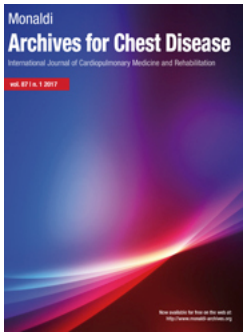

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# The impact of pharmacist engagement on satisfaction with inhalers among patients with chronic obstructive pulmonary disease: a prospective interventional study

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**Abstract**

Chronic obstructive pulmonary disease (COPD), predicted to become the third leading cause of death by 2030 with 3 million annual fatalities, imposes significant health and economic burdens due to its diverse respiratory conditions. Effective management strategies include symptom relief, disease progression control, and exacerbation prevention through interventions like smoking cessation, medication, rehabilitation, and vaccination, with inhalation therapy (pressurized metered-dose inhalers, dry powder inhalers, and nebulizers) playing a pivotal role, yet challenges in proper inhaler use persist, impacting disease control and healthcare utilization, necessitating improved patient education, inhaler designs, and healthcare system support.

The objective of this study was to examine the inhaler proficiency of COPD patients and evaluate their health status, along with their satisfaction regarding inhaler usage. COPD patients were enrolled, with their demographics recorded before evaluating inhaler skills through teach-back; health status was assessed using the COPD Assessment Test (CAT) and satisfaction with inhaler use with the Feeling of Satisfaction with Inhalers Questionnaire (FSI-10), followed by pharmacist-led education and leaflet distribution, with 6-week and 3-month follow-ups for monitoring and support. Pharmacist involvement significantly improved COPD patients' satisfaction with inhalers, shifting from 91.81% to 36.36% reporting high satisfaction and from 8.18% to 63.63% reporting low satisfaction ($p<0.001$). Additionally, pharmacist intervention reduced the proportion of patients with very high CAT scores (>30) from 6.36% to 4.54% and high CAT scores (>20) from 48.18% to 24.54%, while increasing those with medium CAT scores (10-20) from 28.18% to 54.54% ($p<0.001$).

Our study highlights that educating patients on proper inhaler techniques significantly improves COPD management, reducing exacerbations and hospital readmissions. Despite improvements in symptoms and quality of life (decreased CAT scores), patient satisfaction (FSI-10 scores) increased, suggesting effective intervention outcomes. The findings underscore the importance of enhancing patient education and adherence strategies, especially for those previously unaware of inhaler techniques. This emphasizes the need for comprehensive COPD management strategies addressing symptom relief and patient well-being.

**Key words:** chronic obstructive pulmonary disease, pressurized metered-dose inhalers, dry powder inhalers, feeling of satisfaction with inhalers questionnaire, COPD assessment test.

## Introduction

Chronic obstructive pulmonary disease (COPD), a prevalent lung condition, leads to airflow limitation and respiratory difficulties. It is a major contributor to long-term illness and poses substantial public health challenges. The disease is characterized by persistent respiratory symptoms and airflow obstruction, often stemming from extended exposure to harmful substances like particles or gases [1].

COPD stands as a major global health concern, posing considerable healthcare and economic burdens. According to the World Health Organization, it ranks third among the leading causes of death worldwide by 2030, claiming over three million lives each year. The prevalence of COPD varies across nations but is frequently associated with smoking rates and urbanization, which heighten exposure to risk factors. Despite being preventable and manageable, COPD often goes undiagnosed and untreated due to its subtle onset and slow progression, leading to delayed medical intervention until the condition has advanced significantly [2].

Inhalation therapy is the cornerstone of symptomatic management in COPD, which includes the use of bronchodilators and corticosteroids to ease symptoms, improve airflow, and reduce exacerbations. The efficacy of these treatments is highly dependent on the proper use of inhaler devices: pressurized metered-dose inhalers (pMDIs), Dry Powder Inhalers (DPIs), and nebulizers. Ensuring that patients can effectively and consistently apply their inhalation technique has profound implications for the control of COPD, influencing clinical outcomes, reducing healthcare utilization, and improving patient quality of life. Therefore, continual efforts to enhance education and support structures around inhaler use are vital components of effective COPD management strategies [3].

Despite the critical role of inhalers in managing COPD, incorrect inhaler technique remains common, contributing to poorer health outcomes, including increased exacerbations and hospitalizations. These challenges are compounded by the variety of available inhaler devices, each requiring different techniques for optimal use.

