

Impact of Educational Programme on Inhalational Device Usage Techniques among the Patients Suffering from Asthma

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ABSTRACT

Introduction: Aerosol inhalation is a mode of drug administration used in the management of asthma. Improper inhaler device usage techniques can lead to suboptimal therapeutic effect. Patients are very often prescribed inhaler devices without proper instructions regarding the correct usage technique, as the provider themselves may not be aware of the same.

Aim: To compare the techniques of inhalational devices usage before and after training the patients suffering from asthma.

Materials and Methods: An institution-based, prospective study was conducted among asthmatics reporting to the Department of Pulmonary Medicine, Mysore Medical College and Research Institute, Mysore, Karnataka, India, from March 2020 to September 2020. A total of 249 asthmatic patients who met diagnostic criteria recommended by Global Initiative for Asthma (GINA), who were on inhaler devices namely: pressurised Meter Dose Inhaler (pMDI), pMDI with spacer, Rotahaler[®], and Revolizer[®], and who consented to be part of the study were included in the present study. Each patient was advised to use the inhaler medication, during which the patient was observed, and the checklist was scored. Subsequently patients were educated regarding the correct, device specific usage technique with demonstration. After one month (post-training visit), using the same checklist, each patient was re-evaluated. For each correct step, the patient received a score of “one”, whereas, each incorrect step, as well as “no-response”

was valued as “zero”. The sum of the scores for all the steps was calculated for each patient and each type of inhaler. The Microsoft Excel 2010 spreadsheet was used to enter the data. Descriptive statistics were represented using percentages, frequencies, graphs and in the form of tables. Mean difference was used to compare the scores before and after the training. A p-value<0.05 was considered statistically significant. The scores were categorised into “handling errors” and “inhalational errors”, percentage of participants committing at least one error, handling and inhalational error was tabulated.

Results: Prior to the training, none of the subjects using pMDI and pMDI with spacer were able to complete all the steps appropriately. Whereas 7.8% of patients (4/51) using Rotahaler[®], 4.5% of patients (2/44) using Revolizer[®] were able to perform all the steps accurately. During post-training follow-up, 59.22% (61/103) and 39.22% (20/51) patients using pMDI and pMDI with spacer, respectively, were able to perform all the steps accurately. Whereas 50.98% (26/51) and 72.73% (32/44) patients using Rotahaler[®] and Revolizer[®], respectively, were able to perform all the steps accurately.

Conclusion: The majority of asthmatics erred while utilising the inhaler devices. Errors were committed both during handling and inhalational steps. When trained, the error percentage was reduced significantly.

Keywords: Asthmatics, Dry powder inhaler, Inhaler, Pressurised metered dose inhaler, Spacer

INTRODUCTION

Asthma is a global problem, with an estimated 300 million affected individuals [1]. The global prevalence of asthma ranges from 1-16% in different countries [1,2]. Data analysis from GINA, World Health Organisation (WHO), and Indian Study on Epidemiology of Asthma, Respiratory symptoms and Chronic bronchitis (INSEARCH) [3] shows that, in India the prevalence of asthma ranges from 2.05-3.50% [1,4].

Aerosol inhalation is a mode of drug administration used in the management of asthma that is commonly administered by three methods namely: 1) pMDI; 2) Dry Powder Inhalers (DPI); and 3) Nebulisers. The pMDI and DPI devices are the most preferred drugs delivery systems in asthmatics as the patients can use by themselves or with minimal assistance. Though these devices are user friendly, their incorrect use can lead to suboptimal therapeutic effect [5].

Each type of inhaler device is unique. Each inhaler device has specific instructions for use. In practice, commonly the steps for inhaler device usage are confusing, as a result, the therapeutic dose of drug available may not be delivered to the patients [6]. Improper inhalation techniques can lead to inadequate medication effects and hence this can lead to the prescription of a higher dose

or additional medication which in turn can have a higher probability of side effects and increased cost of treatment for the patient [7].

The prescribing physician bears the primary responsibility of educating the patient regarding the correct usage of inhaler devices. However, other Healthcare Workers (HCW) also should be aware of the correct usage of an inhaler, as the technique has to be re-evaluated on subsequent revisits by the patient [8]. Patients are very often prescribed inhaler devices without proper instructions regarding the correct usage technique, because the provider themselves may not be aware of the same [9,10]. Several studies have revealed that improper use of inhaler devices by patients is very common [10,11].

There is a scarcity of data on studies assessing the correct usage of inhaler techniques among asthma patients in India. Thus, the aim of the present study was to compare the techniques of inhalational devices usage before and after training the patients suffering from asthma.

