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A novel approach of using educational pharmaceutical pictogram for improving inhaler techniques in patients with asthma

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ABSTRACT

Background: Proper inhaler technique is essential to maximize the benefit of medications and improve asthma outcomes.
Objective: To evaluate newly developed pictogram-incorporated medals and their utility on improving the inhaler techniques in asthmatic patients.
Methods: A prospective, an open label, randomized controlled clinical study was conducted in Jordan from November 2016 to November 2017. The recruited patients were randomly allocated into two groups; control and intervention. Both groups were verbally counselled about proper use of their inhaler devices, however, pictogram medals were attached to the inhalers of patients in the intervention group only. Both groups were met at baseline and followed-up after 3 months to evaluate their inhaler techniques using standard checklists.
Results: Of the 219 patients that were recruited and randomized in our study, 49.8% (n = 109) were allocated in the intervention group and 50.2% (n = 110) were in the control group. Both groups had comparable baseline demographics and clinical data ($P > 0.05$). Significant differences in the improvement of metered dose inhaler (MDI; $p < 0.001$) and Turbohaler ($p = 0.005$) techniques were observed between the two groups at the end of study. Patients who used MDI (OR = 7.06, 95% CI = 3.21–15.56, $p < 0.001$) and Turbohaler (OR = 5.08, 95% CI = 1.57–16.43, $p = 0.007$) in the intervention group were 7 and 5 times more likely to have improved inhaler techniques as compared to those in the control group respectively.
Conclusions: Educational pharmaceutical pictograms represent an inexpensive and feasible intervention that can positively affect the proper use of inhalers in asthmatic patients.

1. Introduction

Bronchial asthma is one of the most common chronic conditions that affects millions worldwide [1]. In Jordan, the prevalence of asthma was doubled in the last decade [2]. However, incorrect handling of inhaler devices was a common problem among asthmatic patients [3,4]. Improper use of inhaler devices decreases drug delivery, patients' adherence and drug effectiveness in addition to financial burden which all lead to drastic consequences on asthma clinical outcomes [5,6]. Asthma patients differ from other patients with chronic conditions, that used tablets or capsules, as they rely solely on the use of inhalers to ensure the adequate delivery of medicines. Though there are several types of inhalers, there is no ideal device and each one has advantages and disadvantages. It has been reported that successful asthma treatment depends mainly on education [7]. Therefore, not only the adherence is challenging to obtain full therapeutic effects but also correct use of inhalers.

Asthma management guidelines recommend educating asthmatic patients about the proper use of inhalers and regularly checking their technique at each clinic visit [8]. However, suboptimal inhaler education by physicians and other healthcare professionals due to time constraints was reported in several studies [9–12]. Moreover, studies revealed that high number of healthcare providers had poor knowledge of the proper use of inhalers; raising concerns about their ability to counsel and educate asthmatic patients even if they had the enough time [10,13,14]. Accordingly, implementation of easily adopted techniques and interventions to improve patients' education on the proper use of inhalers is of a paramount importance.

The International Pharmaceutical Federation (FIP) has reinforced the importance of pictograms as a way of communication with patients [15]. According to the United States Pharmacopeia (USP), pictograms are defined as" standardized graphic images that help convey

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medication instructions, precautions and/or warnings to patients and consumers" [16]. This approach has been shown to improve patients' cognition and ability to understand and recall drug related information [17]. In addition, previous studies in hypertensive and diabetic patients showed that using pharmaceutical pictograms, as labels, improved patients' medication adherence and knowledge about disease complications [18,19]. However, the impact of adopting pictograms on the proper use of inhalers has not been assessed yet. The aim of this study was to investigate a newly developed pictogram-incorporated medals and their utility on improving the inhaler techniques in asthmatic patients. In addition, the effect of this approach on other clinical parameters such as adherence, asthma control and unscheduled medical intervention were evaluated. To the best of our knowledge, this is the first study that evaluated this new educational strategy in patients with asthma.

