DOI: https://doi.org/10.53350/pjmhs22167469

ORIGINAL ARTICLE

Evaluating Community Pharmacist Provided Short Education Program to Improve Clinical Status of Selected Asthmatic Patients

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ABSTRACT

Background: Incorrect inhaler usage is very common issue that leads to poorly managed asthma. Clinical pharmacist enhanced patient education is critical in reducing such errors. Education on inhaler technique is one area where pharmacists may significantly impact on asthma therapy and improvement in clinical features.

Aim: This study aim to evaluate the efficacy of a pharmacist-delivered education program for improving patients' inhaler technique and clinical outcomes.

Patients and Methods: This prospective cohort trial included 51 individuals with asthma, divided up between an intervention group of 26 participants who were subjected to pharmacist intervention as well as a control group of 25 participants. MDI and turbuhaler users were gathered to participate in the study from five community pharmacies in different areas of the Thi-Qar province (Nasirriya, Suq Al-Shoyookh, and Al Eslaah cities). Basic asthma control and spirometry parameters were evaluated using standardized questionnaire of asthma control test and spirometer respectively. Patients in intervention group were taught how to properly use their inhalers using a combination including demonstrations and re-demonstrations counselling with aid of advices leaflet. After one month for both groups, clinical outcomes (asthma control and spirometry) were reassessed and comparisons were made.

Results: A total of 51 patients were involved, with 35 using a turbuhaler and 16 using an MDI. At first session of assessment for all participants, a low asthma control and low median value of FEV1/FVC ratio were recording. After intervention, the median values for asthma control test and all pulmonary parameters was increased significantly (for ACT of 18.5 to 21, p=0.000, for PEF of 2.2 to 2.8, p=0.001, for FEV1 of 1.6 to 1.9, p=0.001, for FEV1/FVC ratio of 63 to 71.5, p=0.002).

Conclusion: Community pharmacist based education program applied to patients with asthma to increase awareness of patients about proper inhaler technique have positive impact in improvement of asthma control level and pulmonary functions parameters. This short education program highly applicable and should be consider as one of daily community pharmacist duties.

Keywords: Community pharmacist, asthma control test, asthmatic patients, spirometer, inhaler technique, Thi-Qar.

INTRODUCTION

Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by a history of respiratory symptoms such as wheezing, shortness of breath, chest tightness, and cough [1]. In Iraq, from a study published in 2018 the prevalence of adult asthma patients was 11.5 %, while was 8.9 % in children age [2]. Asthma treatment aims to create optimal symptoms control and, as a consequence, highest life's quality. Inhalers considered as a main tool for medication delivery in asthma therapy. As inhalation by inhalers enables for a smaller dose of drug to have a quicker onset of action and producing less side effects [3]. Deposit of inhaling therapies at target location is influenced by numerous factors whether relating to device like particle size of drug molecules or relating to patient like inhalation rate or procedure of using [4]. Using an inhaler is a complicated process of steps that must be carried out correctly. The effectiveness and safety of therapy can be significantly reduced if one or more steps of technique processes are not performed appropriately [5]. Many people are unable to properly utilize their inhalers, as up to 90 % of patients using pressurized metered dose inhaler MDIs and 54 % of patients using dry powder inhalers [DPI] have inhaler technique errors, according to estimations from various studies [6]. Correct inhaler technique has been shown to have a significant positive impact on medication adherence, clinical outcomes, improved patients life's quality, and medical resources [7]. Patients' health outcomes can be improved by patient education about inhaler technique [5], [6], [8]. In a limited number of physicians especially in underdeveloped country like Iraq, patients with asthma may benefit from the education offered by pharmacists, who are part of a medical team and who can be serving as first and most available point of contact for patients [5]. Pharmacist have been found to have a favorable influence on enhancing inhalation technique performance in people with asthma and also a positive impact on overall clinical status [9]. It is remarkable that only a few of studies have particularly studied the involvement of pharmacist with treating asthmatic patients especially in poor countries like Iraq [10]. This study aimed to assess clinical outcomes represent by asthma control and spirometer parameters of asthmatic patients living at Thi-Qar governorate. Furthermore, it intended to examine the impact of pharmacist education program which applied to asthmatic patients to improve these clinical outcomes.

