

Comparison of Inhaler Device Techniques Before and After Training in Patients with Chronic Obstructive Pulmonary Disease

S RAJESH KUMAR JAIN



ABSTRACT

Introduction: In the treatment of Chronic Obstructive Pulmonary Disease (COPD), the administration of drugs with an inhaler is often used. Improper usage of inhaler devices can result in suboptimal therapeutic effects which in turn can lead to the prescription of additional dose or drug with a higher tendency of developing side-effects. Very often patients are prescribed inhaler medications without adequate education on device usage.

Aim: To compare the techniques of inhaler devices usage, before and after training in patients with COPD.

Materials and Methods: An institutional-based, prospective study was conducted among COPD patients attending the Department of Pulmonary Medicine, Mysore Medical College and Research Institute, Mysuru, Karnataka, India, from March 2020 to September 2020. A total of 250 patients who met the diagnostic criteria recommended by Global initiative for chronic Obstructive Lung Disease (GOLD), previously on inhaler medications using pressurised Meter Dose Inhaler (pMDI), pMDI with spacer, Rotahaler® or Revolizer®, were included in the present study. The investigator employed a device-specific checklist to evaluate inhaler device usage by the participants. This checklist was scored, while the patient was observed utilising the inhaler device. Following which, each patient was educated regarding inhaler device usage by a doctor or nurse. For each correct and incorrect step, the patient received a score of "1" and "0" respectively. For each patient, the total score for all the steps was calculated

and was compared with the total score of post-training visit. The maximum score for pMDI was 11, for pMDI with spacer was 13 and for both Rotahaler®, and Revolizer® was 8. The minimum score for all the inhalation devices was 0. The R software was used for statistical analysis and descriptive statistics were represented in the form of tables, percentages, and frequencies. A p-value of <0.05 was considered statistically significant.

Results: A total of 250 patients using various inhalers (pMDI=54; pMDI with Spacer=80; Rotahaler®=67, Revolizer®=49) with mild to very severe COPD. The mean age of the participants was found to be 58.26 years (SD 6.48). Before training, only 1.25% (1/80) patients using pMDI with spacer were able to complete all the steps whereas none of the patients using pMDI, Rotahaler®, and Revolizer® were able to complete all the steps accurately. After training, 31.25% (25/80) of patients using pMDI with spacer, 11.94% (8/67) patients using Rotahaler®, and 44.89% (22/49) of patients using Revolizer® were able to accurately complete all the steps whereas none of the patients using pMDI were able to complete all the steps.

Conclusion: The majority of patients committed errors, both handling, and inhalational steps. When trained, the error percentage was reduced significantly among patients using all types of inhalers. Patients using Revolizer® conducted the least of handling errors, whereas those using pMDI committed the maximum handling errors. Patients using Revolizer® had erred the least with inhalation errors, whereas those using Rotahaler® had erred the most with the inhalational errors.

Keywords: Inhaler medications, Pressurised meter dose inhaler, Rotahaler, Revolizer, Spacer, Therapeutic effect

INTRODUCTION

At present, globally, Chronic Obstructive Pulmonary Disease (COPD) is the fourth most common cause of death [1]. By 2020, it is predicted to be the third most common killer disease. In the year 2012, more than 30 lakh people died of COPD. This represents about 6% of all deaths worldwide. As of 2016, three of the five leading causes of death in India are non communicable diseases, of which COPD holds second place [2]. Prevalence of COPD varies in different states of India. It ranges from 2 to 22% in males and 1.2 to 19% in females [3].

