; in the 3 months' evaluation point								

Table 3: Effect of pharmaceutical care on HRQOL in the included patients with COPD.

Several Measures of HRQOL	Three Months' Evaluation				Six Months' Evaluation			
	Control Group (n = 58)	CV %	Intervention Group (n = 64)	CV %	Control Group (n = 41)	CV %	Intervention Group (n = 61)	CV %
General health	1.8 (0.6)	33	2.7 (0.7) ^{a,b}	26	1.9 (0.7)	37	3.8 (0.9) ^{a,b,c}	24
Unhealthy days (physically)	8.4 (2.6)	31	5.8 (1.5) ^{a,b}	26	8.1 (2.3)	28	4.8 (1.0) ^{a,b,c}	20
Unhealthy days (mentally)	7.6 (2.3)	30	6.3 (1.8) ^{a,b}	29	7.5 (2.3)	31	5.1 (1.0) ^{a,b,c}	20
Days of activity limitation	12.2 (3.8)	31	8.2 (2.1) ^{a,b}	26	12.0 (3.1)	26	6.2 (1.3) ^{a,b,c}	21
Values are expressed as mean (SD)								
HRQOL: Health related quality of life, COPD: Chronic obstructive pulmonary disease, CV%: Coefficient of variation percent, n: Numbers of patients								
Three months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the first 3 months								
Six months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the second 3 months								
Differences and changes were tested by student "t" tests								
a: Significant difference when compared with control; in the 3 months' evaluation point								
b: Significant difference when compared with control; in the 6 months' evaluation point								
c: Significant difference when compared with intervention group; in the 3 months' evaluation point								

Table 4: Effect of pharmaceutical care on the clinical outcome in the included asthmatic patients.

Studied Measures	Three Months' Evaluation				Six Months' Evaluation			
	Control Group (n = 81)	CV %	Intervention Group (n = 94)	CV %	Control Group (n = 67)	CV %	Intervention Group (n = 85)	CV %
PEFR, % predicted, mean (SD)	71.6 (14.4)	20	80.3 (13.6) ^{a,b}	17	70.8 (13.2)	19	87.2 (11.2) ^{a,b,c}	12
Numbers of self limited attacks of symptoms	5.2 (1.3)	25	4.1 (1.0) ^{a,b}	24	5.4 (1.3)	24	3.4 (0.7) ^{a,b,c}	21
Numbers of visits to (PCs) or (OPCs)	2.1 (0.46)	22	1.8 (0.32) ^{a,b}	18	2.2 (0.51)	23	1.1 (0.20) ^{a,b,c}	18
Numbers of ER visits and hospitalization	0.72 (0.26)	36	0.41 (0.14) ^{a,b}	34	0.73 (0.27)	37	0.34 (0.10) ^{a,b,c}	29
Values are expressed as mean (SD)								
PEFR: Peak expiratory flow rate, PCs: Private clinics, OPCs: Out-patient's clinics of hospitals, ER: Emergency room , CV%: Coefficient of variation percent, n: Numbers of patients								
Three months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the first 3 months								
Six months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the second 3 months								
Differences and changes were tested by student "t" tests								
a: Significant difference when compared with control; in the 3 months' evaluation point								
b: Significant difference when compared with control; in the 6 months' evaluation point								
c: Significant difference when compared with intervention group; in the 3 months' evaluation point								

Table 5: Effect of pharmaceutical care on the clinical outcome in the included patients with COPD.

Studied Measures	Three Months' Evaluation				Six Months' Evaluation			
	Control Group (n = 58)	CV %	Intervention Group (n = 64)	CV %	Control Group (n = 41)	CV %	Intervention Group (n = 61)	CV %
PEFR, % predicted, mean (SD)	50.4 (17.2)	34	54.6 (19.3)	35	50.3 (18.1)	36	56.2 (19.4)	16
Numbers of self limited attacks of symptoms	7.4 (1.8)	24	5.1 (1.1) ^{a,b}	22	7.6 (1.9)	25	4.1 (0.8) ^{a,b,c}	20
Numbers of visits to (PCs) or (OPCs)	4.1 (0.9)	22	2.8 (0.5) ^{a,b}	18	3.9 (0.9)	23	1.8 (0.4) ^{a,b,c}	22
Numbers of ER visits and hospitalization	1.77 (0.63)	37	0.7 (0.25) ^{a,b}	36	1.9 (0.68)	36	0.81 (0.16) ^{a,b,c}	20
Values are expressed as mean (SD)								
COPD: Chronic obstructive pulmonary disease, PEFr: Peak expiratory flow rate, PCs: Private clinics, OPCs: Out-patient's clinics of hospitals, ER: Emergency room CV%: Coefficient of variation percent, n: Numbers of patients								
Three months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the first 3 months								
Six months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the second 3 months								
Differences and changes were tested by student "t" tests								
a: Significant difference when compared with control; in the 3 months' evaluation point								
b: Significant difference when compared with control; in the 6 months' evaluation point								
c: Significant difference when compared with intervention group; in the 3 months' evaluation point								

