

A study to monitor errors in use of inhalation devices in patients of mild-to-moderate bronchial asthma in a tertiary care hospital in Eastern India

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Abstract

Context: Bronchial asthma is a chronic respiratory disorder which affects over 300 million people worldwide. Inhalation pharmacotherapy is the cornerstone in treatment of asthma, which is administered using inhaler devices. Studies show high prevalence of incorrect technique while inhaler usage, which renders to compromised disease control and increased healthcare cost.

Aims: This study was aimed to monitor errors in use of inhalers and explore their relationship with patient characteristics and training given by healthcare providers, in patients suffering from mild to moderate bronchial asthma.

Settings and Design: This was an observational cross-sectional study conducted after approval of Institutional ethics committee in a tertiary care hospital.

Methods and Material: A total of 207 patients were recruited after they met the inclusion criteria and their informed consent was taken. Data regarding the patients' socio-demographic information, education status and history of illness were logged on a case record form. Their inhalation techniques were assessed according to the checklist, errors were noted and patients were educated regarding correct technique using 'teach-back training' method.

Statistical analysis used: Chi-square test, SPSS software.

Results: Among the inhalers used, pMDI was most commonly prescribed (58%), followed by DPI (37.7%) and pMDI with spacer (4.3%). Irrespective of the type of inhaler used, overall 75.36% patients included in the study, showed errors in use of inhaler. Prevalence of errors in DPI, pMDI and pMDI with spacers was 78.2%, 77.8% and 22.2% respectively. Our study showed that education status of patient, training by healthcare provider and duration of inhaler use have statistically significant association ($p < 0.05$) with the prevalence of errors in inhaler usage.

Conclusion: It is emphasized that dedicated and trained staff should be available for instructing patients and reinforcing by follow up checks should be considered.

Keywords: Dry-powder inhalers, errors in inhalation technique, inhaler, pressurized metered-dose inhalers

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INTRODUCTION

Chronic respiratory diseases include bronchial asthma as the most common disease, followed by chronic obstructive pulmonary disease, occupational lung diseases, and pulmonary hypertension. The prevalence of bronchial asthma varies from 10% to 12% in adults and around 15% in children^[1] which affected 339 million people worldwide in 2016.^[2]

Bronchial asthma is classified as intermittent, mild persistent, moderate persistent, and severe persistent,^[3] the treatment of which is tailored according to the severity of the disease. The drugs used for its treatment include corticosteroids, beta-2 agonists, methylxanthines, leukotriene antagonists, and mast cell stabilizers. Despite the availability of these recommended drugs, not every patient achieves complete asthmatic control.

To avoid or minimize adverse drug effects, many of the antiasthmatic drugs such as beta-2 adrenergic agonists, corticosteroids, and anticholinergics are administered by the inhalation route, using devices called inhalers, which include nebulizers, pressurized metered-dose inhalers (pMDIs), and dry-powder inhalers (DPIs). Difficulty in use of inhalers contributes to errors and suboptimal drug delivery to airways rendering compromised response and increased health-care costs. LAVORINI *et al.* have shown that between 4% and 94% of patients, depending on the type of inhaler, do not use their inhalers correctly.^[4] However, KLIJN *et al.* have demonstrated that training on inhaler use resulted in correct use in more than 90% of patients.^[5] A recent global position document from the Global Initiative for Asthma (GINA) gives a significant prominence to assessing and correcting the inhalation technique before escalating drug therapy.^[6]

Although the technique of inhaler use can be improved by proper training of the target population, there is a paucity of such data in our country.^[7] This study aimed to monitor errors in use of inhalation devices and explore the relationship between these errors, patient characteristics and training by health-care providers, of patients who are diagnosed as cases of mild-to-moderate bronchial asthma, attending respiratory medicine clinics of a tertiary care hospital.

