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Original Article

Assessment of the Inhaler Handling Technique In Patients With Chronic Obstructive Pulmonary Disease In A Chest Clinic.

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Abstract

Background: Improper handling of inhaler devices can result in errors that affect drug delivery to the lungs and ultimately influence disease outcomes. This study assessed inhaler techniques and risk factors for critical errors in COPD patients at a tertiary chest clinic in Nigeria.

Methodology: Spirometry-confirmed COPD patients were evaluated using a standardized inhaler technique checklist. Demographic and clinical data were collected. Inhaler use was classified as correct/no error, non-critical errors, or critical errors.

Results: Eighty patients participated, with 49 (61.3%) being males. All participants used pressurized metered dose inhalers (pMDI), and 70 (87.5%) used dry powder inhalers (DPI). Correct inhaler technique was observed in 7.5% of pMDI users, significantly lower than the 20% among DPI users ($p = 0.025$). Critical and non-critical errors occurred in 62.5% and 77.5% of pMDI users, and 68.6% and 65.7% of DPI users, respectively. The most common critical error among pMDI users was failure to actuate during deep slow inhalation, while among DPI users it was failure to exhale fully before inhalation. Self-reported inhaler dissatisfaction predicted critical errors among pMDI users. Among DPI users, predictors included female sex, lack of recent inhaler technique training, and lower inhaler satisfaction.

Conclusion: Critical inhaler technique errors are highly prevalent among COPD patients in this setting, particularly among pMDI users. Factors such as inhaler dissatisfaction, female sex, and lack of recent inhaler training increase the risk of errors. These findings highlight the need for regular assessment of inhaler technique and personalized patient education to optimize device use and improve outcomes.

Keywords: Inhaler, Errors, Handling Technique, COPD

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Introduction

Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide, causing significant economic and social burdens. [1,2] Nearly 90% of COPD-related deaths in individuals less than 70 years of age occur in low- and middle-income countries (LMIC). [1] The prevalence and burden of COPD are projected to increase in the coming decades due to continued exposure to COPD risk factors and the aging global population.[3] The primary goals of COPD management are to reduce both current symptoms and future risks, and these goals can be reached with minimal side effects from inhaled drug therapy.[2]

Inhalation therapy is a crucial and common method for managing COPD and other obstructive airway diseases.[4] It allows for direct delivery of small doses of bronchodilators and corticosteroids to the lungs, leading to a rapid onset of action and a lower incidence of side effects compared with the oral delivery route.[5] The various inhalational devices available for delivering treatments to patients with COPD include nebulizers, pressurized metered-dose inhalers (pMDIs), dry powder inhalers (DPIs), and soft mist inhalers (SMIs).[6-8] While each of the delivery devices provides similar outcomes in patients when the correct technique is utilized, a significant limitation to effective use is the inability to use these devices properly.[9-11] Although inhaled devices are relatively simple devices to operate, their proper use is not entirely intuitive. Each device has technical requirements that can limit its effectiveness.[4] In some cases, the steps can be confused between devices, resulting in severe reductions in the amount of medication delivered to patients. [12]

Research indicates that poor inhalation technique leads to inadequate disease control in patients with obstructive airway disease, diminished medication efficacy, increased likelihood of prescription escalation, higher probability of side effects, and increased healthcare costs. [13-14] To address these issues, patients require thorough education in the correct inhaler use. Healthcare providers (HCPs) can also play a key role by regularly checking patients' inhaler techniques and providing effective inhaler training. It is also important for HCPs to maintain their knowledge of correct inhaler techniques, as incorrect assumptions about their proficiency can hinder patient education.[15]

A systematic review and meta-analysis review of device errors in asthma and COPD patients reported an alarmingly high rate of overall and critical errors across all devices, ranging from 50-100% and 14-92%, respectively. [7] However, there is a notable lack of data on the correct use of inhaler devices among COPD patients in Nigeria and sub-Saharan Africa.

This study aimed to evaluate the prevalence and types of inhaler technique errors among COPD patients in a Nigerian tertiary hospital and to identify patient-related factors associated with critical errors.