MATERIALS AND METHODS

Study design: The aim of this pre-post intervention research was to examine the effect of pharmacist intervention on clinical status of adults with asthma. The participants were randomly assigned to either the intervention group or the control group. After a month of follow-up, patients' baseline data and one-month post-intervention data were compared to determine the efficacy of the pharmacist intervention in enhancing pulmonary functions and assessing asthma control by asthma control test ACT. The research was conducted in five community pharmacies located in diverse parts of Thi-Qar governorate [Nasirhiya, Suq Al-Shoyoakh and Al Eslaah cities]. The study conducted over four month's period of November 2021 to March 2022.

Study Population: Male and female patients aged 18 years old or more with a confirmed diagnosis of asthma using an inhaler (MDI or Turbuhaler) for their condition were included in the study. Asthmatic patients who come to pharmacy to refill their inhaler and match the inclusion criteria were directly referred to the researcher to be included in the study.

Sample size: Nonrandom sample was selected. Due to lack of the required statistics on the prevalence of asthmatic patients, sample size was not specified so the patients that matched the criteria during time of study were included. Fifty-one patients completed the whole study. Twenty-six designed as intervention group and the reminders 25 in control one.

Ethical Approval: Thi-Qar health division of the Iraqi Ministry of Health provided ethical approval. Before beginning the study, all participants were given a summary of the research's goals and given the opportunity to give their informed consent verbally.

Data Collection instruments:

1 Standardized Questionnaire in English-language developed from previous researches, and was designed to gather demographic and sociodemographic data like age, sex, cultural area, education status, and duration of asthma.

2 Asthma control test ACT: The main outcome was measure of asthma control, which evaluated by asthma control test (ACT) Questionnaire. This is a clinical validated asthma control measure comprised of 5 questions, each having five answer options (graded by decreasing quality of asthma control, graded from 5 to 1) for each question. ACT score (range of 5 to 25) was obtained by summing the answers scores to the five questions; the more score, the more asthma control. Patients with a maximum score of 25 were classified "completely controlled"; a score of 20–24 classified "well-controlled" asthma; a score of 16–19 classified "insufficiently controlled"; and a score of 15 or less suggested "uncontrolled". ACT evaluation conducted for both groups at basic and follow up sessions, [11], [12].

3 Spirometer: MIR SPIROLAB III diagnostic colors spirometer was used to measure and recording the major pulmonary function parameters that used in the study (FEV1, FEV1/FVC ratio and PEF).

The Spirolab III is a multipurpose spirometer that used to accurately monitor and diagnoses respiratory disorders (like COPD and Asthma) and suitable for fast screening at the pharmacy.

Intervention tool: The intervention group received a structured plan [education program] which already prepared by researcher that focused mainly on education the patients about proper inhaler technique. At baseline session, patients were assessed asthma control level and major spirometer parameters then trained directly in face to face manner by the clinical pharmacist (researcher) in terms of the inhaler technique using placebo devices similar to their own devices.

We started by evaluating their baseline technique of inhaler that used, and then, a teach-to-goal approach were used with correction of identified errors. Then, we asked patients to demonstrate the inhaler technique, and again, committed errors will be corrected by demonstration. We repeated all correct steps as many times as needed for patients in order to ensuring performing them correctly.

An intervention leaflet was employed in the research. The leaflet was used to help in advising the patients, which included basic guidelines and recommendations on asthma, such as its causes, trigger factors for worsening, and frequent myths, as well as a procedure of steps for using an inhaler correctly, along with photos to clarify each step.

Control group just involved in assessment without intervention of pharmacist in basic session according to study design but for ethical cause all patients in this group received full education at end of final session.

Format knowledge paper for data collection and Asthma control test questionnaires have been fully validated by 4 experts [two PhD pharmacists and two respiratory specialist doctors] for use in clinical trials. It is reliable and valid in both long and cross-sectional studies. All questionnaires also show high levels of sensitivity and stability.

Statistical analysis: SPSS software, version 22.0 (IBM Corporation, USA), was used for the statistical analysis. Continuous variables are expressed as the median and interquartile range (IQR 25–75). Categorical variables are expressed as percentages or frequencies. Comparisons between the intervention group and control groups were assessed using the chi-square test for categorical variables, the Mann-Whitney U test for skewed continuous variables. For pairwise comparisons of each group, the Wilcoxon test was used. In all cases, statistical significance was determined to exist when the p-value was less than 0.05. Finally, the data was arranged in tables and figures.

