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Evaluation of symptom control in chronic obstructive pulmonary disease after reinforcement of proper inhaler technique

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Abstract

Chronic obstructive pulmonary disease (COPD) remains a leading cause of morbidity and mortality worldwide. Proper inhaler technique is a critical component of effective COPD management, yet it is often suboptimal in clinical practice. This study aimed to evaluate the impact of reinforcing proper inhaler techniques on COPD symptom control. This was a pre-post, prospective study conducted in the Department of Pharmacology at a tertiary care hospital in Delhi. A total of 118 COPD patients using inhalers were enrolled. A prospective study of 118 COPD patients using either dry powder inhalers or metered dose inhalers was carried out in the outpatient clinic of our hospital. Participants received structured demonstrations of proper inhaler technique at baseline (day 0), week 4, and week 8, with final evaluations at week 12. Symptom control was assessed using the COPD Assessment Test (CAT) score, and inhaler technique was evaluated using the Inhaler Technique Score (ITS). Adverse effects were monitored and documented. The study demonstrated a significant improvement in both CAT and ITS scores over the 12-week follow-up. The proportion of participants achieving optimal CAT scores (0-10) increased from 4.24% at baseline to 12.7% by week 12. Concurrently, the percentage of participants scoring the maximum ITS of 10 increased from 0% at baseline to 90.7% by week 12. Adverse effects were minimal, with 92.37% of participants reporting no adverse effects. A negative correlation was observed between changes in ITS and CAT scores, highlighting the effectiveness of the intervention in improving COPD symptom control. In conclusion, reinforcing proper inhaler technique through structured educational interventions significantly improves COPD symptom control, as evidenced by enhanced CAT and ITS scores. This study emphasizes the need for routine education and reinforcement of inhaler use in COPD management to achieve optimal clinical outcomes.

Key words: COPD, inhaler technique, symptom control, COPD assessment test, patient education, adherence, quality of life.

Introduction

Chronic obstructive pulmonary disease (COPD) is a prevalent and treatable condition characterized by persistent respiratory symptoms and airflow limitation.¹ COPD is a leading global cause of morbidity and mortality, contributing to a substantial economic and social burden [1,2]. COPD accounted for approximately 3.2 million deaths worldwide, ranking it third among leading global causes of death and seventh in disability-adjusted life years (DALYs) [2,3]. Despite advancements in therapeutic interventions, COPD remains poorly controlled in many patients due to inadequate adherence to prescribed treatment, particularly inhaler therapy [2,3].

While inhaler devices have evolved significantly over the years, the effectiveness of these devices heavily relies on proper inhalation manoeuvres and patient adherence. Studies indicate that improper inhaler technique is a significant barrier to achieving optimal outcomes in COPD management [4,5]. Proper inhaler technique is a cornerstone in the management of COPD, as it ensures efficient drug delivery, optimal therapeutic benefit, and symptom control. However, research suggests that more than half of COPD patients fail to use their inhalers correctly. Common errors include failure to exhale before inhalation, incorrect positioning of the inhaler, and inadequate breath-hold following inhalation. These mistakes contribute to insufficient drug deposition in the lungs, diminished symptom control, and increased disease progression [4,5].

Patient education and reinforcement of correct inhaler technique have been shown to improve treatment efficacy and disease control [6]. Despite this, there is a paucity of literature exploring the impact of structured reinforcement of inhaler technique on COPD outcomes. This study aims to address this gap by assessing the qualitative impact of reinforcing correct inhaler technique on COPD control using the COPD Assessment Test (CAT) [7]. By focusing on patient education and repeated reinforcement, this study seeks to demonstrate the importance of proper inhaler technique in improving symptom management and overall quality of life in COPD patients.

Materials and Methods

A single centre, hospital-based, prospective study was conducted to evaluate the impact of reinforcing proper inhaler technique on COPD control. The study was conducted in the Department of Pharmacology in collaboration with the Department of Pulmonary Medicine at a tertiary care centre in Delhi, India. The total duration of the study was 18 months.