Aerosol therapy is preferred in the treatment of COPD. In clinical practise, aerosol therapy is delivered commonly by 3 methods: viz., 1) Nebulisers; 2) Dry Powder Inhalers (DPI); and 3) pressurised Meter Dose Inhaler (pMDI). Among these, pMDI and DPI devices are the preferred drug delivery systems in COPD patients. Although these devices are user friendly, improper usage can have suboptimal therapeutic effects [4]. Each sort of inhaler device has its own set of instructions about how to use it. In certain situations, the usage sequence gets mixed up amongst devices, leading to significant reduction of medicine delivered to target organ [5]. Inadequate therapeutic results due to improper inhaler technique are common,

can result in prescription of more or extra medicine, which has a higher risk of side-effects and expenses [6]. Inhaler device usage education to the patient is the foremost duty of the prescribing physician. Apart from clinicians, all other healthcare workers should be well aware of device specific instructions for usage, as the inhaler usage technique has to be checked for correctness during patient's revisits [7]. Very often, patients are prescribed inhaler medication devices without proper instructions for usage as the prescriber themselves may be ignorant regarding usage instructions [8,9]. Numerous studies have revealed that, it is very common that patients use their inhaler devices incorrectly [9,10].

A review of the literature reveals that in India there is a dearth of data regarding the assessment of correct usage of inhaler devices among COPD patients. Thus, the present study was conducted to compare the techniques of inhaler devices usage, before and after training among COPD patients. The present study was a part of a larger project done on inhalational device usage techniques among the patients suffering from asthma and COPD patients. The study on asthma patients concluded that majority of the asthmatics erred while utilising the inhaler devices and when trained, the error percentage reduced significantly [11].

MATERIALS AND METHODS

An institutional-based, prospective study was conducted among COPD patients attending Department of Pulmonary Medicine, Mysore Medical College and Research Institute, Mysuru, Karnataka, India, from March 2020 to September 2020. The Ethical Clearance certificate was obtained from Institutional Ethics Committee (dated: 10th March 2020, bearing No: EC-REG:ECR/134/Inst/KA/2013/RR-19).

Inclusion criteria: Patients who gave consent for the study and who met diagnostic criteria recommended by Global initiative for chronic Obstructive Lung Disease (GOLD) [12], previously on inhaler devices using pMDI, pMDI with spacer, Rotahaler[®] or Revolizer[®] were included in the study.

Exclusion criteria: Patients, below the age of 45 years and above 75 years were excluded from the study.

Sample size calculation: The sample size was found to be 223 with an estimated prevalence of 82.4% with a precision of 95% and allowable error of 5%. A final sample of 250 patients were included in the study.

Procedure

A device specific checklist was used by the investigator to evaluate inhaler device usage, which was scored, while the patient was observed using the inhaler medications. Subsequently, each patient was trained, to use the inhaler device with a demonstration by a doctor or a nurse. After 30 days (post-training visit) all the patients were re-assessed using the same checklist. For each wrong step, patients received a score of "0" (zero) and were rated "1" (one) for each correct step. Sum of the scores for all the steps was calculated for each patient, each type of inhaler and was compared with the subsequent evaluation. 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).

After training, during the follow-up, participants were checked for mistakes in using the type of the inhalational device assigned. '**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 5-10 seconds after inhalation, incomplete expiration before inhalation, no deep and slow inspiration, no forceful and deep inspiration, after inhalation and no exhalation with pursed up lips.

Checklist for pMDI users [11,13]:

1. Remove the cap of the pMDI.
2. Shake the pMDI well while keeping 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 pMDI from your mouth while holding your breath.
9. Gently breath out away from mouthpiece.
10. If an additional dose is required, wait for 60 seconds, and repeat steps 2 to 9.
11. Put the cap back on.

Checklist for pMDI with spacer users [11,13]:

1. Assemble spacer.
2. Remove the cap of the pMDI.
3. Shake the inhaler well while keeping it upright.
4. Insert pMDI 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 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 pMDI out of the spacer.
12. If an additional dose is required, wait for 60 seconds, and then repeat steps 3 to 11.
13. Put the cap of pMDI back on and disassemble spacer.

