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Predictors of Correct Technique of Pressurized Metered Dose Inhalers among Patients with Obstructive Airway Diseases At A Tertiary Care Hospital In Rajasthan, India

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Abstract
Background*: Correct inhaler technique is strongly associated with disease control, exacerbations, and healthcare costs. The objective of the study is to determine real life predictors of correct technique of pMDIs in obstructive airway disease patients.*
Materials and methods*: 100 diagnosed patients of obstructive airway diseases, aged ≥18 years from respiratory outpatients were recruited for this cross-sectional study. A questionnaire containing 14 real life predictors was administered and the pMDI technique (with or without spacer) was observed by a trained researcher on a 12-point checklist, of which 4 were considered critical.*
Results*: 22% patients did ≥10 steps correctly and only 19% patients could do the steps without any critical error. Statistically significant predictors among patients who did ≥10 steps correctly included, doctor - follow-up, explanation of technique, number of times explained & time taken, technique information from other source (p<0.0001), patient self-rating of technique on a scale of 1-10 (p<0.001), pneumococcal and influenza vaccination (p<0.0001), use of a spacer (p<0.001), patient perceived effectiveness of pMDI on their disease (p<0.001) and ease of use (p<0.0001). As regards to predictors for no critical errors, doctor : follow-up, explanation of technique, number of times explained & time taken, technique information from other source (p<0.0001), patient self-rating of technique on a scale of 1-10(p<0.001), pneumococcal and influenza vaccination (p<0.0001), use of a spacer (p<0.001), patient perceived effectiveness on their disease (p<0.001) and ease of use (p<0.0001). Occurrence of heart disease (p=0.039) and rating of the inhaler technique as difficult (p=0.027) are significant predictors for correct critical steps but are negatively correlated.*
Conclusion*: Predictors such as doctor follow-up, technique explanation by a medical practitioner and technique information from other sources were confirmed whereas the diagnosis or duration of inhaler use did not have any effect in their inhalational technique and the use of spacer came out as a positive predictor in our study. Patients' self-assessment correlated well with actual performance. These findings may be useful in correcting and optimizing the inhaler technique.*
Keywords*: Obstructive airway disease, critical error, inhalation technique.*

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I. Introduction

Obstructive airway diseases include a wide number of diseases, out of which Chronic Obstructive Pulmonary disease (COPD) and Asthma are the most common diseases, affecting up to 10% of world population. Many of them suffer from uncontrolled symptoms and may present to community healthcare settings with life-threatening exacerbations affecting about 50% of patients yearly[1].

Since these respiratory diseases affect a considerable proportion of world population, with increasing morbidity and mortality as the years goes on, active intervention should be taken to prevent as well as to optimize their treatment, with giving due importance to their medication adherence as well. Inhaler therapy forms the corner stone of the treatment of all obstructive airway diseases, with maximum use of it in control of Asthma and COPD. Recommended treatment strategies by the GOLD and GINA guidelines includes the use of inhaler devises, most importantly pressurized metered dose inhalers (pMDI) with or without spacer devices, dry powdered inhalers (DPI) and nebulizers [2,3].

Inhalation therapy being the preferred route of drug delivery in asthma and COPD patients, have the therapeutic advantage that the drugs are being directly administered into the lungs, thus providing a rapid onset of action [4]. It also has the advantage of the need of smaller doses, compared to systemic drugs, with a higher efficacy to safety ratio than systemic therapy.

If correct use and adherence are made sure then, this inhalational therapy can provide a normal life for the mild to moderately affected patients of obstructive airway diseases with very little or no symptoms, virtually

nil exacerbations, occasional reliever usage, normal lung function and very minimal adverse effects [5]. Poor handling and incorrect usage of these inhalation devises are the main factors behind the frequent exacerbations and poor disease control [1].

Previous studies have reported that only 10-50% of patients are able to use their inhaler devices, free of error [7]. Two studies have clearly mentioned about poor inhaler technique being associated with respiratory symptoms worsening [7,8]. This study aims to identify real life predictors of inadequate inhaler performance, from an array of possible predictors, which includes physician contact, smoking status, comorbidities, vaccination history, sources of information and training of inhaler technique, so that they may be used in clinical practice.