Studies have described that a significant percentage of patients do not use their inhalers correctly. Common errors include incorrect timing of inhalation, failing to shake the inhaler, not holding the breath after inhalation, and improper storage of the device. These mistakes can lead to inadequate dosing, where the medication does not reach the lungs effectively, thereby reducing its efficacy and potentially leading to worsening symptoms.

Compounding the issue, many patients do not receive proper instruction on inhaler techniques at the point of prescription or in follow-up appointments. Healthcare providers may assume

patients understand their devices or may themselves lack the training to instruct effectively. Moreover, the short duration of typical medical consultations might not provide sufficient time to assess and correct inhaler technique thoroughly.

Another significant challenge in effective inhaler use is patient adherence to prescribed regimens. Several factors influence adherence, including the entanglement of the inhaler regimen, the patient's perception of the medication's effectiveness, side effects, and the physical or psychological ability to follow the treatment plan consistently. Non-adherence can lead to poor disease control and increased risk of severe exacerbations requiring hospital care. Educational interventions have been shown to improve inhaler technique and adherence; however, these programs are not universally available and may not be repeated regularly to reinforce proper technique over time. Additionally, some educational materials may not be tailored to meet diverse patient needs, particularly in terms of language, literacy, and cultural context, which can hinder effective learning and engagement.

While inhalers are a fundamental component of COPD management, their effectiveness is closely tied to the correct usage by patients. Addressing the challenges associated with inhaler use requires a multifaceted approach, including better patient education, simpler and more intuitive inhaler designs, and greater support from healthcare systems to ensure regular assessment and reinforcement of inhaler techniques. Such efforts are needed to enhance patient outcomes and induce the burden of COPD on individuals and healthcare systems alike [4].

***Stages of COPD by GOLD (Global Initiative for Chronic Obstructive Lung Disease)***

The GOLD (Global Initiative for Chronic Obstructive Lung Disease) stages of COPD assess the severity of COPD by evaluating the extent of airflow obstruction using spirometry, particularly the forced expiratory volume in 01 second (FEV1).

Stage 1 (Mild): FEV1 is at least 80% of the predicted value. Patients might have a persistent cough and produce mucus, but these symptoms usually do not significantly interfere with daily activities.

Stage 2 (Moderate): FEV1 ranges from 50 % to 79 % of the expected value. Symptoms such as shortness of breath during physical activities become more apparent, often leading patients to seek medical advice.

Stage 3 (Severe): FEV1 is between 30% and 49% of the estimated value. Symptoms intensify, including greater breathlessness, decreased exercise tolerance, fatigue, and frequent exacerbations that considerably impact quality of life.

Stage 4 (Very Severe): FEV1 is below 30 % of the estimated value, or below 50% with chronic respiratory failures. Symptoms are very severe, with frequent exacerbations that pose a high risk of life-threatening incidents, greatly limiting daily activities and diminishing quality of life4. The GOLD classification also incorporates symptom severity and history of exacerbations alongside spirometry results to personalize treatment and management strategies effectively.

## Materials and Methods

### *Study design and subject*

This prospective interventional study was conducted on adult patients diagnosed with COPD and attending the respiratory department of Tertiary Care Hospital, Belagavi. Institutional Ethics Committee, Belagavi granted approval for the study protocol (reference number-KLECOPBGMEC/D014-2023). Each subject provided written informed permission prior to enrolment.

### *Participants*

Sample size: 105

$n = z2 \times p \times q\ d2$

$n = (1.96)2 \times 0.074 \times 0.926\ (0.05)2$

$n = 105.28$

Where, z = 1.96 (corresponding to a 95% confidence level)

p = 7.4% (prevalence of COPD)

d = 0.05 (desired level of precision)

q = (1-p) =1-0.074 = 0.926

Inclusion criteria encompass patients diagnosed with COPD using inhalers, while exclusion criteria excludes COPD patients not using inhalers, patients who were on alternative medicines like Ayurveda or Homeopathic, individuals in the terminal phase of the disease, and special populations such as pregnant, and lactating women. The study included patients who had been using a metered dose inhaler continuously for the past 6 months. Patients without documented current or previous use of MDIs were excluded from the study. Additionally,

patients using nebulizers or other types of inhalers apart from MDIs, as well as those unable to self-administer their pMDI, were also excluded.

***Study procedure***

COPD patients were recruited based on predefined inclusion and exclusion criteria. Their demographic information and inhaler usage were recorded, and their inhaler technique was evaluated using a teach-back approach. The health status of each patient was assessed using the COPD Assessment Test (CAT) questionnaire to gauge the severity of their condition. Additionally, levels of patient satisfaction with inhalers were measured using the Feeling of satisfaction with inhalers (FSI-10) questionnaire. A pharmacist conducted an educational intervention focused on proper inhaler technique, supplemented by a validated patient information leaflet. Follow-up assessments were scheduled between 6 to 12 weeks post-recruitment, with the first follow-up occurring at 6 weeks and the second at 3 months. Throughout the study, patients were provided with the leaflet to support their understanding and use of inhalers effectively.