RESULTS

Characteristics of the study population: Total participants of 51 patients complete all the sessions of study, as 26 were in intervention group while 25 in control one. Table 1; show the basic sociodemographic data of study participants. 31% percent of the study group and 40% percent of the control group were in age demographic range of 40 to 49 years old. Seventy-three percent of those who took part in intervention group were female, whereas male made up a larger share of the control group (64 %). The number of illiterate participants were more in intervention group (26.9%) than in control

Table 1: Basic demographics characteristics of the study patients.

Variables	Category	intervention group n=26	Control group n= 25	P value
Age, years, n,(%)	Less than 20 years	3 (11.6)	2 (8.3)	0.246
	20 to 29 years	3 (11.6)	0 (0.0)	
	30 to 39 years	3 (11.6)	6 (25)	
	40 to 49 years	8 (31)	10 (40.3)	
	50 to 59 years	7 (27.1)	3 (11.9)	
	More than 60 years	2 (7.7)	4 (16.0)	
Sex n,(%)	Male	7 (26.9)	16 (64.1)	*0.007
	Female	19 (73.1)	9 (35.9)	
Cultural area n,(%)	Rural	5 (20.0)	12 (48.0)	*0.038
	Urban	20 (80.0)	13 (52.0)	
Education level n, (%)	Illiterate	7 (26.9)	1 (4.0)	0.176
	Read & write	1 (3.9)	3 (11.0)	
	Primary school graduate	4 (15.4)	7 (28.0)	
	Intermediate school graduate	5 (19.2)	5 (20.0)	
	High Institute graduate	5 (19.2)	3 (11.0)	
	University graduate	3 (11.5)	6 (24.0)	
	Higher education (post graduate)	1 (3.9)	0 (0.0)	
Marital history n, (%)	Single	5 (19.3)	4 (17)	0.345
	Married	19 (73.0)	21 (83)	
	Widowed	2 (7.7)	0 (0.0)	
Income per monthly in IQD	less than 300.000 IQD	3 (11.5)	0 (0.0)	0.289
	301.000-600.000 IQD	13 (50.0)	10 (40.0)	
	601.000- 900.000 IQD	5 (18.2)	4 (16.0)	
	901.000 -1.200.000 IQD	4 (16.4)	8 (32.0)	
	1.201.000- 1.500.000 IQD	1 (3.9)	2 (8.1)	
	1.501.000 or more	0 (0.0)	1 (4.0)	

Note: Data are expressed as n (%) percentages and frequencies for variables. Values of * =P < 0.05 were considered as significant. Abbreviations: IQD =Iraqi dinnar.

group (4%) while high institute graduate participants were more in control group (28%) than intervention group (15.2%). The majority of the population in both groups of study was married, table 1. Figure 1 illustrates the percentage of smokers in the intervention and control groups. 44% of participants in the control group had asthma 1-5 years ago and 32% of participants in the intervention group had asthma 6-10 years ago, figure 2.

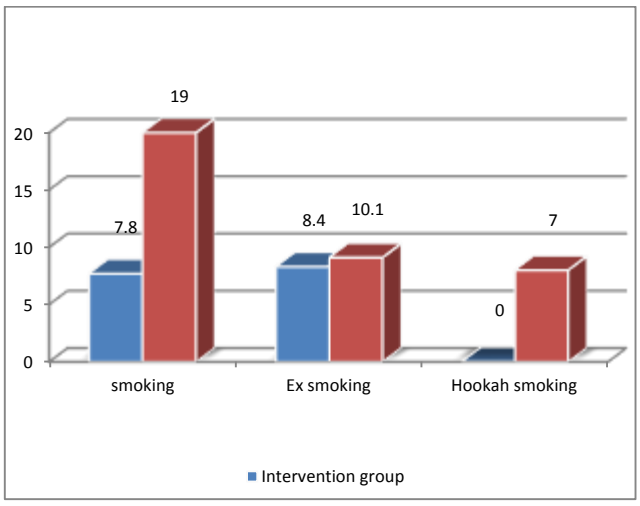

Figure 1: Smoking history of study population representative as percent.