2. Methods

2.1. Study design

A prospective, an open label, randomized controlled clinical study was conducted at two main hospitals in North Jordan for one year: King Abdullah University Hospital (KAUH)-Irbid and Princess Basma Hospital-Irbid. These are considered the only two referral centers in North Jordan where asthmatic patients can see pulmonologists. The study was approved by institutional review board in Jordan University of Science and Technology and Ministry of Health. The primary outcome in this study was to improve proper inhaler administration technique in patients with asthma. The study was piloted for two months at the same hospitals to assess the feasibility of using the intended intervention and to modify any potential barriers. For example, the received feedback from asthmatic patients were considered for the appropriate attachment of the medals to inhaler devices and using larger label's font. Based on literature, metered dose inhaler (MDI) is the most common inhaler device that is used for treating respiratory diseases [4,20]. Basically, we used dichotomous primary end point (proper inhaler technique/ improper technique) and two independent study groups (intervention and control). Assuming the anticipated percent of patient in control group that received usual pharmaceutical care (without pictogram) and use the inhaler properly is 30%. A sample of 70 patients in each group was required to detect 100% increase in the number of patients who used MDI with proper inhalation technique in the intervention group compared to the control group at 95% statistical power and 5% significance level. Recruitment of patients was carried out during the period November 2016 to November 2017.

2.2. Study subject

All eligible patients who attended the outpatient hospital pharmacy for dispensing their prescriptions were invited to participate in the study. Patients who fulfilled the inclusion criteria were included in the study only after they have been fully informed and signed the consent form. Adult patients, ≥18 years, that were diagnosed with bronchial asthma by respiratory specialist were included. In addition, the recruited patients should take their inhalers regularly for at least 3 months and come personally for the refill. Exclusion criteria included immunocompromised patients, coexistence of other chronic respiratory conditions (e.g. chronic obstructive pulmonary disease (COPD) and bronchiectasis), newly diagnosed asthmatic patients, patients who did not self-administer their medications, and those who were difficult to communicate (i.e. patients with severe clinical presentation or special needs (e.g. deaf) that prevented them from participating). Patients were recruited and randomly allocated into one of the two groups; ordinary care group (control) and intervention group. Simple randomization approach was adopted in the study; odd number for intervention and even number for control.

2.3. Outcomes measures

Face-to-face interview was conducted by a trained clinical pharmacist with all patients in both groups in quiet area near the outpatient hospital pharmacy. Both groups were verbally counselled about the proper use of their inhaler devices, however, pictogram medals were attached to the inhalers of patients in the intervention group only. The pictogram illustrates medication instructions and how to use the inhaler correctly. For the four common asthma inhaler devices in Jordan (MDI, Diskus, Aerolizer, Turbohaler), pictogram labels were designed and printed in colors with Arabic language then attached to the inhaler devices as medals. The designs of pictograms were adapted from Asthma Canada organization [21]. Examples of pictogram incorporated labels, translated to English, are presented in Fig. 1 and Appendix 1. Demographic, clinical and medical data were collected from the patients and their medical files.

Patients were seen at baseline and after 3 months to observe and evaluate inhaler techniques using standard checklists that were prepared using the content of published research [3,12], discussion within research team and feedback from the piloting. Checklist is a tool that objectively evaluates the inhaler technique profile through series of steps that should be performed correctly to ensure the proper delivery of medicines. At the beginning, the patients demonstrated the inhaler technique without giving them any instructions regarding the proper use. Observation of inhaler technique was evaluated by score of 7 steps

Fig. 1. Pictogram-incorporated medal of metered dose inhaler.

Table 1
Step-by-step checklist of proper inhalation.

Metered dose inhaler	Diskus	Aerolizer	Turbohaler
1-Shake inhaler	1-Push lever back completely	1-Prepare the inhaler (place capsule)	1-Keep inhaler upright
2-Breathe out slowly away from the mouthpiece	2-Exhale to residual volume, away from mouthpiece	2-Exhale to residual volume, away from mouthpiece	2-Rotate grip anti-clockwise then back until a click is heard
3-Hold inhaler in the upright position	3-Place mouthpiece between teeth and lips	3-Place mouthpiece between lips and teeth	3-Exhale to residual volume away from the mouthpiece
4-Place mouthpiece between your teeth and lips	4-Keep the device horizontal	4-Keep the device horizontal	4-Place mouthpiece between teeth and lips
5-Press down the inhaler and inhale forcefully and deeply by mouth	5-Inhale forcefully and deeply by mouth	5-Inhale forcefully and deeply by mouth	5-Inhale forcefully and deeply by mouth
6-Remove the device from mouth and hold breath for 10 s then exhale	6-Remove the device from mouth and hold breath for 10 s before exhale	6-Remove the device from mouth and hold breath for 10 s before exhale	6-Remove the device from mouth and hold breath for 10s before exhale
7-Rinse your mouth with water	7–Rinse your mouth with water	7-Rinse your mouth with water	7-Rinse your mouth with water