***Evaluation instrument***

The satisfaction level of patients with their metered dose inhalers was assessed using the FSI-10 questionnaire, for which permission was obtained from the authors under legal protocols regarding copyright. This tool evaluates patient satisfaction across 10 questions covering aspects like portability, ease of use, affordability, difficulties in handling, and overall satisfaction. Each question uses a 5-point Likert scale ranging from "very" to "hardly at all," with scores from 5 to 1 respectively, resulting in a minimum score of 0 indicating total dissatisfaction and a maximum of 50 indicating high satisfaction. The questionnaire was also translated into Urdu for native-speaking patients. Patients independently completed the questionnaire both before and after the intervention, and satisfaction levels were categorized according to predefined criteria: scores below 43 indicating low satisfaction and scores of 43 or higher indicating high satisfaction [5].

The CAT questionnaire was used during the initial baseline and first visit to assess patients. Three months later, patients were revisited to evaluate their condition and complete the CAT again. This questionnaire focuses on 8 aspects: cough, mucus production (expectoration), difficulty breathing (dyspnea), chest tightness, self-confidence, limitations in daily activities,

quality of sleep, and energy levels. Scores on the CAT range from 0 to 40, where higher scores indicate more severe health impacts and lower scores indicate better health [6].

### *Statistical analysis*

Statistical analysis was conducted using IBM SPSS 27. Continuous variables were presented as mean ± standard deviation, while categorical variables were expressed as frequencies and percentages. Descriptive statistics were computed for the variables of interest. An ANOVA test was used to compare the means across different groups. A paired t-test was performed to analyze pre-post differences in continuous variables, while the Wilcoxon signed-rank test was applied for non-normally distributed data. Spearman's rank correlation test was employed for non-parametric correlations.

## Results

At the beginning of the research, 128 Chronic Obstructive Pulmonary Disease patients were recruited with consent, but only 110 patients could complete the follow-up. Demographic details of study subjects are summarized in Table 1.

Table 2 shows a Comparison of the level of satisfaction with inhalers. The study investigated the impact of pharmacist involvement on COPD patients' satisfaction with their inhalers, comparing pre- and post-intervention outcomes. Prior to the intervention, a substantial majority of patients (91.81%) reported high satisfaction with their inhalers, while a small percentage (8.18%) expressed low satisfaction. Following the intervention involving pharmacist participation, there was a significant shift in satisfaction levels: the proportion of patients reporting high satisfaction decreased to 36.36%, whereas those reporting low satisfaction increased notably to 63.63% ($p < 0.001$). These findings suggest that pharmacist involvement may influence patient satisfaction with inhaler usage, highlighting a potential role for pharmacists in improving patient outcomes in COPD management.

Table 3 shows a Comparison of CAT scores. The study conducted a Comparison of CAT scores to evaluate changes in health status (severity) among COPD patients before and after pharmacist intervention. Before the intervention, most patients had CAT scores indicating high impact levels on health status: 48.18% had scores >20 (High) and 28.18% had scores ranging from 10-20 (Medium). A smaller proportion reported very high impact levels (>30), low impact levels (<10), and very low impact levels (0-5) at 6.36%, 13.63%, and 0.9%, respectively. Following pharmacist intervention, there were notable improvements in health status as

indicated by CAT scores: the percentage of patients with very high impact scores decreased to 4.54%, and those with high impact scores decreased to 24.54%. Conversely, the proportion of patients in the medium impact category increased significantly to 54.54%. There were minimal changes in the low and very-low-impact categories, with slight decreases noted. These results suggest that pharmacist involvement may improve COPD patients' health status, particularly in reducing the severity of symptoms as measured by CAT scores.

The Wilcoxon matched pair test was used to compare the pre and post CAT (COPD Assessment Test) and FSI (Feeling of Satisfaction with Inhaler) scores at different time points. The pharmacist-led intervention demonstrated a statistically significant impact ($P<0.001$). The results are summarized in Table 4.

