DOI: https://doi.org/10.31351/vol32iss2pp9-17

Effect of Pharmacist Interventions on Asthma Control and Pulmonary Functions Parameters of Iraqi Asthmatic Patients: A comparative Study

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Abstract

Despite the fact that asthma is a long-term disease that may be treated, many people are unable to control their symptoms due to a lack of knowledge about their condition. Additional efforts are necessary by health workers particularly clinical pharmacists to educate asthmatic patients about the disease and its consequences.
This study was designed to assess the effect of pharmaceutical care on asthma control and pulmonary functions test.

A interventional randomized study conducted at outpatient's clinic of respiratory diseases/ Baghdad teaching hospital for about eight months. Adult patients of both genders were enrolled in this study and divided into two groups: **Group 1** consists of 23 asthma patients who were randomly assigned to receive conventional therapy for chronic bronchial asthma based on disease stage and severity, as well as a pharmaceutical care plan that includes patient care and education, for three months. **Group 2:** Included in the study were 21 asthma patients who were randomly assigned to receive only conventional therapy for chronic bronchial asthma based on illness stage and severity for three months. All individuals included in this study had their asthma control test and pulmonary function test levels checked at the start and three months later.
Patients who received a verbal and written pharmaceutical care plan significantly improved their asthma control, which was demonstrating by an improvement in mean ACT and PFT scores for group 1 when compared to group 2 after 3 months of follow up.

The results of the study approved the important role of the pharmacist intervention to improve asthma control, enhancing ACT and PFT.
Keywords: Asthma, Pharmaceutical care, ACT, PFT.

تأثير التداخلات الصيدلانية على السيطرة على الربو ومعايير وظائف الرئة لدى مرضى الربو العراقيين: دراسة مقارنة

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الخلاصة

على الرغم من حقيقة أن الربو مرض طويل الأمد ويمكن علاجه ، فإن العديد من الأشخاص غير قادرين على السيطرة على أعراضهم بسبب نقص المعرفة حول حالتهم المرضية . من الضروري بذل جهود إضافية من قبل العاملين الصحيين وخاصة الصيادلة السريريين لتوعية مرضى الربو بالمرض وعواقبه.
صممت هذه الدراسة لتقييم تأثير الرعاية الصيدلانية على السيطرة على الربو واختبار وظائف الرئة.
دراسة عشوائية تداخلية أجريت في العيادة الخارجية لأمراض الجهاز التنفسي/ مستشفى بغداد التعليمي لمدة ثمانية أشهر. شارك عدد من المرضى البالغين من كلا الجنسين في هذه الدراسة وتم تقسيمهم إلى مجموعتين: المجموعة الأولى تتكون من ٢٣ مريضًا بالربو تم اختيارهم عشوائيًا لتلقي العلاج التقليدي للربو القصبي المزمن بناءً على مرحلة المرض وشدته ، بالإضافة إلى خطة الرعاية الصيدلانية التي تشمل العناية بالمرضى وتثقيفهم حول المرض لمدة ثلاثة أشهر. المجموعة الثانية: شملت الدراسة ٢١ مريضًا بالربو تم اختيارهم عشوائيًا لتلقي العلاج التقليدي للربو القصبي المزمن فقط على أساس مرحلة المرض وشدته لمدة ثلاثة أشهر. خضع جميع الأفراد المشمولين في هذه الدراسة لاختبار السيطرة على الربو و اختبار وظائف الرئة في البداية وبعد ثلاثة أشهر.
المرضى الذين تلقوا خطة رعاية صيدلانية شفهية ومكتوبة حسّنوا بشكل كبير من قدرتهم على التحكم في الربو ، والذي كان واضحًا من خلال تحسن متوسط درجات ACT و PFT للمجموعة الاولى عند مقارنتها بالمجموعة الثانية بعد ٣ أشهر من المتابعة. أقرت نتائج الدراسة الدور المهم للتداخل الصيدلاني لتحسين السيطرة على الربو ، وتعزيز ACT و.PFT
الكلمات المفتاحية: الربو ، الرعاية الصيدلانية، ACT ، PFT.