Checklist for Rotahaler[®] users [11,14]:

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. Exhale gently 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 for Revolizer[®] users [11,15]:

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. The R software was used for statistical analysis. Descriptive statistics were represented in the form of tables, percentages, and frequencies. The comparison of pretraining and post-training of inhaler devices usage was performed using Wilcoxon Signed Ranks test. A p-value of <0.05 was considered statistically significant for a confidence interval of 95%.

RESULTS

A total of 250 patients using various inhalers (pMDI=54; pMDI with Spacer=80; Rotahaler[®]=67, Revolizer[®]=49) with mild to very severe COPD.

Patient's characteristics are presented in [Table/Fig-1]. The mean age of the participants was found to be 58.26±6.48 (years). The average years with history of COPD were 6.34±3.94 (years). The average years of inhalers among these patients were found to be 4.96±3.27 (years).

Variable	n (%)
Gender	
Male	210 (84%)
Female	40 (16%)
Marital status	
Single	1 (0.4%)
Married	147 (58.8%)
Divorced	15 (6%)
Widowed	87 (34.8%)
Educational status	
Illiterate	165 (66%)
Less than 10 th standard	35 (14%)
More than 10 th standard	50 (20%)

[Table/Fig-1]: Demographic details.

[Table/Fig-2] presents the frequency distribution of inhaler devices and other variables like types of inhalers used, level of confidence (each patient was asked whether they are confident to use their inhaler device or not? If they were confident, they were rated as "yes" if not then "no") for using the inhalers, source of inhaler usage education, name of the inhaler medication known to the patient or not.

Variable	n (%)
Type of inhalational device used	
pMDI	54 (21.6)
pMDI with spacer	80 (32)
Rotahaler®	67 (26.8)
Revolizer®	49 (19.6)
Confidence of usage of device	
Confident	219 (87.6)
Not confident	31 (12.4)
Source of inhaler usage education	
Doctor	49 (19.6)
Literature	29 (11.6)
Nurse	55 (22.0)
Pharmacist	51 (20.4)
Audio-visual aid	22 (8.8)
Respiratory care technologist	44 (17.6)
Name of medication	
Known to the patient	111 (44.4)
Not known to the patient	139 (55.6)

[Table/Fig-2]: Inhalational devices.

Majority of the patients used pMDI with spacer (32%) followed by Rotahaler® (26.8%). Total 87.6% of the participants were confident of using inhalation device. Only 19.6% were taught how to use the device by a Doctor and others it was either a Nurse (22%) or Pharmacist (20.4%). Only 44.4% of the users knew the name of the medication which was being used.

The score for all the steps is summated for all types of inhalers i.e., pMDI, pMDI with spacer [Table/Fig-3], Rotahaler® and Revolizer® [Table/Fig-4]. The pretraining scores were also compared with post-training assessment.

None of the patients using pMDI, before and after training were unable to complete all the steps. Whereas only 1.25% (1/80) patients using pMDI with spacer were unable to complete all the steps appropriately before training and 31.25% (25/80) were able to perform all the steps accurately after training.

Score	pMDI (n=54)				pMDI with spacer (n=80)				
	Before training		After training		Score	Before training		After training	
	n	%	n	%		n	%	n	%
0	0	0	0	0	0	0	0	0	0
1	0	0	0	0	1	0	0	0	0
2	2	3.7	0	0	2	0	0	0	0
3	1	1.85	0	0	3	0	0	0	0
4	8	14.81	0	0	4	0	0	0	0
5	11	20.37	1	1.85	5	0	0	0	0
6	17	31.48	1	1.85	6	8	10	0	0
7	8	14.81	9	16.66	7	4	5	0	0
8	6	11.11	14	25.92	8	17	21.25	0	0
9	1	1.85	20	37.03	9	14	17.5	0	0
10	0	0	9	16.66	10	6	7.5	0	0
11	0	0	0	0	11	15	18.75	6	7.5
					12	15	18.75	49	61.25
					13	1	1.25	25	31.25