The Spearman rank correlation test was used to examine the relationships between pre-post CAT (COPD Assessment Test) and FSI (Feeling of Satisfaction with inhaler) scores. The Spearman correlation coefficient (Spearman R) is -0.5362, indicating a moderate negative correlation between first-visit CAT and first-visit FSI scores and the t-value is -6.6019, with a p-value of 0.0001,The Spearman correlation coefficient (Spearman R) is -0.5958, indicating a moderate to strong negative correlation between second-visit CAT and second-visit FSI scores, and the t-value is -7.7093, indicating that this negative correlation is statistically significant shown in Table 5.

**Discussion**

In this study, we explored how pharmacist participation affects COPD patients' satisfaction with their inhalers and overall health status. Patient satisfaction and health status was evaluated through self-administered questionnaires, specifically the FSI-10 and CAT. Participants reported finding both questionnaires easy to understand and complete.

According to our study's inclusion and exclusion criteria, 110 patients with COPD were included. The demographic data indicates that most COPD patients are between 61 and 70 years old. When comparing these findings with Miravitlles et al observational cross-sectional study, it shows that the average age of the patients in their study was 66.1 years [7]. Among the 110 patients in our study, 77 (70%) were male and 33 (30%) were female. In comparison, the study by Kulkarni et al reported that the majority of patients were male, with 47 (55.3%) males and 38 (42.7%) females [8]. Our study revealed that 67 (60.90%) of COPD patients resided in rural areas, while 43 (39.09%) lived in urban areas; these findings are comparable to the study conducted by Arora et al which showed that 168 (56.2%) of COPD patients were

from rural areas and 131 (43.8%) were from urban areas [9]. In our study, we found that most patients, 31 (28.18%), were unemployed. In comparison, the study conducted by Plaza et al reported that 40.8% of patients were unemployed [10]. This high rate of unemployment is likely due to the age factor, as most patients are elderly. According to our study, 28 (25.45%) of the patients were illiterate, and 32 (29.09%) had only a primary education. In comparison, a similar study by Jang et al found that only 10 (11.8%) of the population were illiterate [11]. This disparity could be because most patients in their study lived in urban areas, whereas many patients in our study were from rural areas with fewer urban residents.

In our study, we assessed patients' inhaler technique using the teach-back method based on the steps outlined in the "Inhaler Technique for People with Asthma and COPD" manual by the National Asthma Council Australia. Patients demonstrated their inhaler technique to the educator, and we found that 79 (71.81%) of the patients made one or more errors, while only 31 (28.18%) performed the steps correctly. In contrast, a study by Arora et al found that 247 (82.3%) of their population made errors in one or more steps, and only 53 (17.7%) executed the inhaler technique correctly [9].

In our study, we assessed the health status of COPD patients using the COPD Assessment Tool (CAT) questionnaires after providing educational interventions. We calculated the mean and standard deviation to evaluate improvements in health status between pre- and post-intervention periods. The t-value and p-value indicated statistically significant results. The overall severity of COPD was measured at two follow-up visits, with baseline data collected during patient enrolment. Counselling was provided based on these data. An improvement in CAT scores was observed after the second follow-up compared to baseline. Our study concluded that the overall CAT scores of COPD patients improved from (2.61 ± 1.55) to (3.25 ± 1.63) as a result of patient education during follow-up. A similar study by Ahn et al showed comparable results [12], with CAT scores improving from (9.92 ± 5.56) to (10.78 ± 6.44).

As per our study, we evaluated the satisfaction of COPD patients with their inhalers using the Feeling of Satisfaction with Inhaler (FSI-10) questionnaires after educational interventions. We calculated the mean and standard deviation to assess improvements between pre- and post-intervention periods, with t-values and p-values indicating statistically significant results. Satisfaction with inhalers was measured at two follow-up visits, with baseline data collected during patient enrolment. Counselling was provided based on these data. An improvement in FSI-10 scores was observed after the second follow-up compared to baseline. The FSI-10 questionnaire includes 10 questions, each scored out of 5, for a total score of 50, where a high

satisfaction score is above 43 and a low satisfaction score is below 43. Our study concluded that the overall FSI-10 scores of COPD patients improved, with high satisfaction increasing from 8.18% to 63.63% and low satisfaction decreasing from 91.81% to 36.36% after the intervention. Similar results were found in a study by Jang et al [11] where high satisfaction increased to 87.7% and low satisfaction decreased to 13.3%. Another study by Shahid et al showed that pre-intervention [13], 95.2% of patients had low satisfaction and 4.5% had high satisfaction, which improved post-intervention to 41.5% low satisfaction and 58.5% high satisfaction. Our research indicates that educating patients on proper inhaler techniques can significantly enhance disease management. Additionally, specific sociodemographic details are not strongly associated with major risk factors; however, social habits like smoking can increase the risk for COPD patients. In addition, 46 (41.8%) of the 110 were unaware of their prior inhaler education. Proper inhaler technique education can enhance disease control and decrease acute exacerbations, reducing the need for hospital readmissions. Also, poor adherence is a significant challenge in managing COPD, often resulting from a lack of awareness about proper inhaler use and the importance of adherence to the prescribed inhaler regimen. As part of the study, an intervention strategy was implemented that included face-to-face instruction on proper inhaler technique and providing a patient information leaflet for further reference, resulting in 77.27% of participants being able to use their inhalers correctly after the intervention.