Materials and Methods

Study Design and Setting

This hospital-based descriptive cross-sectional study was conducted among stable COPD patients aged 40 years and older at the respiratory outpatient clinic of a tertiary health care facility in Nigeria over a three-month period.

Sampling Method

A non-probability convenience sampling method was used, where all consecutive consenting patients who met COPD diagnostic criteria recommended by the Global Strategy for the Diagnosis, Management and Prevention of COPD were recruited for the study. [2]

Sample Size

The minimum sample size required for this study was calculated using Cochran's sample size formula for categorical data. [16] The initial calculation assumed that the population size exceeded 10,000, using the following parameters.

Thus

$$n = \frac{Z2pq}{d2}$$

Where n = the desired sample size when the target population exceeds 10,000.

Z = standard normal deviation, usually set at 1.96, corresponds to a 95% confidence level.

p = proportion in the target population was estimated to have a particular characteristic. The prevalence of COPD is 7.7% in Nigeria [15], p =0.077.

q = 1- p,d = degree of accuracy desired, which is set at 0.05. Therefore, the sample size will be:

$$n = \frac{(1.96)2 \text{ X } (0.077) \text{ X } (0.92)}{(0.05)2} = 108.9 \text{ approximately } 109$$

Given that the actual number of COPD patients who were on follow-up management at the outpatient chest clinic of the hospital is less than 10,000 (approximately 200 patients in 2019 based on the respiratory unit record statistics), we applied a finite population correction factor to adjust the sample size.

The finite population correction factor of $nf = \frac{n}{1 + n/N}$

where nf = the desired sample size when the population is less than 10,000, and where n was the calculated sample size when the population is greater than 10,000, N = Total number of patients on treatment for COPD in the Hospital.

Therefore, $nf = \frac{109}{1 + 109/200}$

Nf = 70.3 subjects, approximately 70 subjects.

To account for potential non-response and recording errors, we increased the sample size by 10%, resulting in a minimum sample size of 77 subjects. Ultimately, 80 consenting subjects were recruited for the study.

Study participants

All patients meeting the inclusion criteria were approached to participate in the study. The inclusion criteria were as follows:

- Patients with spirometry-confirmed stable COPD who had been on inhaler therapy for at least six months. Stable COPD patients were defined as those with no exacerbation or hospital admission in the preceding four weeks and no recent change in maintenance COPD medications during the preceding three months.
- Patients with no evidence of severe cognitive impairment.

Data collection

Data was collected through face-to-face interviews conducted by postgraduate resident doctors in respiratory medicine using a structured questionnaire after an informed written consent was obtained. The questionnaire captured sociodemographic information, respiratory symptoms, COPD history, inhaler technique education, and medication type. Following the survey, the resident doctors assessed the patients' inhaler techniques using a standardized checklist. If any mistakes were identified, patients were educated on the correct use of their inhaler medications.

Outcome Measures
Correct/No error inhaler use refers to the completion of all the steps for the correct use of the inhaler device. [7,11]

Critical errors are those that affect lung deposition of inhaled drugs, potentially resulting in little or no drug deposition **[**7,17]

Non-critical errors are those that cause **suboptimal administration**, but the patient may still inhale some portion of the drug dose into the airways [7]

Due to a lack of consensus on the standardized inhaler checklist, we adopted a checklist of critical errors from previous literature.[11] The details of the checklist used to assess inhaler technique are listed in Supplement S1, and the critical steps are indicated in asterisks.

Statistical Analysis
All statistical analyses were performed using SPSS software (version 24.0; SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as the mean ± standard deviation and compared using Student's t-test or the Mann–Whitney U-test. Categorical variables will be compared using the chi-squared test or Fisher's exact test. Post-hoc pairwise comparisons with a Bonferroni correction were used to find where the difference lies between the patients' related variables and the type of inhaler errors. The factors associated with correct/error-free technique with a p-value < 0.2 in the univariate analyses were further analyzed in multivariate analyses to determine odds ratios (ORs) and 95% confidence intervals (CIs) by the backward method.