for each inhaler device (Table 1). One point was given per each correct performed step with a maximum of 7 points score for each device. All steps of inhaler depend on each other and if one step is incorrect this would affect the whole process. Thus, proper use of inhaler device was defined if the patient correctly performed the 7 steps of inhaler use. After initial evaluation of the inhaler technique, the pharmacist counseled the patients about the proper use of inhaler using pictogram for patients in the intervention group and without pictogram for patients in the control group. The counseling was repeated in the same session until patients in both groups demonstrated the correct technique, scored 7/7. Phone calls were conducted monthly with the patients in both groups to make sure that they still use the same inhalers and participants in the intervention group who had refilled a new inhaler were reminded to attach the pictogram medal to their new inhaler.

Different clinical measures were also evaluated in the recruited patients: Asthma Control Test (ACT), adherence to medications, and unscheduled medical intervention due to asthma exacerbation. Asthma control status was measured by a validated Arabic version of self-administered 5-item ACT questionnaire [22]. The questionnaire is composed of 5 questions and a score less than 20 indicates that the patient has uncontrolled asthma [23]. The adherence to asthma medication was measured by a self-reported Medication Adherence Scale that was developed and validated by AbuRuz et al. [24]. The patient was considered adherent if he/she had answered “never” or “rarely” to all 5 questions [24]. The patients at baseline and at the end of study were asked about unscheduled medical intervention in the last 3 months due to asthma exacerbation such as emergency room visits, systemic steroid use or hospital admission. The average time spent for the meeting was 12 minutes for control group versus 9 minutes for intervention group.

2.4. Statistical analysis

All data were coded and entered to statistical software SPSS (version 19). Continuous variables were presented as mean ± standard deviation while categorical variables were presented as counts and percentage. The differences in the responses between two groups were examined using unpaired *t*-test or Mann–Whitney *U* test (continues variables) and Chi-square ($\chi 2$) test or Fisher's exact test (categorical variables) as appropriate. For analysis purposes, the score of inhaler use for each participant was labeled as categorical variable. A participant was categorized as having proper inhaler technique if the score was 7/7 and improper technique if the score was < 7. After 3 months, the outcome was either “no change” or “improved” in the status of proper use of inhaler technique. “No change” means that the inhaler use was improper at baseline and remained improper at the end of study or it was proper at baseline and remained proper at the end of study. “Improved” means that the inhaler use was changed from improper at baseline to proper at the end of study. Logistic regression was used to calculate odds ratio (OR) and 95% confidence interval (95% CI) for the significant associations between study group and proper inhaler use. All tests are two-sided, and statistical significance were set at p-value < 0.05. Intension to treat analysis was adopted in the current study to handle the missing data.