MATERIALS AND METHODS

An institutional-based, prospective study was conducted among asthma patients reporting to the Department of Pulmonary Medicine, Mysore Medical College and Research Institute, Mysore, Karnataka,

India, from March 2020 to September 2020. The ethical clearance (ECR/134/INST/KA/2013/RR-19, dated:10-03-2020) was obtained prior to the study.

Inclusion criteria: The patients who met diagnostic criteria recommended by GINA [12], and on inhaler medications devices, namely pMDI, pMDI with spacer, Rotahaler®, and Revolizer®, and who consented to be part of the study were included in the study.

Exclusion criteria: Patients not consenting for the study, and below the age of 18 years and above 75 years were excluded from the study.

Sample size calculation: The sample size estimated was 223 with an estimated prevalence of 82.4% with a precision of 95% and allowable error of 5%. A final sample of 249 subject were included in this study.

Study procedure

The investigator used an inhaler device specific administration checklist to assess the technique of usage of the inhaler device by the asthmatics [13-15]. The patient was advised to use the inhaler medication, during which the patient was observed, and the checklist was scored. Subsequently patients were educated regarding correct, device specific usage technique with demonstration by a doctor or a nurse with a total duration of training for about 20 minutes. After one month (post-training visit) using the same checklist, each patient was re-evaluated. For each correct step, the patient received a score of "1" (one) whereas each incorrect step, as well as "no-response" was valued as "0" (zero). The maximum score for pMDI and pMDI with spacer was 11 and 13, respectively. The maximum score for both Rotahaler®, and Revolizer® was 8. The minimum score for all the inhalation devices was 0 (zero). The sum of the scores for all the steps was calculated for each patient and each type of inhaler and was compared between first and revisit performance.

Checklist comprising 11 steps for use of pMDI [13]:

1. Remove the cap of the inhaler.
2. Shake the inhaler well while holding it upright.
3. Gently exhale.
4. Without biting the mouthpiece, place it between your teeth and tighten your lips to make a strong seal.
5. Begin to inhale slowly through mouth while pressing firmly on the canister.
6. Continue to inhale deeply and slowly.
7. Hold your breath for five seconds or as long as you feel comfortable.
8. Remove the inhaler from your mouth while holding your breath.
9. Gently exhale away from mouthpiece.
10. In case an additional dose is required, wait for one minute and repeat steps 2 to 9.
11. Put the cap back.

Checklist comprising 13 steps for use of pMDI with spacer [13]:

1. Assemble spacer.
2. Remove the cap of the inhaler.
3. Shake the inhaler well while holding it upright.
4. Insert inhaler upright into spacer.
5. Gently exhale.
6. Without biting the mouthpiece, place it between your teeth and tighten your lips to make a strong seal.
7. Keep the spacer at the level and firmly press down on the canister once.
8. Inhale slowly and deeply, then hold your breath for five seconds or as long as you feel comfortable, or take four normal breaths in and out.

9. Remove spacer from mouth.
10. Gently exhale.
11. Take the inhaler out of the spacer.
12. In case an additional dose is required, wait for one minute, and then repeat steps 3 to 11.
13. Replace cap and disassemble spacer.

Checklist comprising eight steps for use of Rotahaler® [14]:

1. Hold the Rotahaler® vertically such that fin is not directly below the Rotacap hole.
2. Insert the Rotacap in the Rotacap hole with the transparent end facing down such that the top end of the Rotacap is in level with the top of the Rotacap hole.
3. Hold the mouthpiece firmly with one hand and rotate the base with the other hand such that the fin separates the two halves of the Rotacap.
4. Breathe out fully through mouth.
5. Place the mouthpiece between the lips and the teeth; keep the tongue from obstructing the mouthpiece and close the lips tightly around the mouthpiece.
6. Breathe in rapidly and deeply as possible which produces a rattling sound, remove the Rotahaler® from the mouth and then hold breath for about 10 seconds or as long as comfortable. (ensure to inhale all the drug in the Rotacap)
7. After use, separate the two halves of the Rotahaler® and discard the empty Rotacap(s).
8. Rejoin the two halves of the Rotahaler®.

Checklist comprising eight steps for use of Revolizer® [15]:

1. Open the Revolizer® by holding the base with one hand and pull back the mouthpiece with the other hand.
2. Insert the Rotacap in the Rotacap chamber with the transparent end facing down.
3. Close the mouthpiece firmly.
4. Breathe out completely through mouth.
5. Place the mouthpiece between the lips and the teeth; keep the tongue from obstructing the mouthpiece and close the lips tightly around the mouthpiece.
6. Breathe in rapidly and deeply as possible which produces a rattling sound, remove the Revolizer® from the mouth and then hold breath for about 10 seconds or as long as comfortable. (Ensure to inhale all the drug in the Rotacap).
7. Open the mouthpiece and discard the empty Rotacap.
8. Close the mouthpiece.