SUBJECT AND METHODS

The study was conducted for a period of 1 year. The sample size was calculated to estimate 95% confidence interval for the proportion of mild-to-moderate cases of asthma correctly using inhalation devices as per guidelines with a 5% absolute error of margin. The sample size worked out

to be 207 assuming that about 52% of mild-to-moderate cases of bronchial asthma are correctly following the inhaler technique^[4] and assuming that there are 420 patients of mild-to-moderate bronchial asthma registered in asthma clinics (according to the hospital data). This was an observational cross-sectional study conducted on patients included as per inclusion and exclusion criteria at a single visit to the respiratory medicine outpatient department after obtaining their written informed consent and clearance from the institutional ethics committee. Inclusion criteria were patients of age more than 18 years with mild-to-moderate bronchial asthma who were using inhalers. Exclusion criteria were patients suffering from severe bronchial asthma and patients concurrently suffering from illnesses other than bronchial asthma, including psychiatric diseases. Data regarding the patients' sociodemographic information, education status, and history of illness were logged on a case record form. Thereafter, inhalation techniques were assessed according to the undermentioned list of steps to be followed for the usage of pMDI with or without spacer and DPI, and errors made at any step were noted down. The checklist was marked accordingly. Once errors were noted, patients were demonstrated the correct inhaler technique, and "teach-back training" method was used.

For pMDI, steps for proper usage were as follows:^[8]

1. Shake the inhaler
2. Hold inhaler upright
3. Exhale completely
4. Place mouthpiece between the lips and teeth and keep the tongue from obstructing the mouthpiece
5. Press the inhaler while inhaling deeply and slowly
6. Inhale completely
7. Hold the breath for as long as comfortable
8. Exhale out slowly.

For pMDI with spacer, steps for proper usage were:^[8]

1. Shake the inhaler, attach it to the spacer
2. Remove the cap of the spacer
3. Exhale completely
4. Place mouthpiece of the spacer between the lips and teeth
5. Press the inhaler once
6. Inhale deeply and slowly
7. Hold the breath for as long as comfortable, before breathing out
8. Exhale out slowly.

For Rotahaler, a DPI, steps for proper usage were as follows:^[9]

1. Take Rotacap and insert transparent end into the square hole

2. Press Rotacap firmly
3. Hold the mouthpiece firmly with one hand and rotate the base with another hand
4. Exhale completely
5. Grip the mouthpiece between the teeth and seal the lips around it
6. Inhale completely through the mouth
7. Hold the breath for as long as comfortable.

The technique was labeled as wrong if the patient committed at least one error. Once errors were noted, patients were demonstrated the correct inhaler technique, and “teach-back training” method was used.

Statistical analysis was done using Chi-square test, SPSS software IBM SPSS Statistics for Macintosh, Version 25.0.

RESULTS

A total of 207 patients were enrolled in the study, and

Table 1: Demographic profile of the study population

Demographic characteristics	n (%)
Gender	
Male	113 (54.6)
Female	94 (45.4)
Age (years)	
18-30	111 (53.6)
Above 45	96 (46.4)
Educational status	
12 th and below	97 (46.8)
Graduate	110 (53.1)

Table 2: Pattern of inhaler used

	Number of patients (%)
Type of inhaler	
pMDI	120 (58)
pMDI with spacer	9 (4.3)
DPI	78 (37.7)
Training regarding the use of inhaler received	
Yes	207 (100)
Educator	
Pharmacist	76 (36.7)
Nursing staff	60 (29)
Doctors	71 (34.3)
Duration of use of inhaler (months)	
Below 6	70 (33.8)
6-24	77 (37.2)
Above 24	60 (29)

DPI=Dry-powder inhaler, pMDI=Pressurized metered-dose inhaler

Table 3: Distribution of patients making errors in inhalation technique

Type of inhaler	Number of patients (%)		
	Making no error	Making errors	Total
pMDI	27 (22.5)	93 (77.5)	120 (100)
pMDI + spacer	7 (77.8)	2 (22.2)	9 (100)
DPI	17 (21.8)	61 (78.2)	78 (100)

DPI=Dry-powder inhaler, pMDI=Pressurized metered-dose inhaler

information regarding patients and their treatment were formulated [Tables 1 and 2].