II. Materials and Methods

This study was initiated after seeking permission from Research review board and Institutional Ethics Committee of SMS medical college, Jaipur, a tertiary care government hospital, and was conducted from January 2020 to January 2021. Initially, the medical officers and the residents were sensitised to screen for all diagnosed cases of stable obstructive airway diseases. The inclusion criteria were age ≥18years and those who were using a pMDI device. We excluded those patients who were on multiple inhalation devices or devices other than pMDI, who required assistance from others to use the device and those who did not give consent for the study. All details about the study were explained to the subjects and their attenders and a written consent was obtained from each subject.

All the participants were interviewed using a pre-validated questionnaire, modified as per local need after discussion with senior faculty members of Respiratory medicine department of our college. The questionnaire included various questions related to patient diagnosis, co-morbidities and vaccinations, physician contacts, technique self-score, possible respiratory outcomes etc. Then, the subjects were asked to demonstrate the pMDI technique just as they do it at home, but demonstrations were done with a placebo device and was observed directly by single investigator (trained in proper inhalation technique based on recent ATS guidelines), to avoid inter-observer variability.

The inhaler technique of all the participants was assessed, using the standard 12-point checklist for metered dose inhaler with or without spacer use adapted from the American Thoracic Society [8], adding the manufacturer's advice to keep the head straight. Among the above 12-point check list, there are four critical steps (steps 2,6,8 and 10) selected from those recommended by Newman [9]. Inhaler technique performance was measured in three different variables: as the presence of at least one error (dichotomous variable); as a score on a 0 - 12 scale (continuous variable, according to the number of correct technical steps performed, among all the necessary steps for pMDI) and whether the patient completed ≥10 steps or not (dichotomous variable).

Table 1: Inhaler technique checklist

Steps	pMDI + Spacer	pMDI
1	Remove the cap from the inhaler.	Remove the cap from the inhaler.
2	**Shake the inhaler well for 5s**	**Shake the inhaler well for 5s**
3	Insert the inhaler into the open end of the chamber and ensure that the inhaler fits properly.	Hold the inhaler firmly by placing your index finger on top of the canister, and thumb on the bottom of the mouthpiece.
4.	Sit up straight or stand up.	Sit up straight or stand up.
5	Tilt your head back slightly	Tilt your head back slightly.
6	**Exhale completely away from the spacer**	**Exhale completely away from the inhaler.**
7	Place the mouthpiece in your mouth and seal your lips tightly around it.	Place the inhaler in your mouth and seal your lips tightly around it.
8	**Press the inhaler and breathe in steadily and deeply.**	**Press the inhaler and breathe in steadily and deeply**.
9	Remove spacer from the mouth.	Remove the inhaler from the mouth.
10	**Hold your breath for 10s or as long as is comfortable**.	**Hold your breath for 10s or as long as is comfortable.**
11	Exhale slowly.	Exhale slowly
12	Remove the inhaler from the chamber and replace covers.	Replace cap on inhaler.

III. Stastistical Analysis

Two criteria for inhaler technique were used with second one more precise than the first. The first one was the comparison of the characteristics of patients who completed ≥10 steps out of the 12 steps with those completing <9 steps and the second criterion where we compared patients with no critical error out of total four with those having atleast 1 critical error.

The presentation of the Categorical variables was done in the form of number and percentage (%). On the other hand, the quantitative data were presented as the means ± SD and as median with 25th and 75th percentiles (interquartile range). The following statistical tests were applied for the results: The comparison of the variables which were quantitative in nature were analyzed using independent t test and those which were qualitative in nature were analyzed using Chi-Square test. If any cell had an expected value of less than 5 then

Fisher's exact test was used. Multivariate forward step wise logistic regression was used to find out independent significant factors affecting 10 correct steps or more and no critical errors. Univariate and multivariate ordinal regression was used to find out factors affecting number of correct critical error. The data entry was done in the Microsoft EXCEL spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, IBM manufacturer, Chicago, USA, ver 21.0. For statistical significance, p value of less than 0.05 was considered statistically significant. Prospective power calculations, at an absolute allowable error of 10%, indicated that the over-all sample size of 84 patients was required, which was rounded off to 100 expecting 20% attrition.