STATISTICAL ANALYSIS

The Microsoft Excel 2010 spreadsheet was used to enter the data. Statistical analysis was done using Epidata Software. Descriptive statistics were represented using percentages, frequencies, graphs and in the form of tables. Mean difference was calculated between the scores before and after the training and t-test was applied. A p-value<0.05 was considered statistically significant for a 95% Confidence Interval (CI). The scores were categorised into "handling errors" and "inhalational errors", and percentage of participants committing at least one error, handling and inhalational error was tabulated.

RESULTS

Total 249 asthmatic patients using different types of inhaler devices (pMDI=103; pMDI with Spacer=51; Rotahaler® =51, Revolizer®=44) were included in this study.

Patient's socio-demographics are presented in [Table/Fig-1]. The mean age of the patients was found to be 37.31 years (SD±9.53).

The average years with history of asthma were 5.9 years (SD±6.29) and average years of inhaler usage among these patients were found to be 4.25 years (SD±3.73).

Variable	n	Percentage (%)
Gender		
Male	184	73.9
Female	65	26.1
Marital status		
Single	55	22.1
Married	170	68.3
Divorced	11	4.4
Widowed	13	5.2
Educational status		
Illiterate	35	14.1
Less than tenth standard	74	29.7
More than tenth standard	140	56.2

[Table/Fig-1]: Demographic details (N=249).

[Table/Fig-2] presents the frequency distribution of inhaler devices and other variables like types of inhalers used, level of confidence in using the inhalers, source of inhaler usage education and whether name of the inhaler medication known to the patient or not.

Variable	n	Percentage (%)
Type of inhaler device used		
pMDI	103	41.3
pMDI with spacer	51	20.5
Rotahaler®	51	20.5
Revolizer®	44	17.7
Level of confidence for using the device		
Confident	230	92.4
Not confident	19	7.6
Source of inhaler device usage education		
Doctor	61	24.5
Literature	21	8.4
Nurse	46	18.5
Pharmacist	53	21.3
Audio-visual (A-V) aid	39	15.7
Respiratory Care Technologist (RCT)	29	11.6
Name of inhaler medication		
Known to the patient	209	83.9
Unknown to the patient	40	16.1

[Table/Fig-2]: Frequency distribution of inhaler devices and other variables associated with their usage (N=249).

The score for all the steps is summated for all types of inhalers considered i.e., pMDI, pMDI with spacer, Rotahaler® and Revolizer®. The pretraining scores were compared with post-training assessment.

Prior to the training none of the subjects using pMDI and pMDI with spacer were able to complete all the steps appropriately. During post-training follow-up, 59.22% (61/103) and 39.22% (20/51) patients using pMDI and pMDI with spacer respectively were able to perform all the steps accurately [Table/Fig-3].

During first visit only 7.84% of patients (4/51) using Rotahaler®, 4.55% of patients (2/44) using Revolizer® were able to perform all the steps accurately but during the post-training follow-up, 50.98% (26/51) and 72.73% (32/44) patients using Rotahaler® and Revolizer® respectively, were able to perform all the steps accurately [Table/Fig-4].

The distribution of incorrectly performed steps by the subjects using pMDI and pMDI with spacer before and after training is presented in [Table/Fig-5], whereas for Rotahaler® and Revolizer® before and after training is presented in [Table/Fig-6].

Score	pMDI (n=103)				pMDI with spacer (n=51)			
	Before training		After training		Before training		After training	
	n	%	n	%	n	%	n	%
0	0	0	0	0	0	0	0	0
1	0	0	0	0	1	0	0	0
2	0	0	0	0	2	0	0	0
3	0	0	0	0	3	0	0	0
4	0	0	0	0	4	2	3.92	0
5	5	4.85	0	0	5	5	9.80	0
6	0	0	0	0	6	10	19.61	0
7	42	40.78	0	0	7	8	15.69	0
8	42	40.78	17	16.50	8	10	19.61	0
9	4	3.88	21	20.39	9	3	5.88	0
10	10	9.71	4	3.89	10	6	11.76	0
11	0	0	61	59.22	11	5	9.80	4
					12	2	3.92	27
					13	0	0	20

[Table/Fig-3]: Score distribution of the patients using pMDI and pMDI with spacer before and after training.