There were 113 (54.6%) males and 94 (45.4%) females. Their mean age was 39 years. The correctness of the technique used for pMDI was evaluated using the checklist mentioned above. Out of the total population 207, 51 (24.6%) patients performed the technique correctly. Ninety-three (77.5%) out of 120 patients using pMDI,

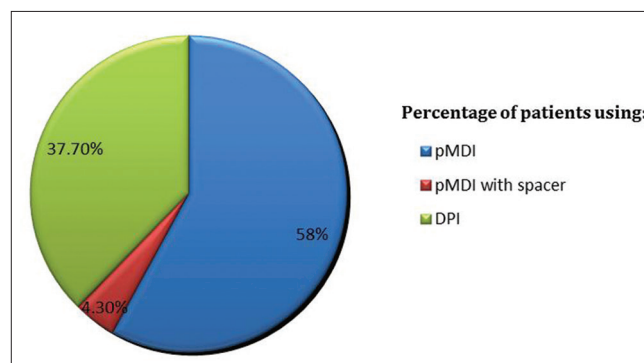


Figure 1: Distribution of patients using different types of inhalers

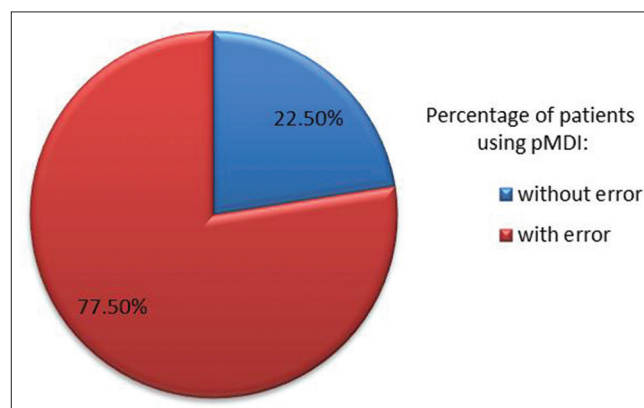


Figure 2: Prevalence of errors in use of pressurized metered-dose inhalers

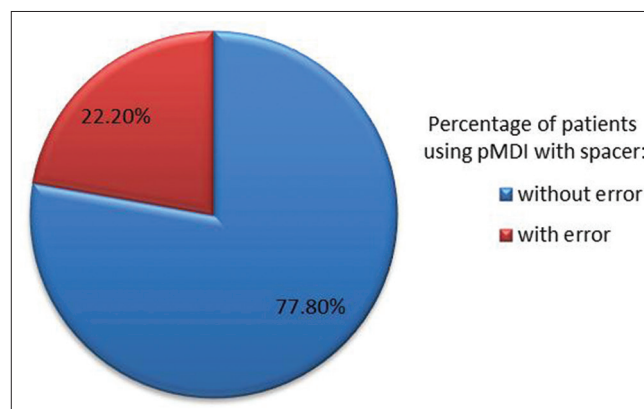


Figure 3: Prevalence of errors in use of pressurized metered-dose inhalers with spacer

2 (22.2%) out of 9 using pMDI with spacer, and 61 (78.2%) out of 78 patients using DPI made errors in their inhalation technique [Table 3 and Figures 1-4].

Patients on pressurized metered-dose inhalers

Patients made errors in exhaling completely (step 3), pressing the inhaler while inhaling deeply and slowly (step 5), and holding the breath for as long as comfortable, before breathing out (step 7). Overall, 63 patients showed incorrect technique in step 5, the second most common mistake was in step 7; about 43 patients made this mistake, whereas 11 made errors in step 3 [Table 4 and Figure 5]. When individual parameters of patients on pMDI were evaluated, it was observed that 47 (86.7%) out of 53 patients who did their schooling up to 12th standard and 46 (68.7%) out of 67 patients who were graduates made errors ($P < 0.05$). All of them were trained about the technique by health-care providers. Forty-two (91.3%) out of 46 patients trained by pharmacists, 23 (71.9%) out of 32 trained by nursing staff, and 28 (66.7%) out of 42 trained by doctors made mistakes ($P < 0.05$). Thirty-nine (90.7%) out of 43 patients who had been using the inhaler for <6 months, 32 (76.2%) out of 42 patients who were using it for 6 months or more but <24 months, and 22 (62.9%) out of the 35 patients who were using inhalers for more than 24 months made mistakes ($P < 0.05$) [Table 5].