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Received: 10/ 5/ 2022
Accepted:17/8/2022

Introduction

Asthma affects about 300 million individuals worldwide, according to a 2014 report [(1)]. Many studies found a correlation between various allergies, different lifestyles, and different civilizations, and that this tendency is expected to continue over the next two decades, according to recent studies [(1, 2)]. Asthma may have a significant influence on a patient`s quality of life [(2)]. If genetic factors alone aren't enough to explain the recent rise in the prevalence of asthma and other allergies (such as eczema), then other risk factors like environmental exposure, must be taken into account. It is expected that cases will rise to more than 400 million worldwide in 2025 [(3)] because of increased air pollution, urbanization, changed immune responses, and a change in way of life brought on by climate change [(4)]. More than half of adult population in USA and South America has asthma, which affects more than 4.3 million people [(5)].

Despite receiving the most advanced medical care, the majority of asthmatic patients may never have enough control over their condition [(6)]. Asthma-related emergency room visits, missed work days, and sleep disturbances were all linked to a lack of knowledge about the disease and the need for its optimal long term treatment [(7)].

It may not be possible to teach every patient in a busy outpatient clinic about the long-term nature of asthma on each appointment. Some patients may also have difficulty following instructions, which can be helped by peer support group training in addition to information provided by healthcare professionals [(8)]. An objective measure of airway resistance to expiratory flow, forced expiratory volume in one second (FEV1) percent predicted, is widely utilized as a crucial end goal in clinical investigations of asthma. Tests like the Asthma Control Test (ACT) have been developed to provide a composite score that integrates subjective patient reported scores of symptoms such as wheezing, shortness of breath, and activity limitation [(9)]. As the results of studies using various tools to measure these symptom control and pulmonary function outcomes vary widely from no significant correlation to strong correlation, the Expert Panel Report-3 Guidelines for the Diagnosis and Management of Asthma and Global Initiative for Asthma 2018 guidelines both suggest that pulmonary function measures may be weakly correlated with asthma (from no significant correlation to strong correlation) [(10)].

The objective of this study was to assess the impact of pharmaceutical care on asthma control and pulmonary function test.

Methods

Study design

A longitudinal interventional randomized study conducted at outpatient's clinic of respiratory diseases/ Baghdad teaching hospital for about eight months. Patients enrolled in this study according to the following inclusion and exclusion criteria:

Inclusion criteria

Adult patients with chronic bronchial asthma mild to moderate severity

1- Both genders with age of 18-70 years.

2- Patients with conventional treatment for chronic bronchial asthma (for mild to moderate chronic asthma)

Exclusion criteria

- Asthmatic patients with other comorbid inflammatory disorder.
- Asthmatic patients who are unable to perform accep Table spirometry.
- Current smokers or history of smoking within five years.
- Asthmatic patients with other chronic respiratory conditions (chronic obstructive Pulmonary disease (COPD), interstitial lung disease).
- Pregnant women or nursing mother.
- Asthmatic patient on chronic oral steroid therapy and on other drugs that affect the inflammatory process.

This is a prospective randomized interventional study, The participants were allocated into two groups:

Group 1: 23 patients with asthma who were randomly assigned o receive conventional therapy for chronic bronchial asthma based on disease stage and severity, as well as a pharmaceutical care plan that included patient care and education, for three months.

Group 2: 21 patients with asthma who were randomly assigned to receive only conventional treatment for chronic bronchial asthma based on illness stage and severity for three months.

According to the severity of the condition and the treatment provided by the physician, conventional therapy employed in this study comprises a variety of medications. Patients using bronchodilator reliever medicine such as salbutamol, methylxanthines (aminophylline), and inhalation preventer medication such as a corticosteroid/long acting 2-agonist combination Some individuals were taking a leukotriene antagonist (montelukast), which might be utilized as well.

At the start of the study, data collected from all enrolled patients, which included their age, gender, family history, concomitant conditions, and the onset of asthma symptoms. All patients involved in this study were clinically evaluated for Asthma control test (ACT) and all measures of Pulmonary function tests (PFTs) at baseline and 3 months later.