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

Score	Rotahaler® (n=67)				Revolizer® (n=49)				
	Before training		After training		Score	Before training		After training	
	n	%	n	%		n	%	n	%
0	0	0	0	0	0	0	0	0	0
1	0	0	0	0	1	0	0	0	0
2	4	5.97	0	0	2	0	0	0	0
3	9	13.43	0	0	3	0	0	0	0
4	13	19.4	5	7.46	4	5	10.2	0	0
5	22	32.83	12	17.91	5	14	28.57	0	0
6	6	8.95	21	31.34	6	27	55.10	3	6.12
7	13	19.4	21	31.34	7	3	6.12	24	48.97
8	0	0	8	11.94	8	0	0	22	44.89

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

During first visit none of the patients using Rotahaler® and Revolizer® were able to perform all the steps accurately but during the post-training follow-up, 11.94% (8/67) and 44.89% (22/49) patients using Rotahaler® and Revolizer® respectively, were able to perform all the steps accurately.

The comparison of pretraining and post-training of inhaler devices usage is depicted in [Table/Fig-5]. This comparison was performed using Wilcoxon Signed Ranks Test.

Inhaler device	Pretraining Mean±SD	Post-Training Mean±SD	z-value	p-value
pMDI	5.72±1.51	8.44±1.13	6.11	<0.0001
pMDI with spacer	9.45±1.97	12.24±0.58	7.47	<0.0001
Rotahaler	4.84±1.46	6.22±1.11	4.91	<0.0001
Revolizer	5.57±0.76	7.39±0.60	6.16	<0.0001

[Table/Fig-5]: Comparison of scores before and after training of inhaler devices usage. Wilcoxon Signed Ranks Test was applied p-value <0.05 considered significant

There was a statistically significant difference between the pretraining and post-training scores of the participants using all types of inhalers, both.

After training, during the follow-up, participants were checked for mistakes in using the type of the inhalational device assigned for handling errors and inhalation errors as depicted in [Table/Fig-6].

All participants (100%) using pMDI, committed atleast one error in using the device, of which 68.5% committed one or more handling

Type of error	pMDI % (n=54)	pMDI with spacer % (n=79)	Rotahaler® % (n=66)	Revolizer® % (n=48)
Atleast one error	100 (54)	31.6 (25)	12.1(8)	45.8 (22)
Handling error	68.5 (37)	17.7 (14)	47 (31)	8.3 (4)
Inhalation error	59.2 (32)	49.3 (39)	75.7 (50)	47.9 (25)

[Table/Fig-6]: Types of errors for each device during post-training visit.

error and 59.2% committed errors in the steps involving inhalation. Among patients using pMDI with spacer, 31.6% committed atleast one type of error. Total 17.7% handled it improperly and 49.3% had erred in the inhalational techniques. Among Rotahaler® users, 12.1% committed atleast one type of error, 47% had done mistake in handling the device and 75.7% of participants had got the inhalational techniques wrong. In the Revolizer® group, 45.8% had committed atleast one error in using the device, whereas only 8.3% had wrongly handled the device and 47.9% were wrong in their inhalational techniques while using the device.

DISCUSSION

Pharmacological treatment of COPD is based mainly on inhalation medications. There is a continuous need to examine and train patients in their inhalation technique [16]. If the patients use inhaler devices appropriately, irrespective of the type of inhaler i.e., nebuliser, DPI and pMDI, all are equally effective in terms of drug delivery. The pMDI can be used conveniently as it is light-weight, portable, multi-dose device which can be stored in any orientation without leakage, but coordination of pMDI actuation and inhalation is crucial step during inhaler usage. This issue can be addressed by using a Spacer device with pMDI [4].

In this study, the mean age of the participants was found to be 58.26 years (SD 6.48). The average years with history of COPD were 6.34 years (SD 3.94) and average years of inhalers among these patients were found to be 4.96 years (SD 3.27) and 84% were males. Majority of the patients used pMDI with spacer (32%), only 44.4% of the users knew the name of the medication which was being used.