Patients on pressurized metered-dose inhalers with spacer

Patients made errors in inhaling deeply and slowly (step 6) and holding the breath for as long as comfortable (step 7). One (50%) patient made error in step 6, whereas in step 7, 1 (50%) made mistake [Table 6 and Figure 6].

Two (66.7%) out of 3 patients educated up to 12th standard, and none among six graduates made errors ($P < 0.05$).

Table 4: Number of patients making errors in different steps of using pressurized metered-dose inhaler

Step	Number of patients (%)
Step 1: Shake the inhaler	0
Step 2: Hold the inhaler upright	0
Step 3: Exhale completely	4 (4.3)
Step 4: Place the inhaler mouthpiece between the lips and teeth; keep the tongue from obstructing the mouthpiece	0
Step 5: Press the inhaler while inhaling deeply and slowly	43 (46.2)
Step 6: Inhale completely	0
Step 7: Hold the breath for as long as comfortable, before breathing out	24 (25.8)
Step 8: Exhale out slowly	0
Step 3 and 5: Details as above	3 (3.2)
Step 3 and 7: Details as above	2 (2.1)
Step 5 and 7: Details as above	15 (16.1)
Step 3, 5 and 7: Details as above	2 (2.1)

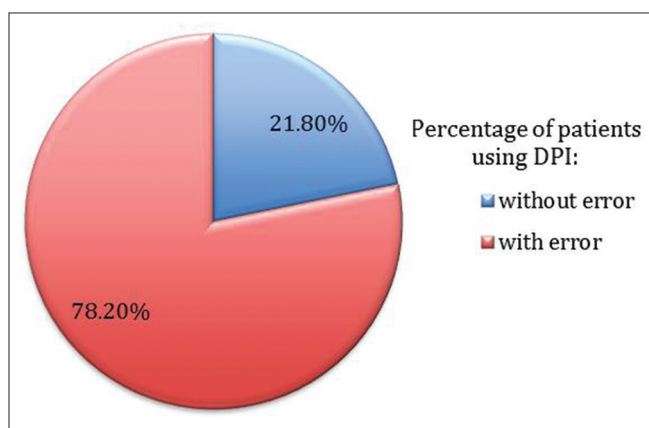


Figure 4: Prevalence of errors in use of dry-powder inhalers

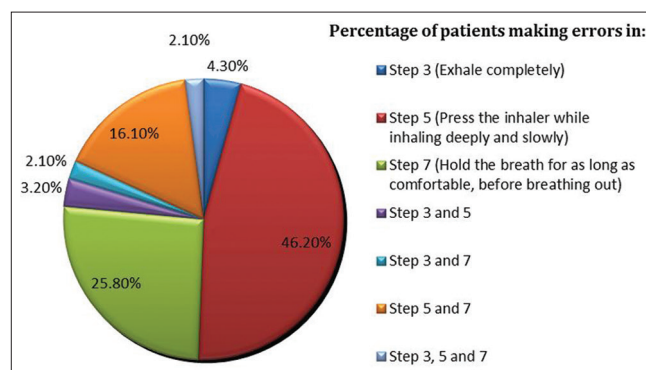


Figure 5: Distribution of patients making errors in various steps in use of pressurized metered-dose inhalers

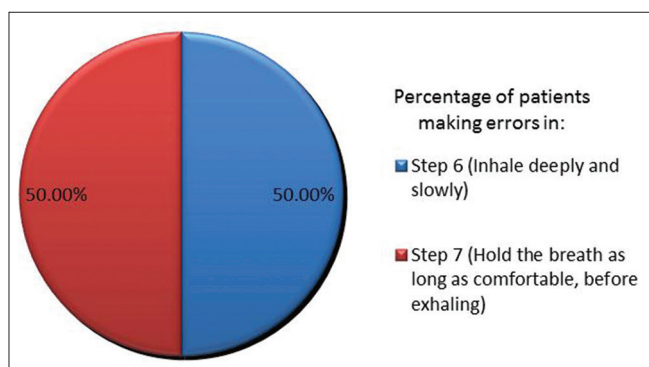


Figure 6: Distribution of patients making errors in various steps in use of pressurized metered-dose inhalers with spacer