Pharmacist interventions

To compare, patients in the group 1 received an ongoing routine therapeutic treatment and pharmaceutical care, whereas patients in the group 2 received just standard care over the three-month follow-up period. A pharmacist's additional education on asthma basics, the role of medications, the distinction between short-term relief and long-term control medications, the impact of proper inhaler technique, avoiding asthma triggers and asthma self-monitoring was well received by patients in the group 1. Patients in this group also received support every four weeks after their initial appointment. The correct way to use an inhaler was demonstrated to the patient physically, and they were asked to return the demonstration [(11)].

The inhaler approach was re-evaluated on based on monthly visit. Asthma action plans were provided to those in the intervention group. Asthma patients were taught how to identify early warning signs of deterioration and how to seek medical assistance if they felt ill. Pharmacy assistance was not provided to the patients in the control group, who received standard medical care [(12)].

Asthma control test (ACT)

The ACT was assigned to all patients in this study before and after therapy to determine the asthma control score for the asthmatic patient during the previous four weeks based on the following scores, which ranged between (5-25) If the score is 25, it means that the asthma has been under control for the last four weeks; if the score is 20-24, it means that the asthma has been on target for the last four weeks. However, a score of less than 20 indicates that the asthma has been uncontrolled for the last four weeks. The ACT questionnaire was used in this study to provide a picture of the frequency of asthma symptoms and the usage of asthma reliever medications during the previous four weeks [(13)].

Pulmonary function test (PFT) using spirometry

Currently, Peak expiratory flow (PEF) measurement is suggested for daily monitoring of ambulatory individuals with difficult-to-manage asthma. In this case, the readings should be compared to an individual patient's baseline measurement acquired while the patient is asymptomatic and under control. Prior to carrying out spirometry, identification of the patient should be checked, height without shoes or boots and weight of the patients also measured (if scales are available, as this is not used in prediction equations but is valuable to know, as volume may be limited in obese patients), and the age, sex and race also recorded. If the patient is unable to stand to have their height measured, arm span can be used as an estimate [(14, 15)].

Forced expiratory volume in one second (FEV1) is a critical parameter for the assessment of lung function for both clinical care and research in patients with asthma, FEV1 is typically assessed during clinic visits. A low FEV1, <60% predicted is a potentially modifiable independent risk factor for exacerbations besides being a risk factor for developing fixed airflow limitation [(14)].

Statistical analysis

The data were analyzed using the Microsoft excel software, Minitab v17, and IBM SPSS V24. The results reported in this study were expressed as mean ± SD., Student independent t-test was used analyze difference between groups, and paired t-test to analyze difference within each group. Chi square test was used for categorical variables. Analysis of covariance (ANCOVA), were used to examine the degree of significance and probability values less than 0.05 were considered significantly different while probability values less than 0.01 were considered as highly significant difference.

Results

Table 1, describes the baseline clinical features and sociodemographic data of 44 asthmatic patients. This study included three individuals above the age of 50 and 41 participants under the age of 50 years old. There was no significant difference in age between study groups ($p>0.05$). In terms of gender, 23 male patients (52.27 percent) and 21 female patients (47.72 percent) were included in this study, and no significant difference was detected between study groups.

Patients with family history of chronic bronchial asthma were 2 patients (8.7%) in group 1, and 3 patients (14.3%) in group 2, no significant difference between group 1 & 2 ($p > 0.05$). Regarding to duration of disease, patients with duration of (< 1 year) were 9 (39.1%) in intervention group and 6 (27.6%) in control group, patient with duration of (1-5 yrs.) were 9 (39.1%) and 12 (71.4%) in intervention and control groups respectively, while patients with chronic bronchial asthma duration > 5 years were 5 (21.7%) in intervention group and 3 (1 %) in control group, with no significant difference between groups.

In respect to residence of the patients in this study, there were 27 patients rural and 17 patients urban and no significant difference noticed between the groups ($p>0.05$). Only one patient in control group present with comorbid disease (4.8%) and no one in group 1, with no significant difference between intervention and control groups ($P > 0.05$). Concerning the education level of patients, there were 4 (17.4%) in group 1 and 5 (23.8%) in group 2 graduated from college and 2 (8.7%) patients in group 1 and 4 (19%) in group 2 with primary level of education while 14 (60.9%) patients in group 1 and 11(52.4%) patients with secondary level of education, Collectively, there was no significant difference between groups 1 and 2 ($p > 0.05$).