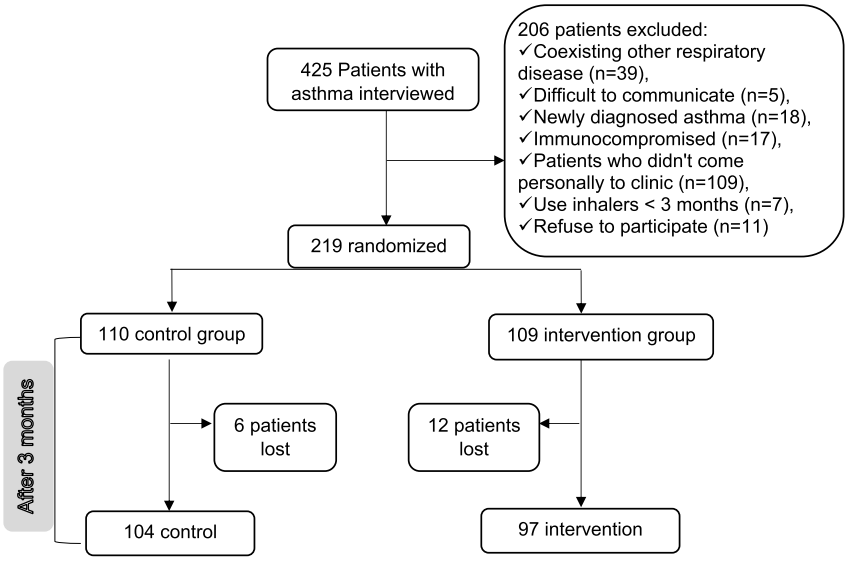

Fig. 2. Summary of patients' recruitment.

3. Results

3.1. Demographic data

Of the 425 patients that were interviewed during the study period, 206 patients were excluded due to different reasons (Fig. 2). A total of 219 eligible patients participated in our study and randomized to control group (n = 110, 50.2%) and intervention group (n = 109, 49.8%). Of the randomized patients, 18 patients were dropped out from the study because they changed their contact number (n = 14), died (n = 1), and stopped their inhalers (n = 3). Out of the 201 patients who completed the study, almost half of them in control group (n = 104, 51.7%) and half of them in an intervention group (n = 97, 48.3%). A detailed summary of the inclusion process is presented in Fig. 2.

Both groups were comparable in age, gender, presence of comorbid disease, level of education and smoking status. In addition, more than half of patients in both groups had uncontrolled and severe form of asthma. Most asthmatic patients (n = 146, 66.7%) used one inhaler and third of them (n = 73, 33.3%) used two inhalers. The most common used inhaler device was MDI (n = 146, 66.7%) followed by Turbohaler (n = 67, 30.6%), Diskus (n = 58, 26.5%), and Aerolizer (n = 21, 9.6%). There was no significant difference between the two groups in relation to the type of inhalers. Aerolizer was excluded from the analysis as few number of patients used this inhaler in both study groups. Importantly, there were no significant differences in all baseline data between the two study groups except for the proper use of MDI, where 20% of control group used MDI properly as compared to less than 6% of those in the intervention group (p = 0.01). Table 2 summaries the baseline demographics and clinical data of the participants.

3.2. The effectiveness of intervention

As shown in Table 3 and Fig. 3, significant differences in the improvement of MDI (P < 0.001) and Turbohaler (p = 0.005) techniques between both groups were observed at the end of study period (after 3 months). Patients that used MDI in the intervention group were 7 times more likely to improve as compared to those in the control group (OR = 7.06, 95% CI = 3.21–15.56, p < 0.001). In addition, patients that used Turbohaler in the intervention group were 5 times more likely to improve as compared to those in the control group (OR = 5.08, 95% CI = 1.57–16.43, p = 0.007). A borderline significant association in the improvement of Diskus inhaler technique was also noted between both study groups (p = 0.069). All patients in the intervention group were satisfied with the new educational approach. On the other hand, there was no significant difference in other asthma related clinical outcomes such as the level of adherence to medication, asthma control or unscheduled medical intervention between both groups at the end of study (Appendix 2).

3.3. Comparison of clinical parameters within groups

Importantly, within related sample of both control and intervention groups, there were significant improvements in the level of adherence, asthma control status, and asthma control score (p < 0.001; Table 4). However, smaller effect size in asthma control score was noted in control group as compared to the intervention group. A significant reduction in the number of patients who sought unscheduled medical intervention due to asthma exacerbation was noted only in the intervention group (p < 0.001).

Table 2
Baseline demographic and clinical data of the study patients.