Score	Rotahaler® (n=51)				Revolizer® (n=44)			
	Before training		After training		Before training		After training	
	n	%	n	%	n	%	n	%
0	0	0	0	0	0	0	0	0
1	0	0	0	0	1	0	0	0
2	0	0	0	0	2	0	0	0
3	4	7.84	0	0	3	1	2.27	0
4	5	9.80	0	0	4	11	25	0
5	14	27.45	0	0	5	7	15.91	0
6	16	31.37	3	5.88	6	19	43.18	1
7	8	15.69	22	43.14	7	4	9.09	11
8	4	7.84	26	50.98	8	2	4.55	32

[Table/Fig-4]: Score distribution of the patients using Rotahaler® and Revolizer® before and after training.

Step no.	pMDI (n=103)				pMDI with Spacer (n=51)			
	Before training		After training		Before training		After training	
	n	%	n	%	n	%	n	%
1	0	0	0	0	1	0	0	0
2	47	45.63	11	10.68	2	0	0	7
3	83	80.58	15	14.56	3	36	70.59	6
4	26	25.24	11	10.68	4	0	0	0
5	10	9.71	11	10.68	5	46	90.20	6
6	57	55.34	11	10.68	6	41	80.39	6
7	22	21.36	11	10.68	7	25	49.02	0
8	19	18.45	0	0	8	28	54.90	6
9	36	34.95	5	4.85	9	0	0	0
10	17	16.50	11	10.68	10	35	68.63	1
11	22	21.36	11	10.68	11	29	56.86	1
					12	19	37.25	1
					13	9	17.65	1

[Table/Fig-5]: Distribution of incorrectly performed steps by the subjects using pMDI and pMDI with spacer before and after training.

There was a statistically significant difference between the scores of the participants using all types of inhalers before the training and after the training. Educating the participants about the steps of using the inhaler served an important purpose in using all kinds of inhalers.

Step no	Rotahaler® (n=51)				Revolizer® (n=44)				
	Before training		After training		Step no	Before training		After training	
	n	%	n	%		n	%	n	%
1	2	3.92	0	0	1	0	0	0	0
2	13	25.49	4	7.84	2	33	75	3	6.82
3	8	15.69	0	0	3	0	0	0	0
4	27	52.94	12	23.53	4	27	61.36	1	2.27
5	23	45.10	0	0	5	14	31.82	5	11.36
6	25	49.02	6	11.76	6	23	52.27	2	4.55
7	12	23.53	3	5.88	7	11	25	1	2.27
8	12	23.53	3	5.88	8	11	25	1	2.27

[Table/Fig-6]: Distribution of incorrectly performed steps among Rotahaler® and Revolizer® users before and after training.

After training, during the follow-up, participants were evaluated for mistakes in using the type of the inhalational device assigned and the results are presented in [Table/Fig-7]. 'Handling errors' were grouped together which included: not removing/opening the cap, not shaking the device before actuation, no upright posture before inhalation, failure to pierce the Rotacap, incorrect rotation and mouthpiece not enclosed tightly with the lips. 'Inhalation errors' group included: not holding breath for about five seconds after inhalation, incomplete expiration before inhalation, no deep and slow inspiration, no forceful and deep inspiration, no breathing out with pursed lip technique after inhalation.

Type of inhaler device	Mean before training	Mean after training	Mean difference	Standard deviation	p-value*
Pressurised metered dose inhaler	8.12	10.06	-1.942	2.355	<0.0001
Pressurised metered dose inhaler with spacer	7.29	12.31	-5.020	1.944	<0.0001
Rotahaler®	5.61	7.45	-1.843	1.433	<0.0001
Revolizer®	5.45	8.16	-2.705	2.298	<0.0001

[Table/Fig-7]: Comparison of scores (paired differences) before and after training of inhaler devices usage.

*t-test

The number and percentage of errors after training the patients (post-training visit) for each device is presented in [Table/Fig-8].

Type of error	pMDI % (n=103)	pMDI with spacer % (n=51)	Rotahaler® % (n=51)	Revolizer® % (n=44)
At least one error	40.8 (42)	60.8 (31)	49.02 (25)	27.27 (12)
Handling error	40.8 (42)	60.8 (31)	13.73 (7)	9.09 (4)
Inhalation error	31.07 (32)	25.5 (13)	35.29 (18)	18.18 (8)

[Table/Fig-8]: Number of errors after the training course for each device.

Patients using Revolizer® conducted the least of handling error whereas those using pMDI committed the maximum handling error. Those using Rotahaler had erred the most during the inhalational sequences as compared to other forms of inhalational devices.