Table 1. Patients sociodemographic and baseline clinical data.

Demographic characters		Group 1 N (%)	Group 2 N (%)	P-Value [a]
Gender	Male Female	13 (56.4) 10 (47.6)	10 (43.6) 11 (52.4)	0.555
Age group (years)	≤ 50 > 50	23 (100) 18 (76.2)	0 (0) 3 (23.8)	0.06
Family History	No Yes	21 (91.3) 18 (85.7)	2 (8.7) 3 (14.3)	0.560
Duration of disease	< 1 year 1-5 years > 5 years	9 (39.1) 9 (39.1 5 (21.7)	6(27.6) 12 (71.4) 3(1.0)	0.487
Residence	Rural Urban	15 (65.2) 8 (34.8)	12 (57.1) 9 (42.9)	0.583
Comorbid disease	No Yes	23 (100) 0 (0)	20 (95.2) 1 (4.8)	0.290
Education level	primary Secondary College P.G	2 (8.7) 14 (60.9) 3 (13.0) 4 (17.4)	4 (19.0) 11 (52.4) 1 (4.8) 5 (23.8)	0.562

Data was presented as numbers and percentages, No: number, %: Percentage, PG: Post graduate, BMI: body mass index, [a] Chi square test used to investigate differences .

As illustrated in Table (2) and Figure (1), patients in group 1 showed highly significant improvement in mean value of ACT after 3 months of follow up when compared with pre-treatment value ($p<0.01$) while group 2 showed no significant increase in ACT mean value after three months as compared to baseline mean value ($p > 0.05$).

Also there was no significant change in the mean value of ACT at baseline between study groups ($p>0.05$) but significant difference was found between groups 1 and 2 after three months ($p< 0.05$).

Table 2. Effect of pharmacist intervention on asthma control test

Study Groups	group 1	group 2	P-Value[(b)]
ACT **Baseline**	18.22 ± 3.11	17.38 ± 3.85	0.431
After 3 months	22.22 ± 4.86	18.48± 5.91	0.026 *
P-Value [(a)]	0.004 **	0.476	
Percent of change	+ 21.9 %	+ 6.3 %	

Data presented as mean ± SD, were: (a) paired t-test were used for comparison within same group, [(b)] independent t-test were used for comparison between groups, *: Significant difference ($p<0.05$), **: Highly Significant difference ($p<0.01$).

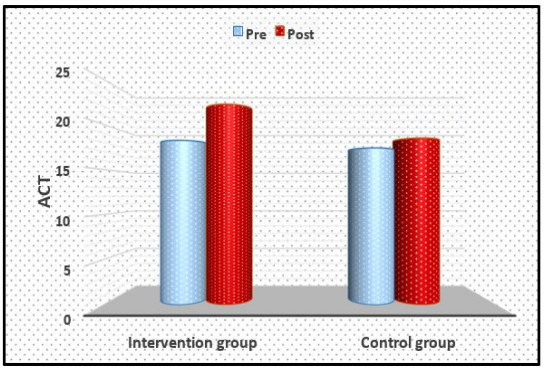

Figure 1. Effect of Pharmacist Intervention on Asthma Control Test

Table (3) and Figures (2 - 5) and (5) demonstrated that group 1 has significant improvement when compared with group 2 after 3 months of follow up for both measured and predicted values of FEV1. However, there was highly significant change in FEV1 values between pre and post treatment values of group 1 while no significant difference presented between baseline and after 3 months of group 1.

Group 1 showed significant improvement in both measured and predicted forced vital capacity (FVC) after 3 months when compared to baseline value, also group 2 showed significant change in FVC value after 3 months when compared to baseline. However, after 3 months there was significant difference between study groups in FVC value (group 1 caused larger significant improvement in FVC than group 2).

Both groups showed significant difference at the end of the study in respect to base line value

of force expiration volume in one second to force vital capacity ratio (FEV1/FVC) (P<0.05).