Sample selection

Participants included COPD patients aged 18 years and above, who had been on inhaler therapy for at least three months. The inhaler therapy was either in the form of MDI or DPI, but the drugs were optimised and on a stable dose. Inclusion Criteria included Age ≥ 18 years and COPD patients using inhalers for at least three months. All age group participants underwent standardized inhaler technique training, which minimized the effect of age-related differences. Exclusion Criteria included presence of other comorbid diseases, including asthma and terminally ill patients.

Sample size

The sample size was calculated based on the mean and standard deviation of pre- and post-CAT scores from a previous study. A total of 118 eligible participants were enrolled, ensuring sufficient power to detect significant differences. No separate control group was taken. The patients were compared pre and post reinforcement of inhaler technique. Non-probability convenience sampling was employed to recruit participants from the outpatient department.

Outcome parameters

Primary Outcome was improvement in COPD control assessed using the COPD Assessment Test (CAT) score at baseline, Week 4, Week 8, and Week 12. Secondary Outcome was severity of adverse drug reactions (ADRs) associated with inhaled COPD medications.

Methodology

The study was conducted in the Ethical clearance for the study was granted by the Institute's Ethical Committee. Approval was obtained after thorough scrutiny of the study protocol, data collection tools, and the bilingual informed consent form. The study adhered to the principles outlined in the Declaration of Helsinki to ensure ethical conduct, including the protection of participants' rights, safety, and well-being. Participants were recruited by the principal investigator based on the inclusion criteria. Eligibility was determined through medical records and clinical evaluation. Written informed consent was obtained from all participants using a bilingual consent form (English and Hindi), ensuring that participants were fully aware of the study's purpose, procedures, and potential risks. A pre-tested structured data collection form was used to record demographic details, inhaler technique scores, CAT scores, and any reported ADRs. Data were sourced from direct patient assessments, medical records, and participant self-

reports. Participants were followed up over a period of 12 weeks, with assessments conducted at baseline (Day 0), Week 4, Week 8, and Week 12 to monitor changes in inhaler technique and COPD control.

Definition of the intervention

The intervention involved structured reinforcement of proper inhaler technique (*Supplementary Table 1*) through demonstrations conducted at baseline (Day 0), Week 4, and Week 8, with a final assessment at Week 12.

Objective inhalation technique assessment was evaluated by looking at the number of steps completed by following the correct sequences of the steps that were recorded.

Participants were monitored for ADRs at each follow-up visit. Any ADRs were documented, assessed for causality, severity, and preventability, and addressed promptly.

Operational definitions

- COPD Control: Defined as a reduction in CAT score, indicating improved symptom management and quality of life.
- Inhaler Technique Score (ITS): A score ranging from 0 to 10, evaluating the accuracy of inhaler use by participants during each visit.
- Adverse Drug Reaction (ADR): There were mainly 4 drugs used that is, formoterol(12mcg), budesonide(400mcg), glycopyrrolate(25mcg), salbutamol(100mcg).
- Any unintended or harmful reaction to inhaled medications documented during the study.

Data collection procedure

Participants' baseline inhaler technique and CAT scores were recorded on Day 0. A stepwise demonstration of correct inhaler use was provided, followed by post-demonstration assessments. Reinforcement of inhaler technique was conducted at Week 4 and Week 8, with final evaluations at Week 12. All data were systematically recorded and securely stored.

Statistical analysis

The study hypothesis was tested using paired t-tests to compare pre- and post-intervention CAT and ITS scores. Data were entered into MS Excel and analyzed using Stata 17.0. Results were presented as mean $\pm$ SD, and p-values < 0.05 were considered statistically significant.

Results

The study included 118 participants, with a majority being male (72.9%, n=86) and the remainder female (27.1%, n=32) as shown in (Table 1). The mean age of the participants was 57.8 years (SD: 9.14). A small proportion of the participants were classified as obese (7.63%, n=9), with a mean BMI of 23.2 (SD: 4.76).

The COPD Assessment Test (CAT) scores showed a significant improvement across the study period (Tables 2 and 3). At Week 0, most participants had CAT scores in the ranges of 11–20 (43.22%) and 21–30 (51.69%). By Week 4, the proportion of participants in the 11–20 range increased to 66.1%, while those in the 21–30 range decreased to 28.8%. Further improvements were observed at Week 8 and Week 12, with 72% and 75.4% of participants, respectively, achieving CAT scores in the 11–20 range. Additionally, participants with scores in the optimal range of 0–10 increased steadily from 4.24% at Week 0 to 12.7% at Week 12, reflecting enhanced symptom control following reinforcement of proper inhaler technique.