IV. Results

a) Distribution of various predictors in the study sample

In our study sample, majority was COPD patients (67%), followed by bronchial asthma (23%) and the rest 10% belonged to others which included diagnosed cases of TB, bronchiectasis, and cystic fibrosis.

Though the treating doctor had explained the inhalational technique to 77% patients on their very first visit, only 22% patients did ≥10 steps correctly and only 19% patients could do the steps without any critical error. The patients who were on regular follow up after receiving the instruction to do so was only 35%. Most of the patients (48%) received only one time explanation. For most of them (54%), the time, doctor took for explanation is only 1 min. 23% patients never received the demonstration from their doctor even once and only 5% of study population received a repeated demonstration from the doctor on their every visit and 4% received a 3 min explanation of the technique.

64% subjects did not receive information about the inhalational technique from any other source apart from their treating physician, whereas 36% patients received the information from other means such as pamphlets, social media, nursing professionals or pharmacists. We had asked the patients to grade their inhaler technique in a score from 1 to 10, with 10 being the best and the mean was 4.17 (SD 2.2) and median - 3 (IQR 3-5). In our study sample 30% were recipient of influenza vaccination (current) and 29% pneumococcal vaccine. The rest of predictor's distribution are mentioned in table 2.

Table 2:-Distribution of Predictors

1. Disease	**Percentage**
Asthma	23.00%
COPD	67.00%
Others	10.00%
2. Smokers	
No	21.00%
Yes	79.00%
3. Spacer Use	
a. Advised	
No	85.00%
Yes	15.00%
b. Observed	
No	90.00%
Yes	10.00%
4. Years of inhaler use	
0 to 5 years	14.00%
5 to 10 years	28.00%
10 to 20 years	49.00%
>20 years	9.00%
5. Effectiveness	
Very effective	23.00%
Effective	50.00%
Not effective	27.00%
6. Ease of use	
Easy	7.00%
Normal	29.00%
Difficult	64.00%
7. Co-morbidities	
Hypertension	42.00%
Heart disease	14.00%
Diabetes mellitus	38.00%
Allergic rhinitis	18.00%

b) Univariate analysis results

Among the study sample it was found that those who were on regular follow-up with a medical practitioner (22%) did more steps correctly ($p<0.0001$) and had a smaller number of critical errors ($p=0.001$)

compared to those who did not follow-up. Also, it was observed that more patients did steps correctly (p=0.003) and without a critical error (p=0.005) when a doctor explained the technique than when he did not. The more times the doctor explained the technique on subsequent visits, more correctly the steps were done with lesser no of critical errors (p<0.0001). Similarly, more time the doctor took for explanation of technique, the greater number of patients did correctly the steps that too without a critical error (both had p<0.0001).

Among the study sample, it was observed that both groups, who did ≥10 steps correctly (54%) and those who did not (70%), were diagnosed cases of COPD. Similar findings were observed for those with no critical error and those with critical errors too.

The other statistically significant predictors among patients who did ≥10 steps correctly included, technique information from other source (p<0.0001), patient self-rating of technique on a scale of 1-10(p<0.001), pneumococcal and influenza vaccination (p<0.0001), use of a spacer (p<0.001), patient perceived effectiveness on their disease and ease of use (p<0.0001). On the other hand, presence of comorbidities, which included mainly hypertension (p=0.273), diabetes mellitus (p=0.499), heart disease (p=0.294) and allergic rhinitis (p=1), duration of inhaler use (p=0.314), the type of disease (p<0.249) and smoking status (p=0.41) turned out be statistically insignificant predictors for the same above criterion. The mean of technique self-score in those who did ≥10 steps correctly is 7.91(SD-0.92) and median is 8 (IQR 7-8).

As regards to predictors for no critical errors, technique information from other source (p<0.0001), patient self-rating of technique on a scale of 1-10(p<0.001), pneumococcal and influenza vaccination (p<0.0001), use of a spacer (p<0.001),patient perceived effectiveness on their disease (p<0.001) and ease of use (p<0.0001). As mentioned for the above criteria, presence of hypertension (p=0.613), diabetes mellitus (p=0.499), heart disease (p=0.294) & allergic rhinitis (p=1), duration of inhaler use (p<0.147), the type of disease (p=0.066) and smoking addiction (p=1) turned out be statistically insignificant predictors. The mean of technique self-score in those made no critical error is 7.47(SD-1.31) and median is 8 (IQR 7-8).