Regarding to the peak expiratory flow, the mean value showed significant increase after 3 months compared to baseline only in patients received pharmaceutical care; group 1 (P<0.05), whereas no significant difference reported between both groups at the end of the study (P >0.05).

Table 3. Effect of pharmacist intervention on pulmonary function tests

Study Groups		Group 1	group 2	P-Value [b]
FEV1 (meas.)	Baseline	1.56 ± 0.12	1.410 ± 0.83	0.03
	After 3 months	1.98 ± 0.10	1.70 ± 0.14	0.04*
	P-Value [a]	0.001**	0.06	
	Percent of change	26.9 %	21.4 %	
FEV1 (%of pred)	Baseline	65.35 ± 10.25	64.05 ± 5.09	0.511
	After 3 months	74.09 ± 8.33	67.95 ± 5.45	0.030 *
	P-Value [a]	0.035 *	0.058	
	Percent of change	13.4 %	6.1 %	
FVC (meas.)	Baseline	2.24 ± 0.17	2.04 ± 0.11	0.055
	After 3 months	2.64 ± 0.11	2.31 ± 0.19	0.03
	P-Value [a]	0.035 *	0.08	
	Percent of change	17.8 %	13.2 %	
FVC (% of pred.)	Baseline	64.09 ± 4.90	61.24 ± 8.07	0.171
	After 3 months	70.52 ± 9.12	65.95 ± 5.45	0.045*
	P-Value [a]	0.025 *	0.04*	
	Percent of change	10.0 %	7.7 %	
FEV1/FVC	Baseline	71.49 ± 3.31	70.73 ± 4.53	0.530
	After 3 months	74.84 ± 3.37	73.60 ± 0.19	0.094
	P-Value [a]	0.046 *	0.045 *	
	Percent of change	4.7 %	4.1 %	
PEFR	Baseline	63.91 ± 6.62	71.48 ± 12.2	0.235
	After 3 months	61.52 ± 6.52	64.19 ± 7.98	0.023
	P-Value	0.014 *	0.274	
	Percent of change	11.8 %	4.3 %	

Data presented as mean ± SD, were**:** [a] t-test were used for comparison within same group, [b] independent t-test were used for comparison between groups, *: Significant difference (p<0.05), **: Highly Significant difference (p<0.01). FEV1: forced expiratory volume in 1 second, FVC: forced vital capacity, PEFR: peak expiratory flow rate.