The Inhaler Technique (IT) scores demonstrated substantial improvement over the study period (Table 3). At Week 0, the most frequent IT scores were in the mid-range, with 38.1% of participants scoring 8 and 28.8% scoring 7. By Week 4, significant improvements were noted, with 44.9% achieving a score of 9 and 24.6% achieving the highest score of 10. This trend continued at subsequent follow-ups, with 58.5% scoring 10 by Week 8 and 90.7% achieving a perfect score by Week 12.

Adverse effects were minimal during the study, with 92.37% (n=109) of participants reporting no adverse effects. Among those who experienced adverse effects, the most common were dry mouth (2.54%, n=3), followed by constipation (1.69%, n=2) and headache (1.69%, n=2). Less frequent adverse effects included thirst (0.85%, n=1) and tremors (0.85%, n=1). These findings indicate that the reinforcement of proper inhaler technique was well-tolerated with minimal side effects.

A negative correlation was observed between improvements in CAT scores and changes in IT scores across the study period, indicating that as IT scores improved, CAT scores decreased, reflecting better symptom control. The correlation coefficient was strongest during the initial 0–4 weeks (-0.42), followed by a moderate correlation from 4–8 weeks (-0.29) and a weaker correlation from 8–12 weeks (-0.19). These findings underscore the importance of early and consistent reinforcement of proper inhaler technique in achieving optimal COPD symptom management.

Discussion

This study underscores the critical importance of proper inhaler technique in managing COPD effectively. Despite advancements in inhaler technology, a significant proportion of patients continue to use their devices incorrectly, leading to suboptimal therapeutic outcomes and disease control. The findings of this study confirm that structured reinforcement of inhaler technique can significantly improve both symptom control and inhaler technique proficiency [8]. The demographic data revealed a predominance of male participants (72.9%), consistent with the higher prevalence of COPD in males. The mean age of 57.8 years aligns with the typical onset and diagnosis of COPD in middle-aged to older adults.

The findings of the present study demonstrate a significant improvement in Inhaler Technique Scores (ITS) across the 12-week study period. At baseline, the mean ITS was 7.36 ± 1.25 , which increased to 8.74 ± 1.15 at Week 4, 9.38 ± 0.818 at Week 8, and 9.89 ± 0.366 at Week 12. These improvements were statistically significant, underscoring the impact of repeated reinforcement of proper inhaler technique.

The results of this study align with similar studies done in past [9]. They reported that score increased from an average of 4.4 to 6.1, MDI with spacer from 4.56 to 6.26, and DPI from 4.92 to 6.24 ($p < 0.001$ for all) after receiving counselling. Significant improvements were also seen in disease control; MDI users' CAT scores dropped from 23.4 to 20.5, MDI with spacers from 23.92 to 20.96, and DPI's from 24.89 to 21.96. Similarly, a study in [2011] highlighted that nearly 60% of patients using inhalers made critical errors at baseline, which were reduced substantially after personalized education and training [10].

The mean post-test ITS scores in this study consistently approached 10 across all follow-ups, reflecting the short-term effectiveness of one-on-one demonstrations. These findings are consistent with earlier study published in [2013], who found that direct observation and correction during clinic visits improved technique to near-perfect scores immediately post-intervention [11].

The findings of this study reveal a significant and progressive improvement in COPD symptom control, as measured by the COPD Assessment Test (CAT) scores. At baseline, the mean CAT score was 20.4 ± 4.22 , reflecting suboptimal control of COPD. This decreased to 18.8 ± 4.08 at Week 4, 17.3 ± 4.36 at Week 8, and 15.6 ± 3.99 at Week 12, indicating a steady reduction in symptom severity over time. These improvements were statistically significant at each follow-up, demonstrating the effectiveness of reinforcing proper inhaler technique.

The consistent improvement in CAT scores over the study period suggests that repeated reinforcement of inhaler technique plays a critical role in achieving sustained symptom control.