Comorbidity with heart disease (β estimate is -1.22, p=0.039) and rating of the inhaler technique as difficult (β estimate is -1.6, p=0.027) are significant predictors for correct critical steps but are negatively correlated. Table 3 reports the most relevant results in Univariate analysis.

Table 3:- Univariate analysis results

Doctor follow up	**>=10 steps (n=22)**	**<10 steps (n=78)**	**P value**	**No critical error (n=19)**	**Critical error (n=81)**	**P value**
No	0 (0%)	35 (44.87%)	<.0001†	0 (0%)	23 (28.40%)	0.005†
Yes	22 (100%)	43 (55.13%)		19 (100%)	58 (71.60%)	
Total	22 (100%)	78 (100%)		19 (100%)	81 (100%)	
Doctor explained the technique						
No	0 (0%)	23 (29.49%)	0.003†	0 (0%)	23 (28.40%)	0.005†
Yes	22 (100%)	55 (70.51%)		19 (100%)	58 (71.60%)	
Total	22 (100%)	78 (100%)		19 (100%)	81 (100%)	
Number of times explained						
0 time	0 (0%)	23 (29.49%)	<.0001†	0 (0%)	23 (28.40%)	<.0001†
1 time	0 (0%)	48 (61.54%)		1 (5.26%)	47 (58.02%)	
2 times	8 (36.36%)	7 (8.97%)		4 (21.05%)	11 (13.58%)	
3 times	9 (40.91%)	0 (0%)		9 (47.37%)	0 (0%)	
At every out patient visit	5 (22.73%)	0 (0%)		5 (26.32%)	0 (0%)	
Total	22 (100%)	78 (100%)		19 (100%)	81 (100%)	
For how long the doctor explained (in minutes)						
0	0 (0%)	23 (29.49%)	<.0001†	0 (0%)	23 (28.40%)	<.0001†
1	5 (22.73%)	49 (62.82%)		5 (26.32%)	49 (60.49%)	
2	13 (59.09%)	6 (7.69%)		10 (52.63%)	9 (11.11%)	
3	4 (18.18%)	0 (0%)		4 (21.05%)	0 (0%)	
Total	22 (100%)	78 (100%)		19 (100%)	81 (100%)	
Information from any other source						
No	2 (9.09%)	62 (79.49%)	<.0001†	1 (5.26%)	63 (77.78%)	<.0001†
Yes	20 (90.91%)	16 (20.51%)		18 (94.74%)	18 (22.22%)	
Total	22 (100%)	78 (100%)		19 (100%)	81 (100%)	
Spacer Use						
No	12 (54.55%)	78 (100%)	<.0001†	9 (47.37%)	81 (100%)	<.0001†
Yes	10 (45.45%)	0 (0%)		10 (52.63%)	0 (0%)	
Effectiveness						
Very effective	15 (68.18%)	8 (10.26%)	<.0001‡	12 (63.16%)	11 (13.58%)	<.0001†
Effective	5 (22.73%)	45 (57.69%)		5 (26.32%)	45 (55.56%)	
Not effective	2 (9.09%)	25 (32.05%)		2 (10.53%)	25 (30.86%)	
Total	22 (100%)	78 (100%)		19 (100%)	81 (100%)	
Ease of use						
Easy	2 (9.09%)	5 (6.41%)	<.0001†	3 (15.79%)	4 (4.94%)	<.0001†

Normal	19 (86.36%)	10 (12.82%)		15 (78.95%)	14 (17.28%)	
Difficult	1 (4.55%)	63 (80.77%)		1 (5.26%)	63 (77.78%)	
Total	22 (100%)	78 (100%)		19 (100%)	81 (100%)	
Influenza vaccine						
No	3 (13.64%)	67 (85.90%)	<.0001†	3 (15.79%)	67 (82.72%)	<.0001†
Yes	19 (86.36%)	11 (14.10%)		16 (84.21%)	14 (17.28%)	
Pneumococcal vaccine						
No	7 (31.82%)	73 (93.59%)	<.0001‡	5 (26.32%)	75 (92.59%)	<.0001‡
Yes	15 (68.18%)	5 (6.41%)		14 (73.68%)	6 (7.41%)	