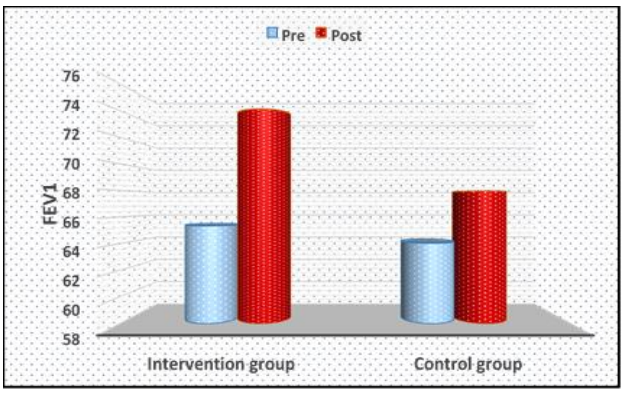

Figure 2.Effect of Pharmacist Intervention on FEV1

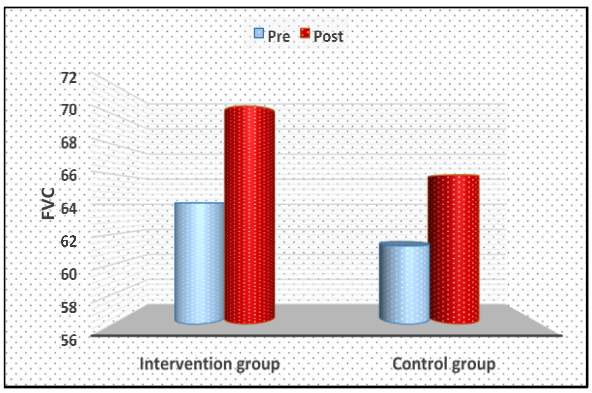

Figure 3. Effect of Pharmacist Intervention on FVC

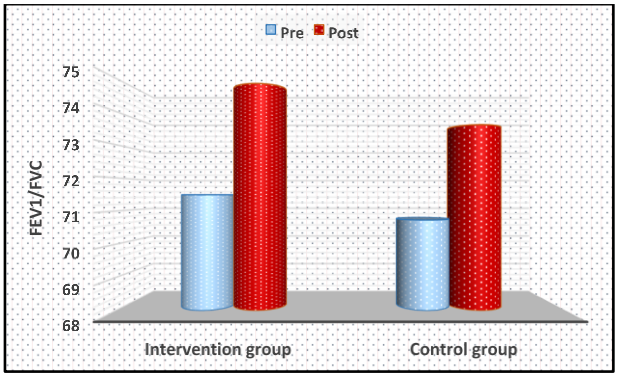

Figure 4. Effect of Pharmacist Intervention on FEV1/FVC

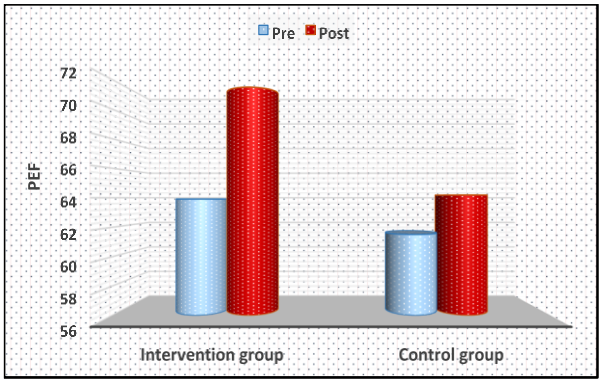

Figure 5. Effect of Pharmacist Intervention on PEF

Discussion

Asthma is a major reason of chronic morbidity and economic problem worldwide. Regardless of a country's degree of development, asthma exists in every nation. In poor and middle-income regions like the Middle East and Africa, however, asthma-related mortality is rising [16, 17]. Even when asthma can be controlled in clinical studies, it is much more challenging to manage in actual life. Asthma treatment has advanced significantly over the last decade, however despite this there are still many patients who are "uncontrolled", placing them at risk for asthma-related morbidity and death [18].

As the current study, previous study focused on the link between pulmonary function (FEV1 predicted) and an established measure of asthma management (ACT score) [19, 20].

These special care plans are a facility that provides pharmacological therapy with the goal of improving symptoms, reduce exacerbation and subsequently improving patient's quality of life. Due to severe workloads or overburdening, some medical practitioners forget to inquire or document the fundamental normal clinical information necessary to determine whether asthma is under control or not, resulting in irregularity and changeability in clinical decision making and practice. Pharmaceutical care is critical in the control and management of asthma. Heru Setiawan *et al.* (2020) revealed in a recent study that the pharmacist in pharmaceutical care plays a vital role in the management of asthma [21].

More than (90%) of the participant's age in this study were (≤ 50 years) with mild to moderate asthma and this agreed with other studies which explained that asthma occur with adult more than children [22, 23]. About (50%) of participants of the current study were underweight and have poor controlled asthma, comparable result was found in another study done on large number of asthmatic patient, most of them were underweight (≤ 18.5). This may be due to some factors like muscle weakness, anorexia nervosa, systemic inflammation, environmental factors and nutritional status [24].

Regarding to family history, more than (80%) of the participants in this study have no family history with asthma or other related allergic disease, this result come in contrast with other studies in which findings showed that asthma occur in the first 30 years of life is strongly related to family history and usually the presence of asthma with parents and siblings may increase the probability of personal incidence of asthma [25, 26], This difference may be attributed to sample size in this study which is small to compare with other studies. There are no statistically significant variations in any of the demographic characteristics of the two research groups, there were a simple variation in both groups regarding to existence of co-morbid disease, type of residence, and level of education.

Referral of the patient to a physician is essential, assuming that the inhalation procedure is accurate and the patient is taking medications as recommended. Patients who do not have adequate asthma control often have an ACT score of 20 [27]. Results of this study agreed with other studies which suggested that patients have uncontrolled asthma if the score of ACT below 20.