The reduction in CAT scores observed in this study also correlates with the improvements in inhaler technique scores (ITS), reflecting the strong relationship between proper inhaler use and symptom management

The present study observed a low incidence of adverse drug reactions (ADRs) among participants, with 92.37% of the 118 patients reporting no ADRs. Mild ADRs such as dry mouth (2.54%), constipation (1.69%), headache (1.69%), thirst (0.85%), and tremors (0.85%) were reported by a small percentage of participants. All ADRs were categorized as mild based on Hartwig's Severity Assessment Scale and were preventable as per Schmuck and Thornton's Preventability Criteria [12]. The findings are consistent with existing literature indicating that inhaled COPD medications are generally well-tolerated when used correctly. The low incidence of ADRs in this study also correlates with the improvement in inhaler technique [13]. Furthermore, the absence of severe ADRs in this study aligns with findings that patient education and proper inhaler technique significantly reduced the occurrence of ADRs, particularly those related to incorrect dosing or poor drug deposition.

This study's findings align with existing literature, emphasizing that proper inhaler technique is a cornerstone of effective COPD management. Previous studies have highlighted similar challenges with inhaler technique and the benefits of patient education. The present study builds on this by demonstrating the sustained impact of reinforcement on both inhaler technique and clinical outcomes. The study's limitations include its single-center design and the use of convenience sampling, which may limit the generalizability of the findings. Future research should explore the long-term impact of such interventions and their cost-effectiveness in diverse healthcare settings.

Conclusions

This study highlights the critical role of reinforcing proper inhaler technique in improving symptom control among COPD patients. Structured educational interventions resulted in significant improvements in COPD Assessment Test (CAT) scores and Inhaler Technique Scores (ITS), with most participants achieving optimal symptom management and correct inhaler usage by the end of the 12-week follow-up. Additionally, the intervention was well-tolerated, with minimal adverse effects reported. The findings underscore the importance of integrating regular education and reinforcement of inhaler technique into routine COPD management to enhance therapeutic outcomes and patients' quality of life. This approach can address a key barrier to effective COPD treatment, ensuring better disease control and reduced healthcare burden.

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Online supplementary material:

Supplementary Table 1. Inhalation technique steps and score.

Table 1. Distribution of participants in the study.

Characteristic	Number	%
Female	32	27.1
Male	86	72.9
Age (mean, SD)	57.8	9.14
Obese	9	7.63
BMI (mean SD)	23.2	4.76

Table 2. Trend in COPD Assessment Test (CAT) score during the study.

CAT score range	Week 0 frequency (%)	Week 4 frequency (%)	Week 8 frequency (%)	Week 12 frequency (%)
0-10	5 (4.24%)	6 (5.08%)	9 (7.63%)	15 (12.7%)
11-20	51 (43.22%)	78 (66.1%)	85 (72%)	89 (75.4%)
21-30	61 (51.69%)	34 (28.8%)	24 (20.3%)	14 (11.9%)
31-40	1 (0.85%)	0 (0%)	0 (0%)	0 (0%)

Table 3. Distribution of participants in the study, pre and post IT score and CAT score improvement.

	Baseline	4 weeks	8 weeks	12 weeks
Age (Mean)	58 years			
Gender (Male)	72.9 %			
Weight (kgs)	63.38 +/- 13.29 kg			
Height (m)	1.60+/-0.088m			
BMI (kg/m²)	23.2 +/- 4.76kg/m ²			
Pretest ITS score^a (mean± SD)	7.36 ± 1.25	8.74 ± 1.15	9.38 ± 0.818	9.89 ± 0.366
Post-test ITS score^a (mean± SD)	10	10	10	10
CAT score^b (mean ± SD)	20.4 ± 4.22	18.8 ± 4.08	17.3 ± 4.36	15.6 ± 3.99
p-Value	< 0.0001	< 0.0001	<0.0001	< 0.0014

a: total score out of 10; b: total score out of 40; * p-value < 0.0001 on paired t-test between scores of week 4 and day 0; ** p-value < 0.0001 on paired t-test between scores of week 8 and week 4 and ***p-value < 0.0014 on paired t-test between scores of week 12 and week 8)