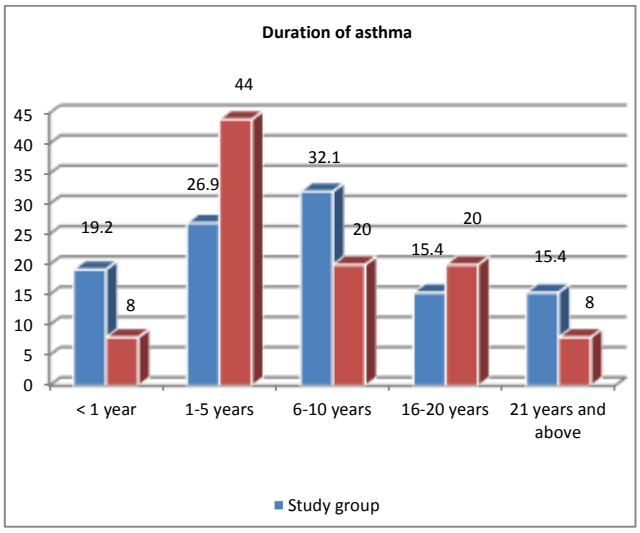

Figure 2: Percent of patients in duration interval of asthma disease history.

The median values of pulmonary function parameters [PEF, FEV1 and FEV1/FVC ratio] at basic session for population in the study were shown in figure 3, no significant deference between two groups in FEV1/FVC ratio values [p= 0.665] while there are significance in values of [PEF and FEV1] between two groups (intervention and control) [p= were 0.04 and 0.02 for PEF and FEV1 respectively].

Most of participants were on Turbuhaler inhaler rather than MDI, as of total number of participants (51) were 18 (69.2%) and 17 (68.0%) in intervention and control groups respectively used Turbuhaler.

Spirometry results: The spirometry results delivered by spirometer showed a low FEV1/ FVC ratio (less than 63) represent as median value for both groups. There was significant difference for intervention group patients between baseline and post intervention session for PEF, FEV1 and FEV1/ FVC ratio median values (p- value less than 0.05 for all parameters), table 2. In the other hand no significant differences were observed for that of control group.

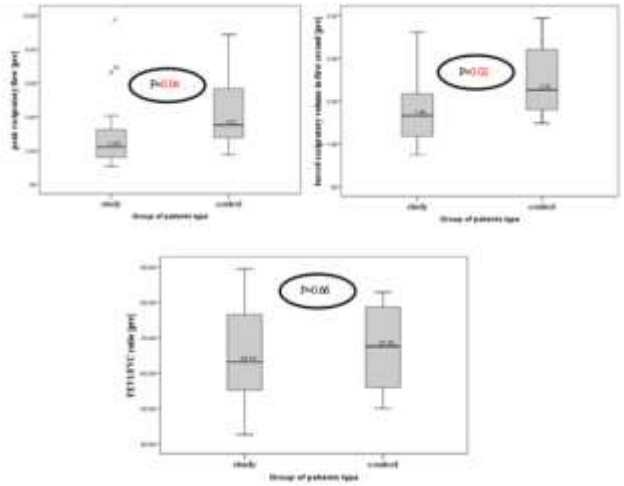

Figure 3: The median values of pulmonary function parameters [PEF, FEV1 and FEV1/FVC ratio] at basic session.

Table 2: Median score of spirometer parameters of asthmatic patient's basic and post -test.

Median score				
Groups	Type	Basic -test	Post –test	P value [a]
Intervention group	PFE	2.2 (1.5-3.2)	2.8 (2.0-4.2)	0.001 [a]
	FEV1	1.6 (1.1-2.1)	1.9 (1.4-2.5)	0.001 [a]
	FEV1/ FVC ratio	63.1 (55.1-77.0)	71.5 (59.7-77.9)	0.002 [a]
Control group	PFE	3.5 (3.4-5.9)	3.3 (2.8-6.1)	0.99 [a]
	FEV1	2.2 (1.7-3.2)	2.2 (1.8-3.4)	0.786[a]
	FEV1/ FVC ratio	67.5 (55.1-78.8)	67.0 (55.0-78.5)	0.289 [a]

[a] P value for differences between basic and post-test in each groups. Statistically significant (P < 0.05). Abbreviations: PEF =peak excpiratory flow, FEV1=forced expiratory volume in first second, FVC=flow volume capacity.