† Fisher's exact test, ‡ Chi square test

c) Multivariate forward step wise logistic regression results

Technique self-score was found to be positively correlated with inhalation technique (β coefficient=2.99, p=0.004) in ≥10 correct steps criteria and patient's reporting of technique as 'very effective' in no critical error criteria (β coefficient=3.4, p=0.04). The significant predictors of univariate ordinal regression affecting the number of correct critical errors are shown in table 3.

V. Discussion

The objective of the study is to assess the association of real-life predictors with correct inhalational technique. There was a total of 100 hospital outpatients who were on regular inhaler treatment with only 35% on regular follow up. The main parameters checked to see whether the patients were doing the inhalation technique correctly are **a)** whether they completed ≥10 steps out of 12 recommended steps and **b)** whether they had atleast a critical error step or not (adapted from Bartolo et al [10]).Bartolo et all [10] in their study observed that patients with asthma receiving inhaled corticosteroids were more likely to perform more correct steps. But on our study, the diagnosis of the patient did not have an effect in their inhalational technique, possibly due to the bias of having more COPD patients in our study population. Also, in our government hospital we see a trend of patients seeking the treatment for the shortness of breath at MMRC grade 3 or 4, by the time it is usually difficult to diagnose the allergic or adult-onset asthma. Hence patients with the diagnosis of asthma were less in our sample population.

While 68% of patients (who did ≥10 steps correctly) were prescribed a spacer, only 45% were using it. The similar ratio was observed in other studies also [10]. But contrary to the previous study, spacer use was a positive predictor for both correct steps and correct critical steps in our study. One can speculate possible explanation that since the spacer was used mainly by older patients and the increased effectiveness from their symptoms while using the spacer might have encouraged for a regular follow up with their doctor and a desire to understand and do the steps as advised by the medical practitioner. The use of spacer devices or holding chambers with pMDIs facilitate the coordination between actuation and inhalation and reduce the impaction of large particles in the oropharynx [11].

Though 77% had received the prior instruction on use of the inhaler, only 22% were able to do ≥10 steps correctly and only 19% of them did all the critical steps correctly. This is much lower from previous studies [10], which was both hospital and community-based study, whereas ours was only a hospital-based study. A follow-up with a medical practitioner and explanation of the technique, the number of demonstrations and the time duration for the explanation, all came out to be positive predictors in both the criteria for a correct inhalation technique. All the above parameters were statistically significant too.

Maricoto et at [(1)], in their study observed that although most patients had received previous inhaler education, in most cases this was performed only once by the doctor at the time of initial prescription, which highlighted the need to improve regular follow-up and further educational interventions. They pointed out that, inhaler review should ideally occur at every appointment, however due to the limited available time during each visit, practical tools may be developed, to help clinicians to prioritize high-risk patients. Another study suggested that placebo device training may be better than verbal explanation alone[12].

Re-education seems to be one of the most important measures to improve the inhalational technique. A series of studies conducted between 1982 and 2000 to assess pMDI use after reading inhaler package inset and/or receiving instructions [13]. The number of patients who can use the inhaler without errors have declined as the years goes on signifying the importance of re-education to maintain and ensure the adequate use of inhalers. In other words, previous ability to correctly use a pMDI is not indicative of correct use during subsequent testing thus continuous re-evaluation is a must.

Patient's own evaluation is one of the best predictors and is a statistically significant positive predictor of our study, which also had been suggested previously by Erikson [14] as well. During the study period, both pneumococcal and influenza vaccine was not free of cost and had to be purchased, and this could explain that as a predictor it probably reflected a stronger motivation to look after oneself [15].