In the current study, impact of pharmacist intervention was obvious as ACT score improved from 18.22 to 22.22 after 3 months of follow up. On the other hand, at the end of the study, results demonstrated a significant difference in ACT score towards patients received pharmaceutical care when compared with control group. This improvement in the ACT is the result of pharmacist efforts to improve patients' education about proper medication use as prescribed by physicians, increase knowledge of trigger factors that lead to deterioration of inflammation, and raise awareness about important side effects of some medications, such as Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or aspirin, which increase bronchoconstriction and may aggravate asthma symptoms. Asthmatic patients should be aware that their condition is incurable, and that if they do not take their prescriptions on a consistent basis, it may

interfere with their usual daily activities. So, if patients understand that, the right use of drugs and equipment, they would be able to improve their ACT score and as a result, their QoL, and this conclusion corresponded with earlier studies that showed the importance of pharmacists in asthma control [28,29,30].

As revealed earlier, when an FEV1/FVC less than 70 %, it is related to reversible airway obstruction [31]. Therapeutic outcomes considered as aims of any therapy, increase the patient`s awareness of the disease and its management, adherence to the medication displays a positive impact on the therapeutic outcomes [32,33, 34]. The current study also shows that a concept of pharmaceuticals care helps to stabilize PFTs at many scales through an active involvement of pharmacists, and is a step in monitoring the application of pharmaceutical services at hospital levels [35].

Both measured and predicted percentage FEV1 of intervention group showed highly significant and significant improvement after 3 months of follow up, respectively. Furthermore, significant change noticed when compared with control group after 3 months which reflect the pharmacist efforts to enhance patient adherence to its treatment through increase patient`s awareness about asthma disease and always remind the patients that asthma is non-curable disease. A comparable result was showed in Zanghelini *et.al* (2013) study, where 26 patients received pharmaceutical care by pharmacist for 6 months which revealed significant improvement in (FEV1) value [36]. This study shows that pharmacists can keep most of the asthma control factors from deteriorating after 3 months [35].

Regarding the measured and predicted values of FVC of the group 1, there was significantly improvement after 3 months of follow up when compared with baseline values, this improvement result from increase patients' adherence to medications of asthma and decrease obstacles that facing patients who undergo structured patient education, which suggest that education has a positive influence on therapeutic outcomes. This result agree with Alotaibi *el. al* (2016) study which suggest that increase patient adherence to medication of asthma by supervision of pharmacist lead to enhance pulmonary functions and improve quality of life [37].

The peak expiratory flow Rate (PEFR) and (FEV1/ FVC) values of intervention group improved significantly after 3 months of follow up for patients who undergo structured patients education. The pharmacists efforts have positive impact on the patients to increase knowledge of inhaler technique (MDI) usage, increase self-confidence of patients, increase awareness about trigger factors and finally proper use of medications, all these might have led to ameliorate the pulmonary functions and quality of life of patients in intervention group [38,39].

Results of the current study come in concordant with many studies, where (PEF) and (FEV1/ FVC) values get better in patients of intervention groups in these studies. These results can be attributed to the impact of pharmaceutical care on asthmatic patients and the important role of pharmacist in asthma control[40,41]

Acknowledgment

The authors would like to thank Mustansiriyah University (www. uomustansiriyah. edu.iq) Baghdad-Iraq and all participants for providing the practical platform of this study.

Conclusion

Asthmatic patients who received a verbal and nonverbal pharmaceutical action plan improved significantly their asthma control, which was demonstrated by an improvement in the mean score of ACT and PFT for the interventional group when compared to the control group after 3 months of follow up.

Funding

Funding of this study was an author's responsibility.

Conflicts of Interest

The authors declare that there is no conflict of interest

Ethics Statements

All patients enrolled in this study well known about the concept and procedure of this study and what are they asked to do. All of them agreed and written consent were taken.

Author Contribution

Marwan S. Ibrahim ; practical (follow up the procedure) and written parts of this study and Mohammed Mahmood Mohammed; supervision, revision, rearrangement and statistical analysis

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