Characteristic[a]	Intervention N = 109	Control N = 110	P value
Age (year)[b]	47 [39–52.5]	49 [41–55]	0.249
Gender			
• Female	79 (72.5)	75 (68.2)	0.487
• Male	30 (27.5)	35(31.8)	
Age at diagnosis (year)[b]	32 [19.5–41.5]	32.5 [20–40]	0.726
Presence of comorbid disease	44 (40.4)	55 (50)	0.152
Level of education			
• Basic education	71 (65.1)	74 (67.3)	0.738
• University degree	38 (34.9)	36 (32.7)	
ACT score[b]	18 [13–22]	19 [15–22.25]	0.222
ACT			
• Uncontrolled	65 (59.6)	59 (53.6)	0.371
• Controlled	44 (40.4)	51 (46.4)	
Adherent to medication	37 (33.9)	46 (41.8)	0.230
Unscheduled medical intervention	43 (39.4)	31 (28.4)	0.086
Asthma severity (GINA, 2017)			
• Mild-moderate (step 1,2,3)	44 (40.4)	38 (34.5)	0.373
• Severe (step 4 and 5)	65 (59.6)	72 (65.5)	
Number of inhalers			
• One inhaler	72 (66.1)	74 (67.3)	0.848
• Two inhalers	37 (33.9)	36 (32.7)	
Types of inhalers			
• Metered dose inhaler	71 (65.1)	75 (68.2)	0.633
• Turbohaler	32 (29.4)	35 (31.8)	0.693
• Diskus	32 (29.4)	26 (23.6)	0.337
• Aerolizer	11 (10.1)	10 (9.1)	0.801
Proper use of inhalers			
• Metered dose inhaler	4 (5.6)	15 (20)	0.010
• Turbohaler	1 (3.1)	6 (17.1)	0.108
• Diskus	3 (9.4)	4 (15.4)	0.689
• Aerolizer	3 (27.3)	3 (30)	1.00

ACT, asthma control test; GINA, Global Initiative for Asthma guideline.
[a] All data expressed as n (%) of patients unless otherwise indicated.
[b] Data described as median [interquartile range].

Table 3
Change in the status of proper use of inhaler technique.

Type of inhaler[a]	Intervention	Control	P value
Metered dose inhaler	N = 64	N = 71	< 0.001
• No change	12 (18.8)	44 (62)	
• Improved	52 (81.2)	27 (38)	
Turbohaler	N = 32	N = 33	0.005
• No change	5 (15.6)	16 (48.5)	
• Improved	27 (84.4)	17 (51.5)	
Diskus	N = 26	N = 23	0.069
• No change	6 (23.1)	11 (47.8)	
• Improved	20 (76.9)	12 (52.2)	

[a] All data expressed as n (%) of patients.

4. Discussion

Despite the availability of many therapeutically effective medications, poor asthma control is considered a serious global health problem [8,25]. We showed previously that two third of recruited asthmatic patients in Jordan had uncontrolled asthma which was positively correlated with low quality of life [26]. Poor asthma control and poor adherence to inhalers are mainly related to difficulties with inhaler devices [12,27]. Mishandling of inhaler devices was documented for patients that were prescribed MDIs as well as those used dry powder

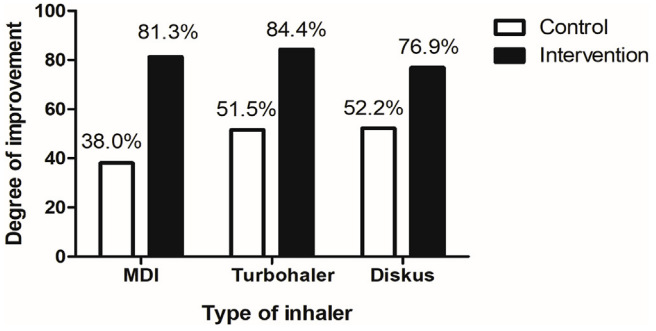

Fig. 3. Degree of improvement in the inhaler technique for both study groups.

inhalers [28]. Previous studies introduced different methods to correct the misuse of inhalers [3,29,30]. Basheti and colleagues reported positive asthmatic patients' outcomes when written instructions reminder labels were added to the inhaler devices [3]. However, Bosnic-Anticevich and colleagues showed that physical demonstration was more effective than verbal or written instructions alone [29]. Additionally, multi-media presentations play a significant role in improving the inhaler techniques among patients with asthma [31,32]. This suggests that using visual aids is an important requirement for a better comprehension and hence better outcomes. In the present study, incooperating pictograms with verbal explanation was used to ensure the understanding and comprehensibility of the instructions. This tool provides the basis of daily education of the appropriate use of inhalers between pharmacy dispensing visits.