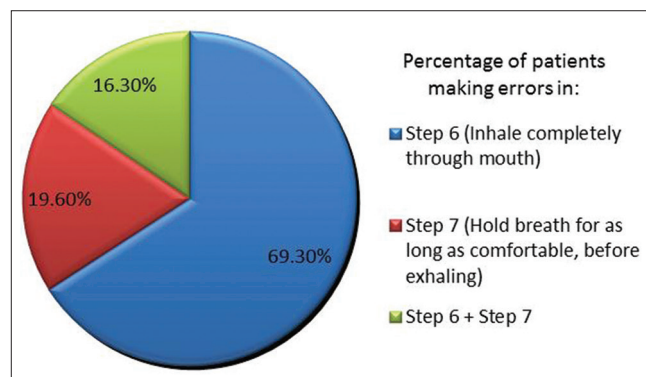


Figure 7: Distribution of patients making errors in various steps in use of dry powder inhaler

Table 5: Association of pressurized metered-dose inhaler use and patient factors

Patient factors	Number of patients (%)			P
	Making no error	Making errors	Total	
Gender				
Male	15 (22.4)	52 (77.6)	67 (100)	0.97
Female	12 (22.6)	41 (77.4)	53 (100)	
Age (years)				
18-45	16 (25.4)	47 (74.6)	63 (100)	0.42
Above 45	11 (19.3)	46 (80.7)	57 (100)	
Educational status				
12 th and below	6 (11.3)	47 (86.7)	53 (100)	0.009
Graduate	21 (31.3)	46 (68.7)	67 (100)	
Educator				
Pharmacists	4 (8.7)	42 (91.3)	46 (100)	0.01
Nursing staff	9 (38.1)	23 (71.9)	32 (100)	
Doctors	14 (33.3)	28 (66.7)	42 (100)	
Duration of use of inhalers (months)				
Below 6	4 (9.3)	39 (90.7)	43 (100)	0.001
6-24	10 (23.8)	32 (76.2)	42 (100)	
Above 24	13 (37.1)	22 (62.9)	35 (100)	

Table 6: Distribution of patients making errors in various steps in use of pressurized metered-dose inhaler with spacer

Step	Number of patients (%)
Step 1: Shake the inhaler and attach it to the spacer	0
Step 2: Remove the cap of the spacer	0
Step 3: Exhale completely	0
Step 4: Place the mouthpiece of the spacer between the lips and the teeth and keep the tongue from obstructing the mouthpiece	0
Step 5: Press the inhaler once	0
Step 6: Inhale deeply and slowly	1 (50)
Step 7: Hold the breath for as long as comfortable, before breathing out	1 (50)
Step 8: Exhale out slowly	0

Both the two patients who got their training from nursing staff and none of the 7 who were trained by doctors made errors ($P < 0.05$) [Table 7].

Patients on dry-powder inhalers

Patients made errors in inhaling completely through the mouth (step 6) and holding the breath for as long as comfortable (step 7). Overall, 49 patients showed errors in step 6 and the second most common error was in step 7 made by 22 patients [Table 8 and Figure 7].

Likewise, when individual parameters of patients on DPI were evaluated, 38 (92.7%) out of 41 patients educated up to 12th standard, and 23 (62.2%) out of 37 graduates made mistakes ($P < 0.05$). Twenty-eight (96.7%) out of 30 trained by pharmacists, 21 (88.5%) out of 26 trained by nursing staff, and 12 (40.9%) out of 22 trained by doctors made mistakes ($P < 0.05$) [Table 9].

DISCUSSION

A total of 207 patients were recruited for the study and

assessment of their technique of usage of inhalational devices was carried out.