Assessment of asthma control (Asthma control test ACT): ACT (Asthma control test) was used to assess asthma disease status whether in control status or not and Wilcoxon test was used for analysis. At baseline, the results showed that 7 patients (26.9%) had poorly control test (ACT score <15) in intervention group, while was 6 patients (24.0%) in control group. Also 10 patients (38.5%) (Intervention group) and 10 patients (40.0%) (Control group) were moderately controlled (ACT score =15-19). The rest of patients of both groups were in asthma well controlled status (ACT score>19), (table 3). There was increase in median scores of ACT from the baseline to final visit for all population groups (intervention and control) as follow: 18.5 to 21 (p=o.ooo) for study group and 19 to 20 (p=0.007) for control group, table 4. Despite that there was increase in ACT median score for both groups, table 4, but there was more improvement in study group patients as shown in table 3, where the number of patients in asthma well controlled category (ACT>19) for intervention group increased from 9 (34.6%) to 19 (73.1%) compared with 9 (36.0%) to 13 (52.0%) for that of control group.

For intervention group, significant correlations were noticed between ACT scores and FEV1/FVC ratio (rho=0.392, p=0.004. No significant correlation between ACT score improvements and age

of patients (rho=.035, p=0.810) or with level of education (rho=.066, p=0.645).

Table 3: Range of asthma control in ACT score interpretation basic and post-test.

ACT		Intervention group n=26		Control group n=25	
Score	Range	basic-test n (%)	Post-test n (%)	basic-test n (%)	Post-test n (%)
<15	Very poorly control	7 (26.9)	1 (3.8)	6 (24.0)	3 (12.0)
15-19	Asthma not well controlled	10 (38.5)	6 (23.1)	10 (40.0)	9 (36.0)
>19	Asthma well controlled	9 (34.6)	19 (73.1)	9 (36.0)	13 (52.0)

n indicates the number of patients. Statistically significant (P < 0.05). Abbreviations: ACT= asthma control test.

Table 4: Level of asthma control (median score) of asthmatic patient's basic and Post-test.

Median score of ACT			
Groups	basic-test	Post-test	P value [a]
Intervention group	18.5 (13.7-20.0)	21.0 (19.0-22.2)	0.000 [a]
Control group	19.0 (14.5-21.0)	20.0 (16.5-22.5)	0.007 [a]
P value [b]	0.747[b]	0.194[b]	

[a] P value to differences among basic and post test in each group. [b] P value to differences between intervention and control group. (P < 0.05) is considered statistically significant. Abbreviations: ACT= asthma control test.

Correlations results: To assess the correlation of intervention group, we used Spearman's rho test. Values of P less than 0.05 were statistically significant.

Table 5: Correlation coefficient for study variables.

		1	2	3	4	5
1. ACT score	Spearman's rho					
	Sig. (2-tailed)					
2. PFF score	Spearman's rho	.197				
	Sig. (2-tailed)	.167				
3. FEV1 score	Spearman's rho	.173	.797**			
	Sig. (2-tailed)	.226	.000			
4. FEV1/ FVC ratio	Spearman's rho	.392**	.468**	.460**		
	Sig. (2-tailed)	.004	.001	.001		
5. Age	Spearman's rho	.035	-.250-	-.439-**	-.194-	
	Sig. (2-tailed)	.810	.077	.001	.172	
6. level of education	Spearman's rho	.066	.378**	.297*	.025	-.130-
	Sig. (2-tailed)	.645	.006	.035	.864	.362

Correlation is considered a significant at the 0.01 level (2-tailed), *. Correlation is considered a significant at the 0.05 level (2-tailed).
Note: the number in horizontal column (1, 2, 3 ect) represent the same words in vertical one with same numbering.