Ethical considerations
The study received approval from the ethics and research review committee of the hospital. Written informed consent was obtained from each participant prior to their inclusion in the study.

Results

Sociodemographic and clinical characteristics of patients

A total of 80 patients were recruited during the study period. The general characteristics of patients are summarized in Table 1. There were 49 (61.3%) males and 31(38.8%) females with a mean age of 64.9 years (SD=10). Most of the patients (64%) were married, and almost half of them (48.8%) had not completed primary education. Most patients reported having intermittent cough (90%), 76.3% had shortness of breath, 42.5% reported intermittent wheezing, and 22.5% experienced chest pain/tightness. The median duration of COPD was 24 months, with an interquartile range of 1-48 months. The median duration of inhaler use was 14 months.

Table 1: Sociodemographic Characteristics of Patients

Patients Characteristics	**n (%)**
Mean age (years)	65±10
Sex	
Male	49(61.3)
Female	31(38.8)

Education	
None	39(48.8)
Primary	7(8.8)
Secondary	11(13.8)
Tertiary	23(28.8)

Results expressed in frequency in %

Table 2: Clinical characteristics of patients

Clinical Characteristics	
Median Duration of COPD (months)	24 (12-60)
Mean number of exacerbations in the preceding 12 months	1.6 ± 1.0
Modified MRC dyspnea scale	
Grade 0	10 (12.5%)
Grade 1	10 (12.5%)
Grade 2	36 (45.0%)
Grade 3	18 (22.5%)
Grade 4	6 (7.5%)
COPD medication	
Inhaled:	
Ventolin inhaler	80(100%)
Seretide Diskus	70(87.5%)
Symbicort Turbohaler	-
Salmeflo inhaler	-
Oral: Aminophylline tablet+ Prednisolone + Salbutamol tablet	16(20%)

Usage pattern of the device

All the patients had been using inhalers for at least 6 months. All the patients were on salbutamol pMDI, while 70 (87.5%) were on a combined inhaled steroid and long-acting beta agonist inhaler. Only 2 (2.5%) patients were on anticholinergic inhalers. Sixteen patients (20%) used oral theophylline, prednisolone, and salbutamol in various combinations (Table 1). Notably, only 20 (25%) of patients felt confident in their inhaler use. Among the patients, 70 (87.5%) received instructions on proper inhaler use in the past, with 58(82.9%) of pMDI users and 6 (8.6%) of DPI users receiving the training from doctors. Most patients (66; 82.5%) reported that their inhaler technique had been rechecked by a health care practitioner in the preceding year, and (56; 70%) preferred pMDI over other devices. Overall, 30 patients (37.5%) were satisfied with the performance of their device.

Frequency of non-error/good inhaler technique

Inhaler technique was evaluated using the nine-step checklist. Among the 80 patients who used pMDI, 6 (7.5%) completed the checklist steps without any error and were denoted as correct/no error with good pMDI use. Of the 70 patients using DPI, 14 (20%) were classified as no-error, meaning they completed the DPI device steps without any error and were denoted as good DPI inhaler use. A significant percentage of

DPI users (20% vs. 7.5%) completed the nine-step technique with no error compared with pMDI users (p = 0.025).

Frequency of critical and non-critical inhaler technique errors

Among 80 pMDI users, 50 (62.5%) made one or more critical errors, and 62 (77.5%) made one or more non-critical errors. Of the 70 patients using DPI, 48 (68.6%) made one or more critical errors, and 46 (65.7 %) made one or more non-critical errors. Among those using pMDI, 32(65.3%) males made critical errors compared to 18 (58.1%) female patients (p=0.515). There was no significant sex difference in the critical error among those using pMDI. However, 25 (89.3%) of the females compared with 23 (54.8%) of the male patients using DPI had one or more critical errors (p =0.002).