Among the inhalers used, pMDI was most commonly prescribed (58%), followed by DPI (37.7%) and pMDI with spacer (4.3%). Irrespective of the type of inhaler used, overall, 75.36% of patients showed errors in the use of inhaler. This high frequency of incorrect inhaler use is in accordance with results in previously conducted studies.^[10,11]

The prevalence of errors in DPI, pMDI, and pMDI with spacers was 78.2%, 77.8%, and 22.2%, respectively. The use of spacer minimizes the error, as hand–mouth coordination is not required as in the use of pMDI. In our study, the frequency of errors with DPI use is almost similar to those with pMDI use which contrasts with previous studies^[12,13] and is likely due to the difference in the study design and population. Although a systematic review of inhaler use also found that though DPIs are expected to perform better, error rates were surprisingly only slightly lower than MDI error rates.^[14]

In patients using pMDI, 46.2% of the patients committed mistakes in inhaling deeply and slowly while pressing the inhaler, 25.8% of the patients made errors in holding their breath for the desired period before exhaling, and 4.3% of the patients did not exhale completely. In patients using DPIs, 63.9% of the patients made errors in inhaling completely through the mouth and 19.6% of the patients made errors in holding their breath for the desired period before exhaling. In patients using pMDI with spacers, 50% of the patients made errors in inhaling deeply and slowly and 50% of the patients made errors in holding the breath for the desired period before exhaling. Among the errors made in various steps by the patients, certain errors would

Table 7: Association of pressurized metered-dose inhaler with spacer use and patient factors

Patient factors	Number of patients (%)			P
	Making no error	Making errors	Total	
Gender				
Male	4 (66.7)	2 (33.3)	6 (100)	0.25
Female	3 (24)	0 (76)	3 (100)	
Age (years)				
18-45	3 (75)	1 (25)	4 (100)	0.23
Above 45	4 (20)	1 (80)	5 (100)	
Educational status				
12 th and below	1 (33.3)	2 (66.7)	3 (100)	0.03
Graduate	6 (100)	0	6 (100)	
Educator				
Pharmacists	0	0	0	0.002
Nursing staff	0	2 (100)	2 (100)	
Doctors	7 (100)	0	7 (100)	
Duration of use of inhalers (months)				
Below 6	2 (66.7)	1 (33.3)	3 (100)	0.66
6-24	2 (100)	0	2 (100)	
Above 24	3 (75)	1 (25)	4 (100)	

Table 8: Distribution of patients making errors in various steps in use of dry powder inhaler

Step	Number of patients (%)
Step 1: Take Rotahaler capsule and insert transparent end into the square hole	0
Step 2: Press the Totacap firmly	0
Step 3: Hold the mouthpiece firmly with one hand and rotate the base with another hand	0
Step 4: Exhale completely	0
Step 5: Grip the mouth piece between the teeth and seal the lips around it	0
Step 6: Inhale completely through the mouth	39 (63.9)
Step 7: Hold breath for as long as comfortable, before exhaling	12 (19.6)
Step 6 and 7: Details as above	10 (16.3)

affect inhalation and drug delivery more as compared to other steps, rendering the inhalational therapy less effective or rather useless.^[15,16]

In our study, the educational status of patients has shown to have a statistically significant role in determining the appropriateness of inhaler use. In patients who were educated up to 12th standard, the prevalence of errors in inhaler technique of patients using pMDI was 86.7%, while 68.7% in graduates. Similarly, in patients educated up to 12th standard, the prevalence of errors in the inhaler technique of patients using DPI was 92.7%, while 62.2% in graduates. In patients educated up to 12th standard, the prevalence of errors in the inhaler technique of patients using pMDI with spacer was 66.7%, while graduates made no errors. Similar findings were brought out in other studies asserting a statistically significant association between the education status of patients and errors in inhalation technique.^[17,18] The reason for this difference may be that, with better education, the patient is more cognizant of his/her disease and can understand the technique better, therefore making lesser errors. However, the sample size

of patients using pMDI with spacer was too less to draw any significant conclusions.