Patient receiving information about inhaler technique from other source also turned out to be a positive predictor for both criteria. According to an observation made by a study, multimedia counseling came out be as

effective and time efficient as conventional counseling in MDIs inhaler technique education [16]. In addition, van der Palen et al [17] have shown us that the use of instructions using a video causes an improvement in inhaler techniques when compared to those who received personal instructions. Some experts have suggested the combination of video as well as personal instructions [18,19].

None of the comorbid conditions (except heart disease), smoking addiction and duration of inhaler use of the subjects reached a statistically significant predictor in our study, which may be due to the smaller sample size. But the occurrence of heart disease as negative predictor may be explained by the fact that cardiac patients might be less keen to use the inhalers, possibly fearing their adverse effects such as palpitations or tremors.

The strength of the study is the extensive number of predictors tested and the fact that the steps were based on evidence from scientific literature allowed a broad analysis of pMDI technique. The main weakness of our study was that inhaler technique was assessed by human observer rather than recording on a video camera, possibly leading to possible inaccurate assessment of the technique and observer bias. Information bias is also a possible another limiting factor.

Though none of the inhaler users were previously informed that their technique would be assessed on the day of their OPD visit, they may have performed the technique more correctly as they were being watched, and hence that performance could be different from their routine original performance and the number of detected errors might be smaller. The cross-sectional design limits the interpretations of the findings and establishment of any cause-and-effect relationships, which should be addressed in a longitudinal cohort study.

The number of asthma patients was small and underrepresented. Even though our sample size was small, a significant number of predictors were detected in our study. Hence it reinforces the fact that these predictors have a strong clinical effect which can be measured too. If we had taken a larger sample, then more predictors might have been detected which may have a lesser impact. Though our results are comparable to the other studies of similar topic conducted worldwide, they may not be generalized to the health care systems or different populations with different cultures and attitudes towards disease.

Previous studies have revealed an incorrect usage of inhaler device even by medical personnel [20.] This can be addressed by specific training courses about the correct technique for healthcare professionals on whom most of the patients rely for information about the technique rather than printed or electronic media. While patient knowledge and competence also need to be addressed, the mode of instruction may also need to be clearly communicated to the less educated patients with visual demonstration in real life or video demonstration[18] and perhaps allocating more time. While one study failed to show any benefit in technique from increased specific knowledge [21], in the experience of the authors, patients who understand the mechanics of inhaler technique are more likely to learn.

VI. Conclusion

This real-life study showed that in this group of patients treated with pMDI, most of them (78%) failed to achieve 9 out of 12 correct steps and only 19% had no critical errors in technique. While previously established predictor instruction by health care professional and technique information from other sources were confirmed, diagnosis and duration of disease were not. Seeking pneumococcal and influenza vaccination predicted fewer critical errors, possibly reflecting a motivation to look after oneself. Use of a spacer was also a positive predictor of good technique possibly as the spacer was used mainly by older patients and the effective symptom control while using the spacer might have encouraged for a regular follow up with their doctor and a desire to understand and do the steps as advised by the medical practitioner. Also, we notice that patient's self-assessment score statistically correlated with their actual performance.

A medical practitioner re-enforcing the technique on each follow up produced optimal results, indicating that many predictors of good pMDI technique are treating-doctor dependent. The possible two methods may achieve better results in the inhaler technique. One can either attempt to optimize and individualize the educational intervention on patients during their regular visit to their treating doctor or conducting an awareness program for them or rely on technological advances in the modern world of inhaler devices making them easier to use.

Our findings emphasize that suboptimal inhaler technique is common in real life with pMDIs emphasizing the potential role of regular assessment and reinforcement of correct inhalational technique in achieving treatment efficiency and improving disease outcomes. Healthcare professionals identify poor adherence with inhalers as a major barrier to the delivery of effective asthma and COPD care, yet practical interventions are lacking. It is to be noted that, in addition to training about the technique at the time of prescription, patient should receive repeated checking and demonstration as the correct technique is usually forgotten over time.

Counseling of patients and their caregivers, performed by health care professionals, plays a key role in inhaler use to minimize errors and optimize treatment. Moreover, it is to be noted that, this is a modifiable risk factor, and some findings of the present study can even act as reference points in the inhaler technique to be

targeted for further improvement, as well as allowing the identification of the profile of those patients who will potentially require further clarification regarding inhaler use.

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