Gregoriano C et al., studied a total of 165 patients, comprising 89 COPD patients, 50 asthmatics and 26 Asthma-COPD-Overlap cases for the assessment of the use and inhalation techniques of inhaler medication. Among COPD patients, 30% cases were reported to have very high impact and high impact on their health condition. Men constituted 71% with mean age of 69.8 years. Depending on the type of inhaler device, inappropriate inhalation techniques ranged from 0 to 53%. Patients using pMDI had erred the most while using inhaler device [17].

In this study, all patients (100%) using pMDI inhalers conducted some form of error in using the device, 31.6% of patients using pMDI with spacer committed atleast, any one type of error. There was a statistically significant difference ($p < 0.05$) between the scores of the participants using all types of inhalers before and after the training. Educating the participants about the steps of using the inhaler formed an important role in using all kinds of inhalers.

In an observational, cross-sectional study conducted by Sriram KB et al., 150 COPD patients were studied. Men constituted 52%, with mean age of 70.3 years. It was observed that irrespective of type of inhaler devices used by the patients, erroneous inhaler device techniques were rampant. Turbuhaler users erred the most (83%), while Handihaler users performed least errors (50%). Inhaler device technique errors and poor adherence was common among COPD patients [18].

In an observational, cross-sectional study conducted by Pothirat C and Percival M 103 COPD patients were studied for assessment of inhaler device usage technique. Males constituted 64.1% with a mean age of 71.2±9.2 years. A 74.8% (77/103) of patients

committed atleast one error. With 42.5%, Handihaler users had the least compliance failure rate. On comparing the Handihaler's Odds Ratio (OR) for failure with other inhaler devices it was observed that Accuhaler had an OR of 2.4 (95% CI=1.1-5.2), pMDI with a spacer had an OR of 3.1 (95% CI 1.2-8.2) and pMDI had an OR of 4.6 (95% CI 1.8-11.8). For all types of inhaler devices, formal education on inhaler usage techniques resulted in a statistically significant reduction in erroneous use [19].

The Real life Experience and Accuracy of inhaLer use (REAL) survey included 764 COPD patients using 4 types of inhaler devices. Respimat®=201, Ellipta®=191, Breezhaler®=186, and Genuair®=194. The mean age of participants was 56±9.8 years. A 30% of the patients did not receive any formal training on inhaler usage. A demonstration in-person was rated "extremely useful" by 83% of patients compared to 58% for a video demonstration. A 29% of patients have never been checked for correct usage of the inhaler technique. Checked individuals were substantially more adherent when compared to those who were not (p -value=0.020). Most of the subjects using Breezhaler® disclosed that they were extremely certain that they have taken a complete dose which was greater than using the other 3 inhalers. Breezhaler® had the highest treatment adherence in 30 days, followed by Respimat®, Ellipta®, and Genuair® [20].

To sum up, 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.

Limitation(s)

The instructor was not common among all the participants which could have created bias among the patients. The patients were followed-up only once at a one-month interval. In future, a larger sample size, follow-up re-evaluation for several visits by the same healthcare workers at frequent intervals would offer much better evidence on the influence of education on inhaler device usage.

CONCLUSION(S)

Inhalation devices form the major stay of treatment in COPD patients. pMDI with spacer was the most commonly used inhalational device among the COPD patients. Majority of patients committed errors while using the device. The errors committed were in both handling and inhalational steps of inhaler device usage. When trained, the error percentage reduced significantly.

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PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Pulmonary Medicine, Mysore Medical College and Research Institute, Mysuru, Karnataka, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. S Rajesh Kumar Jain,
House No. 376, New No: D-38, A. Ramanna Street, Devraja Mohalla,
Mysuru, Karnataka, India.
E-mail: rajeshh2310@gmail.com

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