Association between patient characteristics and pMDI errors

Table 3 demonstrates that there was a significant association between inhaler technique errors and their self-reported inhaler confidence (p= 0.018) as well as patients' reported satisfaction with the device (p=0.046). Post-hoc pairwise comparisons with a Bonferroni correction indicated that non-error was significantly associated with self-reported patients' inhaler confidence (p=0.014). Critical errors were significantly associated with no/unsure reported patient satisfaction (p = <0.001).

Association between patient characteristics and DPI errors

As shown in Table 4, there was a significant association between DPI technique errors and sex (p=0.010), inhaler confidence (p =< 0.001), and patients' reported satisfaction with the device (p=0.029). Post-hoc pairwise comparisons with a Bonferroni correction indicated that non-error was associated with reported inhaler confidence (p=0.001), and critical error was significantly associated with no reported patient inhaler confidence (p = <0.001). Non-errors were also associated with reported patient satisfaction (p = <0.021), and critical error was significantly associated with no/unsure reported patient satisfaction (p = <0.001).

Table 3: Association between patient characteristics and inhaler use errors in pMDI Users

Patients Characteristics	**Critical Errors n=50**	**No Critical Errors n =62**	**No-Errors n=6**	**p Values**
Age (years)				
< 65	22(44)	22(35.5)	3(50)	0.573
65 and above	28(56)	40(64.5)	3(50)	
Sex				
Male	32(54)	38(61.3)	3(50)	0.793
Female	18(36)	24(38.7)	3(50)	
Self-reported confidence in using the Inhaler correctly				
Yes	8(16)	14(22.6)	4(66.7)	**0.018**
No/Not sure	42(84)	48(77.4)	2(33.3)	
Sources of inhaler training				
Doctors	40(80)	50(80.6)	6(100)	0.483
Others HCP	10(20.)	12(19.4)	-	

Method of inhaler technique training				
Verbal	8(16)	10(16.1)	0	0.789
Demonstration	26(52)	32(51.6)	4(66.7)	
Verbal + Demonstration	8(16)	12(19.4)	2(33.3)	
Product insert	8(16)	8(12.9)	-	
HCP inhaler technique training in the past 1year				
Yes	28(56)	34(54.8)	6(100)	0.098
No	22(44)	28(45.2)	-	
Most preferred inhaler device				
pMDI	34(68)	44(71)	6(100)	0.532
Diskus	0(0)	2(3.2)	--	
pMDI + Diskus	2(4)	2(3.2)	-	
None	14(28)	12(22.6)	-	
Satisfaction with the device performance				**0.046**
Yes	10(20)	24(38.7)	4(66.7)	
No	6(12)	10(16.1)	0	
Not sure	34(68)	28(45.2)	2(33.3)	

Results expressed in frequency in %

Table 4: Association between patient characteristics and DPI errors

Patients Characteristics	**Critical Errors n=48**	**No Critical Errors n =46**	**Non-Errors n=14**	**p Values**
Age (years)				
<65	15(31.3)	1634.8)	8(57.1)	0.201
65+	33(68.8)	30(65.2)	6(42.9)	
Sex				
Male	2347.9)	28(60.9)	13(92.9)	**0.010**
Female	25(52.1)	18(39.1)	1(7.1)	
Self-reported confidence in using the Inhaler correctly				
Yes	4(8.3)	8(17.4)	8(57.1)	**<0.001**
No/Not sure	44(91.7)	38(82.6)	6(42.9)	
Source of inhaler training				
Doctors	40(83.3)	38(82.6)	14(100)	0.246
Others HCP	8(16.7)	8(17.4)	-	

Method of inhaler technique training				
Verbal	8(16.7)	6(13)	4(28.6)	0.394
Demonstration	26(54.2)	30(65.2)	4(28.6)	
Verbal + Demonstration	10(20.8)	6(13)	4(28.6)	
Product insert	4(8.3)	4(8.7)	2(14.3)	
HCP inhaler technique training in the past 1year				
Yes	42(87.5)	36(78.3)	10(71.4)	0.300
No	6(12.5)	10(21.7)	4(28.6)	
Most preferred inhaler device				
pMDI	36(75)	32(69.6)	12(85.7)	0.679
Diskus	-	2(4.3)	-	
pMDI + Diskus	2(4.2)	2(4.3)	-	
None	10(20.8)	10(21.7)	2(14.3)	
Satisfied with the device performance				
Yes	12(25)	16(34.8)	10(71.4)	**0.029**
No	8(16.7)	6(13)	-	
Not sure	28(58.3)	24(52.2)	4(28.6)	
	-			