DISCUSSION

In this study, of the 249 participants, 26.1% (65) were woman and 73.9% (184) were men. The mean age of participants was found to be 37.31 years, with an average history of asthma of 5.9 years and average years of inhaler device usage was 4.25 years. Irrespective of pMDI or DPI, most of the asthmatics used their inhaler devices inappropriately, even though 92.4% (230) of the participants were confident of using their inhalation device. All the subjects using pMDI and pMDI with spacer were incompetent in completing all the steps of inhaler usage appropriately. Whereas, 7.8% of patients (4/51)

using Rotahaler®, 4.5% of patients (2/44) using Revolizer® were able to perform all the steps accurately. In India, Patil SB et al., studied 108 asthmatics, among them 22.1% (17/77) patients using pMDI and 41.9% (13/31) patients using DPI were able to complete all the steps [16]. In Nigeria, Onyedum CC et al., studied 140 asthmatics, among them 22.1% (31/140) of pMDI users and 37.3% (19/51) of DPI users completed all the steps [17].

In present study, it was observed that DPI users were able to perform the correct usage sequence of inhaler devices when compared to patients using pMDI and pMDI with spacer. In the past, numerous studies have revealed that DPI users can perform more accurately when compared to pMDI users [7,18]. Hence, selection of an inhalation device based on patient's individual preference and skill is one of the key determinant factors for erroneous inhalation techniques and treatment outcomes [19,20]. The present study revealed that a patient's educational status also affected the technique of inhaler device usage, and it was observed that, higher the education, the finer is inhaler usage technique. The study results were comparable to earlier studies which also revealed the same [8,17,18].

Educating the participants about the steps of using the inhaler served the important purpose in using all types of inhaler devices. In the present study, there was a statistically significant difference between the scores of the participants using pMDI, pMDI with spacer, Rotahaler®, and Revolizer® before the training and after the training. Among patients using pMDI 40.8%, pMDI with spacer users 60.8%, Rotahaler® users 49.02%, and Revolizer® 27.27% patients had committed, at least one error in using the device. The patients using Revolizer® conducted the least handling error whereas those using pMDI committed the maximum handling error. Those using Rotahaler had erred the most during the inhalational sequences as compared to other forms of inhalational devices.

In Saudi Arabia, Al-Jahdali H et al., studied 450 asthmatic patients, 39.1% (176/450) were males, 60.9% (274/450) were females. The incorrect usage of inhaler devices was observed in 45% (203) patients. The incorrect usage of inhaler devices was attributed to inconsistent hospital revisits by the patients and a lack of education on asthma [21]. A questionnaire-based, observational study by Ganguly A et al., enrolled 105 patients with asthma and Chronic Obstructive Pulmonary Disease (COPD). A 29.5% (31/105) patients used DPI, 47.6% (50/105) patients used pMDI, and 22.8% (24/105) on pMDI with spacer. There was statistical significance of errors committed between DPI and MDI users (difference of SE is 2.56) and between spacer and MDI users (difference of SE 2.92), at confidence limit of 95%. The pMDI with spacer was concluded as the most appropriate method. Often, doctors did not provide inhaler device usage technique education to the patients because of insufficient time [22]. Patil SB et al., studied 108 asthmatics using an inhaler device. A 28.7% (31/108) patient used DPI and 71.2% (77/108) patients used pMDI. The commonest error during usage of pMDI was the failure to coordinate between accentuation and inhalation. Among DPI users, the commonest error was the failure to inhale deeply and forcefully [16]. Ravikumar P et al., studied 120 asthmatic subjects, assessment during the first visit revealed that 152 types of mistakes were done by 104 (86.6%) subjects and during revisit, 40 types of mistakes were done by 23 (19.1%) subjects. Patient training regarding proper usage of inhaler devices resulted in the reduction of errors, which were statistically significant [23].

Limitation(s)

The instructor was not common among all the participants which can create bias among the patients. The study included only asthmatics and patients with other respiratory diseases requiring inhalation devices were excluded. Patients were followed-up only for one revisit at an interval of one month. As future perspective, a larger sample size, with patients' multiple revisits at periodic interval followed-up by same HCW would provide a much better information regarding the impact of education on device usage.

CONCLUSION(S)

Inhalation devices form the mainstay of treatment in asthma patients. The pMDI was the most used inhalational device. Majority of the patients committed errors while using the devices. The errors committed were in both handling and inhalational steps of inhaler device usage. When trained, the error percentage reduced significantly, thus assessing the inhaler device techniques during every hospital visit must be mandatory.

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