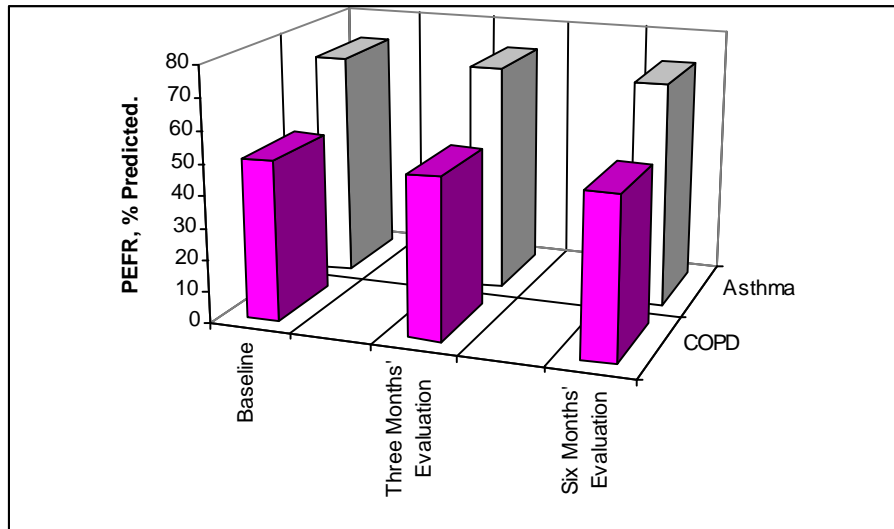


Fig. 2: Peek expiratory flow rate (PEFR), % predicted for the control groups.

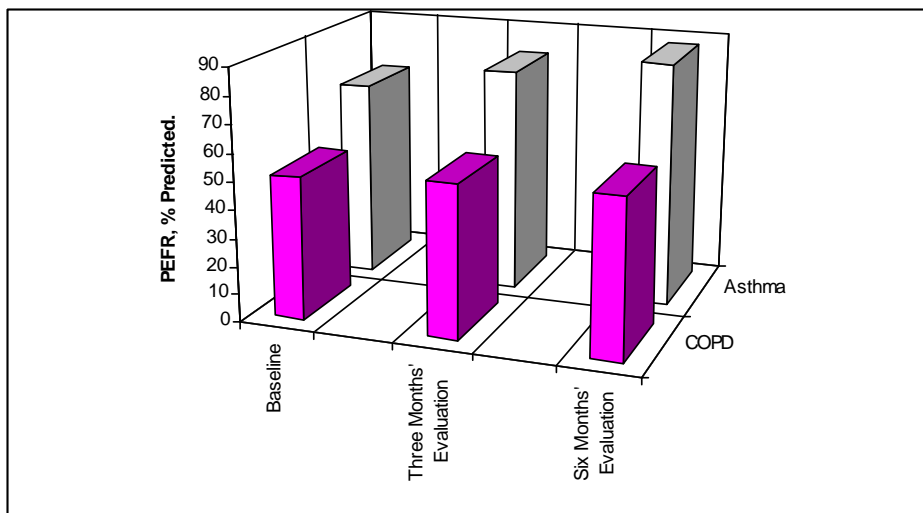


Fig. 3: Peek expiratory flow rate (PEFR), % predicted for the intervention groups.

Table 6: Effect of pharmaceutical care on costs in the included asthmatic patients and patients with COPD.

	Asthmatic patients						Patients with COPD					
	Control Group	n	CV %	Intervention Group	n	CV %	Control Group	n	CV %	Intervention Group	n	CV %
Three Months' Evaluation	486 (175)	81	36	344 (120) ^{a,b}	94	35	890 (338)	58	38	421 (135) ^{a,b}	64	32
Six Months' Evaluation	491 (177)	67	36	225 (77) ^{a,b,c}	85	34	902 (342)	41	38	340 (116) ^{a,b,c}	61	34
Values in L.E. are expressed as mean (SD)												
COPD: Chronic obstructive pulmonary disease, CV%: Coefficient of variation percent, n: Numbers of patients												
Three months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the first 3 months												
Six months' evaluation: mean values of "n" averages; each average is the mean value of 3 readings taken for each patient during the second 3 months												
Differences and changes were tested by student "t" tests												
a: Significant difference when compared with control; in the 3 months' evaluation point												
b: Significant difference when compared with control; in the 6 months' evaluation point												
c: Significant difference when compared with intervention group; in the 3 months' evaluation point												

DISCUSSION

Patients with RAW disease are often on more complex regimens, which can result in lower medication adherence and increased morbidity, adverse drug events, hospital admission, death, and health care costs.¹⁷⁻¹⁹ The importance of drug related events has, in part, led the pharmacy profession to redefine its role in the health care delivery system, particularly through pharmaceutical care. Pharmaceutical care is "the responsible provision of drug therapy for the purpose of achieving outcomes that improve a patient's quality of life."⁸ Thus, pharmaceutical care represents a fundamental paradigm shift emphasizing that pharmacists can help improve patients' health related quality of life, rather than simply providing a product or service. Pharmaceutical care activities are particularly important when caring for patients with chronic disease, where it is estimated that over 50% of patients do not take their medication properly. A recent position research paper by The American College of Physicians American Society of Internal Medicine recognizes the increasing scope of pharmacists and outlines "how the medical profession can work with pharmacists to enhance patient safety and quality of care."²⁰ In the present study, we examined the impact of a pharmaceutical care program implemented to improve outcomes and optimize quality of life in Egyptian patients with bronchial

asthma or chronic obstructive pulmonary disease (COPD).