It was observed that all patients were given training regarding the inhaler use and the trainer played a substantial role. If training was given by treating physicians, the tendency of patients to commit errors was significantly lesser *vis-à-vis* when it was imparted by pharmacists and nursing staff. When pMDI users were trained by the pharmacists, nursing staff, and doctors, the prevalence of errors was 91.3%, 71.9%, and 66.7%, respectively. Among the DPI users, the prevalence of errors was 96.7%, 88.5%, and 40.9% when the patients were trained by pharmacists, nursing staff, and doctors, respectively. When pMDI with spacer users were trained by the nursing staff and doctors, the prevalence of errors was 100% and 0, respectively. A parallel pattern of errors has been reflected in previously conducted studies.^[11,15,18,19] Periodic interactions with medical representatives and continuous medical education of physicians, as compared to other health-care workers such as pharmacists and nurses, can be the reason for this difference.

Clinicians play an important role in reinforcing inhaler technique as they are the primary point of contact with the patients and they choose the most appropriate inhaler device for the patient before prescribing. They can encourage their patients to ask any queries concerning the device handling, especially when an inhaler novel to their use is prescribed. Moreover, the clinicians can coach other health-care professionals including pharmacists and nursing staff by acquainting them with “check-correct-confirm” cycle^[20,21] to ensure the effective use of inhaler devices among their patients. Patient training is usually facilitated by demonstration with the help of video instructions

Table 9: Association of dry-powder inhaler use and patient factors

Patient factors	Number of patients (%)			P
	Making no error	Making errors	Total	
Gender				
Male	7 (17.5)	33 (82.5)	40 (100)	0.34
Female	10 (26.3)	28 (73.7)	38 (100)	
Age (years)				
18-45	12 (27.3)	32 (72.7)	44 (100)	0.18
Above 45	5 (14.7)	29 (85.3)	34 (100)	
Educational status				
12 th and below	3 (7.3)	38 (92.7)	41 (100)	0.001
Graduate	14 (37.8)	23 (62.2)	37 (100)	
Educator				
Pharmacists	2 (6.7)	28 (96.7)	30 (100)	0.003
Nursing staff	5 (11.5)	21 (88.5)	26 (100)	
Doctors	10 (59.1)	12 (40.9)	22 (100)	
Duration of use of inhalers (months)				
Below 6	5 (20.8)	19 (93.3)	24 (100)	0.96
6-24	7 (21.2)	26 (78.8)	33 (100)	
Above 24	5 (23.8)	16 (76.2)	21 (100)	

and written material,^[22] but there must be an emphasis on tailored education according to the patient and re-training in case of erroneous technique exhibited on every visit. Follow-up studies are essential to assess improvement in inhalational techniques after an educational intervention as advised in the GINA strategy since errors often recur till 4–6 weeks after initial training.^[6]

Among the pMDI users, when their duration of inhalers use was below 6 months, 6 months to 24 months, and above 24 months, 90.7%, 76.2%, and 62.9% of patients, respectively, committed mistakes. Hence, it was found that patients using pMDI with longer duration of device use had a better technique of inhalation than those with shorter duration. This possibly represents an improvement in the level of understanding of the device usage on part of the patient by repeated reinforcement on correct use in subsequent visits.

The prevalence of errors has not been found associated with the gender of patients in our study, which has also been reflected in other studies.^[23] There has been no significant association between the age of the patients and the errors in the inhalation technique, which is in contrast to other studies.^[11,16,19,20] The pretext to this contrariness could be that in our study, the range of age of patients enrolled was assessed to be 18–65 years, excluding the elderly and children population. Hence, the difference in error rates among different age groups might not have been brought out.

CONCLUSION

Inhalational medications are the cornerstone in the treatment of bronchial asthma. Incorrect inhaler use can act

as a big obstacle in symptomatic management of asthma. From this study, it is concluded that the education status of the patient, training given by the health-care provider, and duration of use of inhaler play substantial roles in minimizing the error rates. There should be an emphasis on the need for new approaches to patient education and training. Moreover, dedicated and trained staff should be available for instructing patients and retraining should be enforced if needed at every opportunity.

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Conflicts of interest

There are no conflicts of interest.

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