Results expressed in frequency in %

Type of inhaler technique errors observed

The most common error among pMDI users overall included not shaking the inhaler (52.5%), and the most common critical error was not triggering the inhaler while breathing in deeply and slowly (30%). (Figure 1). On the other hand, for DPI users, the most common error overall was not exhaling deeply, away from the mouthpiece before inhalation (48.6%). This was also the most common critical error. (Figure 2).

Factors associated with critical inhaler technique errors

Multivariate analysis shows that critical error among MDI users was independently predicted by self-reported satisfaction with the device. The predictors of critical error among the DPI users were female gender, inhaler technique training by Doctor/HCP in the past 1year, and patients' reported satisfaction with the device (Table 5)

Table 5: Predictors of Inhaler Critical Error in pMDI and DPI users

Predictors	**aOR**	**95% CI**	***p*-value**
pMDI			
Self-reported dissatisfaction with the device	3.06	1.63-5.75	<**0.001**

DPI			
Female	7.95	1.46-43.40	**0.017**
Lack of inhaler technique training by the Doctor/HCP in 1year	17.51	2.46-124.66	**0.006**
Self-reported dissatisfaction with the device	16.41	2.73-98.79	**0.002**

Discussion

This study identified the high prevalence of inhaler technique errors among COPD patients in our locality, with pMDI users exhibiting more overall errors and DPI users having more critical errors. To the best of our knowledge, this is the first study that determines the prevalence of pMDI and DPI errors in COPD patients while also identifying the most problematic steps and determinants of critical errors. Our findings revealed that a large proportion of COPD patients at our chest clinic used their inhaler incorrectly by performing at least one step on the checklist for inhaler technique wrongly. The most common critical errors among the pMDI users were not triggering the inhaler while breathing in deeply and slowly, and for DPI users, it was failure to exhale fully before inhalation.

Although inhalers are the best way to administer medicine to COPD patients, our research indicates that many patients still struggle with proper usage. Nine of 10 patients who used pMDI made at least one inhalation technique error, while 8 of 10 patients who used DPIs made at least one inhalation technique error. Our results are comparable to previously reported findings in a systematic review and meta-analysis that found most patients using various devices made errors with inhaler use, with around 50-100% of them making at least one mistake. [15] Also, the overall error rate was higher for pMDI devices compared to DPI devices, and the pMDI and DPI critical error rates varied between 14-92% across different devices. We also observed a very high critical error rate of 62.5% among pMDI users and 68.6% for DPI users. This was higher than frequencies reported in a similar study, which was 45.6% for critical errors among pMDI users and 21% among DPI users [15,17], demonstrating less effective techniques in our locality. When compared to a previous study on asthmatic patients 18, this study showed higher error rates among COPD patients. In the asthma study, 77.9% of pMDI users and 62.7% of DPI users made errors, compared to 92.5% and 80% in this study, respectively. The differences in inhaler performance between asthma and COPD patients may be attributed to age, socioeconomic conditions, and disease duration. [19-21]