In the asthmatics, the intervention group had a better general health, higher activity, and less impact on their daily life, as detected by HRQOL measures, compared with the control group. We were also able to show that the intervention group in patients with COPD was associated with improved health-related quality of life in the 2 evaluation times; 3-months' and 6-months. Our results illustrate two important points. First, asthmatic patients experienced, on average, 9 days each month of activity limitation due to impaired physical or mental health, almost could be reduced to an average of 4 days after only 6-months of pharmaceutical care implementation. Second, patients with COPD experience more activity limitation days, on average, 12 days each month due to impaired physical or mental health, which almost could be reduced to an average of 6 days after only 6-months of pharmaceutical care implementation. This might be indicative to more and more benefits with continual patients' education.

Gallefoss *et al.*²¹ assessed the effect of patient education on HRQOL in a randomized controlled study on asthma and COPD and they observed, after one year follow up, a clear improvement in the intervention group relative to the control group among asthmatics, but not for the patients with COPD. They attributed their results to the applied questionnaire; SGRQ (St. George's

Respiratory Questionnaire) and they postulated that it may be theoretically less sensitive to changes in quality of life in the patients with COPD than in the asthmatics. However, the SGRQ has been shown to respond to changes in health over time in patients with COPD.²²

The intervention group, in the asthmatic patients of our study, had overall positive clinical outcomes. They had improved PEF, less symptoms, exacerbation, visits to private clinics, out-patient clinics, emergency room and hospitalization, compared with the control group. The intervention group in patients with COPD also had less symptoms, exacerbation, visits to private clinics, out-patient clinics, emergency room and hospitalization, compared with the control group, however no statistically significant differences between the control and the intervention groups were noted regarding lung function; PEF. Pulmonary functions have great effects on overall patient general health and determine patient's pulmonary status, therefore peak flow test results are very predictive for clinical outcome, prognosis and treatment response.^{23&24} The decreased pulmonary function test results, for COPD patients, may explain in part the general deteriorated conditions, the weak response to treatment, the high rate of exacerbations and hospitalization of these patients.

The Pharmaceutical care plan may suit the asthmatic patients better than

the patients with COPD. Asthmatic patients have a higher reversibility element than do patients with COPD. The asthmatics may be motivated to stick to the self-management plan by experiencing that it works. Changes in PEF values and symptoms lead to changes in medication according to the plan and a subsequent improvement in these measures. If the patients with COPD observe limited changes in PEF and symptoms when following a treatment plan, they may be less inclined to stick to the plan at the next exacerbation. The education given to the patients with COPD may have suited their needs less than the education given to the asthmatics.²⁵

The asthmatics and patients with COPD received education- about the nature of their disease; what brings and what relieves, the used drugs; how to use and how to reduce adverse effects- showed a mean drop in monthly cost, whereas patients in the control group who received the usual hospital care only showed a mean increase in the monthly costs. This finding agrees with results of previous studies.^{26&27}

The benefits of interventions by pharmacists have been described in the literature. Recently, more and more articles have appeared which indicate the cost savings associated with the efforts of pharmacists to intervene in inappropriate drug therapies. These studies indicate an enhanced quality of life for patients, and an improved profit potential for the pharmacy.²⁸ Pharmacists routinely perform activities that result in

economic and therapeutic benefits to the patients. In one large scale study conducted by Rupp *et al*, it was noted that roughly 2% of prescriptions examined had one or more prescribing errors.²⁹ Through the interventions of pharmacists, a value of \$2.32 was added to each prescription filled. In a study completed in Minnesota, Iverson³⁰ also found that 2% of prescriptions needed dosage corrections or other actions. Iverson concluded that the cost savings amounted to \$16.74 per prescription. In another study, Rupp found that \$123 in medical care costs were avoided through pharmacists' interventions.³¹ In a further study, Rupp and DeYoung found that frank prescribing errors represented the most common error detected in physician prescribing.³² Elsewhere, the influence of pharmacists has produced lower drug expenditures, and in some cases the administration of fewer doses.³³ In managed care settings, the interventions of pharmacists have been calculated to be \$24.00 per intervention.³⁴

Conclusion

The pharmacist's role and place in the health care structure has changed, and new opportunities have emerged. Results from this study provide evidence that through providing structured, co-operative, patient-oriented Pharmaceutical Care, pharmacists can help patients with reactive airway disease achieve desired health outcomes, optimize

health related quality of life in realistic economic parameters.

Our recommendation is: Pharmaceutical care would have maximum impact if its effect on patients' outcomes could be demonstrated in community pharmacies by well trained pharmacist. Community pharmacies have the capacity to rapidly implement programs system wide. However, for programs to be integrated into these pharmacies, a rigorous change in pharmacy education in Egypt will be necessary.

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