In the current study, patients who were randomized to receive inhaler pictograms medals showed significant improvement in asthma inhaler techniques as compared to control group at the end of study. However, the patients in the control group used the inhaler devices better than those in the intervention group at baseline. Therefore, pictograms were successful in retrieval of memory and information recall over the study period of time. Evidence suggested that even after a successful traditional intervention, many patients returned to use the inhalers incorrectly after a short period of time [33]. Bashiti and colleagues showed declined improvement in the intervention group when there was no education received by patients [3]. Previous studies stressed on the importance of repeated instructions to maintain long term correct inhaler technique and improve asthma outcomes [3,34].

One potential advantage of this approach that it avoids the boredom that may be associated with traditional routine education at the study site. At same time, this approach provides a suitable way to check and self-correct the instructions that leads to gradual change in behavior and maintains the accurate inhaler use [3]. Elderly patients who have difficulty in learning and illiterate patients may take a great benefit of this approach as inhaler technique deteriorates with time. Using pictogram acts as “show and tell” technique that is attached to the device itself and seen every time the patient needs or uses the inhaler devices. This approach overcome the problem of forgetting to use any provided supplementary material.

In the present study, asthma control, unscheduled medical intervention as well as adherence were all improved in patients without a significant difference between the two study groups. This points toward the benefits of simple counseling/education (routine/traditional way) on how to use inhalers. However, longer follow-up (6 months or 12 months) may reveal a difference between the two groups in terms of symptoms control or exacerbations as a result of improved inhaler technique. Future work is recommended to establish the utility of inhaler pictogram labels on larger number of asthmatic patients and with other chronic respiratory disease such as COPD. It is worth mentioning that responses from patients in the intervention arm revealed a high level of satisfaction with this novel educational tool.

The limitation of this study includes: first, recall bias that could affect participants' answers to the questionnaires. However, both groups in our study have the same chance of recall bias as they answered the same types of questionnaires. To minimize this problem, a standardized method was adopted to contact all patients as one clinical pharmacist conducted all face-to-face interviews. Second, we were unable to investigate the effect of using pictogram approach on other objective asthma outcome measures such as spirometry and exhaled nitric oxide due to limited study resources.

5. Conclusion

This is the first study that evaluated the use of pictographic diagram in asthma patients. We demonstrated that poor inhaler technique can be corrected by the use of educational pictograms attached to inhaler devices and subsequently improved asthma outcomes. Further studies that incorporate patients' beliefs about asthma medications (necessity and concerns) into the evaluation of proper inhaler technique is recommended. Pictogram label can provide a simple, low cost and sustainable way of improving asthma status especially in developing countries. This approach has the potential to save time, resources and reduce side effects caused by poor controlled asthma.

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Declarations of interest

The Authors declare no conflict of interest with regards to this Manuscript.

Table 4
Comparison of clinical parameters within each study group.

Characteristics[a]	Intervention			Control		
	Baseline	End of study	P value	Baseline	End of study	P value
Adherent to medication	36 (37.1)	72 (74.2)	< 0.001	43 (41.3)	75 (72.1)	< 0.001
ACT						
• Uncontrolled	58 (59.8)	29 (29.9)		55 (52.9)	41 (39.4)	0.008
• Controlled	39 (40.2)	68 (70.1)	< 0.001	49 (47.1)	63 (60.6)	
ACT score[b]	18 [13–22]	22 [19–24]	< 0.001	19 [15–22.25]	21 [17–24]	< 0.001
Unscheduled medical intervention	37 (38.1)	18 (18.6)	< 0.001	31 (30.1)	25 (24.3)	0.154

ACT, asthma control test.
[a] All data expressed as n (%) of patients unless otherwise indicated.
[b] Data described as median [interquartile range].

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.rmed.2018.09.004.

Abbreviations

ACT	Asthma Control Test™
CI	Confidence interval
COPD	Chronic obstructive pulmonary disease
FIP	International Pharmaceutical Federation
KAUH	King Abdullah University Hospital
MDI	Metered dose inhaler
OR	Odds ratio
USP	United States Pharmacopeia

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