We also observed that ‘not shaking the inhaler" was the most common error by pMDI users, while the most common critical error was ‘not triggering the inhaler while breathing in deeply and slowly’. This finding partly agrees with a previous study that identified "no exhalation before actuation’ and ‘not continuing to inhale slowly after activation of the canister’ as the most common critical errors. [20] Furthermore, we observed that about half were not shaking the inhaler, and one in three patients were "not holding the inhaler upright" and "not triggering the inhaler while breathing in deeply and slowly." The data from the literature

show that up to 7-57% of subjects do not shake their pMDI before actuation, and this has been noted to be common in clinical practice. [10,23-24] The variation in the most common critical errors may be due to the patient characteristics, study setting, universally accepted checklist steps, and heterogeneity of the studies. Previous research also reports negative impacts of not shaking pMDI suspensions on pharmacological outcomes, including erroneous administration, reduced systemic availability, and a 25% decrease in emitted dose if not shaken.[25-27] Other previous studies had reported poor hand–lung synchronization as the most common critical error, and poor actuation–inhalation coordination was observed in about 20–40% of patients with asthma and COPD. [18,22,28]

The most common critical error among DPI users was 'not exhaling deeply away from the device' (48.6%), followed by 'not exhaling gently away from the mouthpiece after inhalation' (40%). However, this error percentage was lower than the 65.8% among 316 patients suffering from asthma or COPD in the Netherlands, but higher compared to the 22% and 21% reported by Melani et al. [22] in an Italian study. It has also been reported that the most frequent error made by users of DPIs was ''not correctly performing the exhalation maneuver before inhaling.[29] This step is important, as without adequate exhalation to functional residual capacity, patients may be unable to inhale forcefully and deeply enough through their DPI to ensure the drug deposition into the lungs. [29]

The independent predictors for critical errors among DPI users were female gender, patient-reported satisfaction with the device, and lack of inhaler training in the past 12 months. Among pMDI users in the present study, patient satisfaction with the device emerged as the sole predictor of critical inhaler errors. These finding aligns with prior evidence indicating that inhaler technique is not a static skill but one that deteriorates over time in the absence of reinforcement.[22] The higher prevalence of critical DPI errors observed among female patients may reflect a combination of physiological factors, such as lower peak inspiratory flow required for optimal DPI performance [29,30] A study by Calzetta et al [31] similarly reported higher rates of critical errors among female users, supporting the hypothesis that sex-specific considerations may be relevant when selecting and training patients on DPI devices.

Consistent with published literature, the lack of inhaler training within the preceding 12 months underscores the importance of periodic reassessment and re-education during routine follow-up visits. [32-34] A systematic review demonstrated that the absence of prior inhaler instruction is associated with a higher frequency of inhaler errors, while structured educational interventions significantly reduce error rates and positively influence both disease control and patient-reported outcomes. [17] Accordingly, healthcare providers are encouraged to assess inhaler techniques at every clinical encounter, actively inquire about the patient's inhaler use, identify errors, provide corrective education through physical demonstration, and reinforce proper techniques at subsequent visits.

Inhaler performance and patient satisfaction appear to be closely interrelated. Devices perceived as easier to use due to factors such as intuitive handling, clear dose indication, comfort, and convenience tend to generate higher patient satisfaction. [35-38] This satisfaction, in turn, is associated with improved adherence, reduced symptom burden, and better clinical outcomes. [39-41] Patients often favor inhalers that feel reliable and manageable, even when their technique is not optimal, highlighting that perceived usability may influence inhaler effectiveness. [35-36]

Our study findings may not be generalizable due to limitations of the study design, patient populations, and outcomes. Employing a prevalence estimate specific to inhaler errors (as reported in global or regional studies) may have been more appropriate and would have potentially strengthened the sample size estimation. Also, our sample of patients may not reflect the wider COPD population in Nigeria, as this

study evaluated patients seen in a tertiary health care setting only. Additionally, we did not consider a wide range of variables affecting inhaler use errors, including patient bias and physical limitations. We also acknowledge the possibility of the Hawthorne effect, where participants may temporarily improve their technique due to being observed. This could be nullified in future studies using video recording or independent blinded assessors to mitigate observer bias. Nonetheless, this study provides very valuable insights into inhaler techniques in patients with stable COPD in a resource-limited setting.

Conclusion:

Inhaler technique errors are highly prevalent among COPD patients in our setting, particularly those using pMDIs. These findings underscore the need for targeted interventions, including routine technique assessments and structured re-education, which are essential to improving inhaler use and therapeutic outcomes in this population.

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