DISCUSSIONS

For optimum control of asthma, it needs the right inhalation technique which should be done by the patient to get maximal efficacy of medicine. Poor inhalation technique is linked to poor asthma control, according to researches [9]. So, it is vital to teach the patient on correct practices in use of inhalers via providing education. Many studies found that the education is very important part in overall management plan of asthma disease and has positive impact on patient clinical status [9]. Despite the Education can be delivered by different methods , the direct face to face demonstration and re demonstration consider as the best method [7]. Pharmacist-led medication counseling has been shown to be more successful than other techniques, such as viewing videos or reading booklets [13]. In this study, 51 patients have been complete to the end of the trial (26 in the intervention group and 25 in the control one). There was minimal variation in the basic fundamentals data of both groups, such as age, education, occupation, monthly income and smoking history between two groups. To our knowledge, this study is of the few studies around the world and the first of its kind in Iraq that conducted spirometer as one of measurable outcomes for determine the improvement in clinical status of adult patients with asthma who faced pharmacist intervention program [9], [14]. The major spirometer parameters used to evaluate the clinical status of patients were (FEV1, FEV1/FVC ratio and PEF). Where this parameters highly reflect the lung functions and rapidly reveals the bronchodilation or improvement that may result of correct inhaler using [15]. At basic session the results showed low median value of FEV1/FVC ratio (less than 70) for all study participants which indicate poor asthma control. After intervention for intervention group, the median values of all parameters increase significantly [PEF of 2.2 (1.5-3.2) to 2.8 (2.0-4.2), p=0.001, FEV1 of 1.6 (1.1-2.1) to 1.9 (1.4-2.5), p=0.001 and FEV1/FVC of 63.1 (55.1-77.0) to 71.5 (59.7-77.9), p=0.002]. The finding of our study were similar to results founded in study published previously [16], that previously founded significant improvement in FEV1 value after pharmacist intervention. This change and increase in values of parameters give measurable evidence for the improvement in clinical control of asthma that result of pharmacist intervention on inhaler technique. For control group, there was no significant change in all parameters between two sessions of assessment and this was expected according to study design. Asthma control was one of primary outcomes that measured in this study using asthma control test ACT. The asthma control test ACT was shown to be as excellent test to measure rapidly and accurately [12]. The majority of participants in our study at baseline, whether in intervention or control groups [17 patients, 66% of intervention group and 16 patients, 64% of control group], were categorized as not well control (ACT score less than 19) of asthma according to ACT score classification. So these patients are prone to show any improvement as increasing in control score according to ACT. At final session, our results showed that there are significant statistically increased in median values of ACT score for both groups (intervention group, of 18.5 (13.7-20.0) to 21.0 (19.0-22.2), p=0.000 and control group, of 19.0 (14.5-21.0) to 20.0 (16.5-22.5), p=0.007) and this was expected especially for the intervention group due to education that increase inhaler technique performance. For improvement of patients in control group, can be explained may be due to bias in questions answers by patients in assessment especially the test depend mainly on patient's judgment about answers, and this also expected to have some effect on the results for study group. Despite the improvement that seen in both groups, there was more improvement in study (intervention) group, as percent of patients with category asthma well control (ACT score more than 19), increase of 9 (34.6%) to 19 (73.1%), while the increase was to less degree of 9 (36%) to 13 (52%) in control group, table 3. The overall present results about ACT especially for intervention group are consistent with those of other studies that focused on community pharmacy based interventions [18,19,20]. The correlation study showed no significant dependencies of clinical outcomes neither on sociodemographic characteristics like age, gender and education or on time since disease diagnosis. The same results presented in previous study that show no relationships between improvement in clinical outcomes with demographic data [21,22]. Correlation study showed a positive relationship between improvement in ACT score and FEV1/FVC ratio (p value=0.004), and this was expected as a result of pharmacist intervention[23,24]..

CONCLUSION

Community pharmacist-based education program applied to patients with asthma to increase awareness of patients about proper inhaler technique have positive impact in improvement of asthma control level and pulmonary functions parameters. This short education program highly applicable and should be consider as one of daily community pharmacist duties.

Limitations:

1 Duration of study: one month follow up is short period of time to evaluate the efficacy of intervention, as it is difficult to say if the beneficial effects of intervention will last for a longer time.
2 Sample size: a sample size consider as one of limitations of this study due to COVID-19 restrictions that prevent of reaching reasonable sample size. So need to conduct a study with more sample size in future.
3 Sample selection bias: participation in this kind of study is often accepted more readily by motivated individuals than by unmotivated ones; hence a selection bias of the participant sample cannot be completely avoided.

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