**Conclusions**

The study concludes that while significant improvements in COPD symptoms and quality of life were observed, as indicated by decreased CAT there was a concomitant increase evidenced by higher FSI scores. This suggests that while the interventions were effective in managing COPD symptoms and enhancing quality of life, and feeling of satisfaction by the patients. Additionally, the moderate adherence to inhaler use and the considerable percentage of patients without prior inhaler education underlines the necessity for enhanced patient education and adherence strategies. These findings underscore the multifaceted nature of COPD management, emphasizing the need for comprehensive approaches that address both symptom relief and overall patient well-being.

***Limitations***

Lack of a control group, introducing potential biases, such as placebo effects. A greater sample size would have been done to make the study successful. Self-reported satisfaction questionnaires may lead to response bias. Long-term follow-up to validate maximal intervention efficacy and sustainability in COPD management.

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**Table 1. Demographic profile.**

| Characteristics | Frequency | % |
|---|---|---|
| **Age groups** | | |
| 50 yrs | 18 | 16.36 |
| 51-60 yrs | 17 | 15.45 |
| 61-70 yrs | 40 | 36.36 |
| 71-80 yrs | 27 | 24.55 |
| >80 yrs | 8 | 7.27 |
| **Gender** | | |
| Male | 77 | 70.00 |
| Female | 33 | 30.00 |
| **Residence** | | |
| Urban | 43 | 39.09 |
| Rural | 67 | 60.90 |
| **Education** | | |
| Illiterate | 28 | 25.45 |
| Pre-primary | 32 | 29.09 |
| Primary | 24 | 21.82 |
| High school | 11 | 10.00 |
| College | 15 | 13.64 |
| **Occupation** | | |
| Housewife | 28 | 25.45 |
| Farmer | 14 | 12.73 |
| Employee | 16 | 14.55 |
| Daily laborer | 21 | 19.09 |
| Others | 31 | 28.18 |
| **Total** | 110 | 100 |

**Table 2. Comparison of the level of satisfaction with inhalers.**

| Variables | Categories | Pre-intervention | Post-intervention | *p-value* |
|---|---|---|---|---|
| Satisfaction with inhalers | Low satisfaction | 09(8.18) | 70(63.63) | <0.001 |
| | High satisfaction | 101(91.81) | 40(36.36) | |

**Table 3. Comparison of CAT score.**

| CAT score | Impact level | Pre-intervention | Post-intervention | *p-value* |
|---|---|---|---|---|
| >30 | Very high | 07(6.36) | 05(4.54) | <0.001 |
| >20 | High | 53(48.18) | 27(24.54) | |
| 10-20 | Medium | 31(28.18) | 60(54.54) | |
| <10 | Low | 15(13.63) | 13(11.81) | |
| 0-5 | Very low | 01(0.9) | 05(4.54) | |

**Table 4. Comparison of pre and post-CAT scores and FSI-10 by Wilcoxon matched pair test.**

| Times | Mean | SD | Mean diff | SD diff | % of change | Z-value | p-value |
|---|---|---|---|---|---|---|---|
| CAT Score | | | | | | | |
| First visit | 20.31 | 6.80 | 2.61 | 1.55 | 12.85 | 8.7068 | 0.0001* |
| Second visit | 17.70 | 6.51 | | | | | |
| FSI-10 | | | | | | | |
| First visit | 33.48 | 5.66 | -7.98 | 3.95 | -23.84 | 9.0622 | 0.0001* |
| Second visit | 41.46 | 6.55 | | | | | |

*p<0.05

**Table 5. Correlation between CAT score and FSI score of pre- and post-intervention by Spearman rank correlation.**

| Variables | n | Spearman R | t-value | p-value |
|---|---|---|---|---|
| First visit CAT and first visit FSI | 110 | -0.5362 | -6.6019 | 0.0001* |
| Second visit CAT and second visit FSI | 110 | -0.5958 | -7.7093 | 0.0001* |

*p<0.05