

Drug utilization evaluation of inhaled corticosteroids among patients with chronic lung diseases in a Tertiary Care Hospital: A prospective observational study

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Abstract

Chronic lung diseases, particularly chronic obstructive pulmonary disease (COPD) and asthma, are major causes of morbidity worldwide and require long-term pharmacological management. Inhaled corticosteroids (ICS) are widely used to control airway inflammation, reduce exacerbations, and improve clinical outcomes. This study aimed to evaluate the drug utilization pattern of inhaled corticosteroids among patients with chronic lung diseases attending a tertiary care hospital in Kerala, India. A prospective observational study was conducted over six months among 60 patients receiving ICS therapy. Data on demographics, disease distribution, prescribing patterns, adherence to the Global Initiative for Asthma (GINA) and Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, inhaler technique before and after pharmacist counselling, and adverse drug reactions were collected using a structured data collection form. COPD was the most common diagnosis, followed by asthma and asthma-COPD overlap syndrome. Budesonide-based ICS-LABA combinations were the most frequently prescribed medications, and most prescriptions adhered to GOLD and GINA guideline recommendations. Pharmacist-led counselling significantly improved inhaler technique, while adverse drug reactions were infrequent and predominantly mild, with hoarseness of voice and oral candidiasis being the most common. The study demonstrated a rational utilization pattern of inhaled corticosteroids. Regular drug utilization evaluation, adherence to evidence-based guidelines, and continuous patient education can further optimize therapeutic outcomes and improve medication safety.

Keywords: Asthma; Chronic obstructive pulmonary disease; Drug utilization evaluation; GOLD guideline; Inhaled corticosteroids; Prescription pattern.

1. Introduction

Chronic lung diseases (CLDs) are among the leading causes of morbidity, mortality, and healthcare expenditure worldwide. These disorders include chronic obstructive pulmonary disease (COPD), asthma, bronchiectasis, and asthma-COPD overlap syndrome (ACOS), all of which are characterized by persistent airway inflammation and airflow limitation. According to the World Health Organization, chronic respiratory diseases affect hundreds of millions of people globally and substantially reduce quality of life through recurrent symptoms, frequent exacerbations, and progressive decline in lung function.³

Among the available therapeutic options, inhaled corticosteroids (ICS) play an essential role in controlling airway inflammation and reducing disease exacerbations. ICS are considered the cornerstone of asthma management and are recommended in combination with long-acting bronchodilators for selected patients with COPD, particularly those with frequent exacerbations or elevated eosinophil counts. Appropriate selection of inhaled corticosteroid therapy according to evidence-based recommendations such as the Global Initiative for Asthma (GINA) and the Global Initiative for Chronic

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Obstructive Lung Disease (GOLD) guidelines is necessary to achieve optimal disease control while minimizing adverse effects.^{1,2}

Drug Utilization Evaluation (DUE) is a structured, continuous process designed to assess the appropriateness, effectiveness, and safety of medication use. It provides valuable information regarding prescribing trends, compliance with standard treatment guidelines, and opportunities to improve the quality of patient care. Drug utilization studies also help to identify irrational prescribing practices, unnecessary polypharmacy, medication errors, and preventable adverse drug reactions, thereby promoting rational drug therapy and better clinical outcomes.⁴

Although inhaled corticosteroids are widely prescribed in respiratory diseases, inappropriate prescribing may expose patients to avoidable adverse effects such as oral candidiasis, dysphonia, sore throat, and an increased risk of respiratory infections. Furthermore, improper inhaler technique remains a major contributor to poor disease control despite appropriate pharmacotherapy. Continuous monitoring of prescribing practices and patient education are therefore essential components of respiratory care.^{8,10}

The present prospective observational study was undertaken to evaluate the utilization pattern of inhaled corticosteroids among patients with chronic lung diseases attending a tertiary care hospital. The study also assessed prescribing practices with reference to current GOLD and GINA recommendations, evaluated inhaler technique before and after pharmacist counselling, and documented adverse drug reactions associated with inhaled corticosteroid therapy. The findings are expected to provide evidence for promoting rational prescribing practices and improving the quality of pharmaceutical care in patients with chronic respiratory diseases.

2. Material and methods

2.1. Study Design

A hospital-based, prospective observational study was conducted to evaluate the utilization pattern of inhaled corticosteroids (ICS) among patients with chronic lung diseases attending the Department of Pulmonology of a tertiary care hospital. The study focused on assessing prescribing patterns, adherence to standard treatment guidelines, inhaler technique, and adverse drug reactions associated with ICS therapy.

2.2. Study Setting

The study was carried out at SH Medical Centre, Kottayam, Kerala, India, a tertiary care teaching hospital with specialized respiratory care services. Data were collected from both inpatient and outpatient departments over a period of six months.

2.3. Study Population

The study included adult patients diagnosed with chronic lung diseases receiving inhaled corticosteroid therapy during the study period.

2.3.1. Inclusion Criteria

- Patients aged 18 years and above.
- Patients diagnosed with chronic obstructive pulmonary disease (COPD), asthma, or asthma-COPD overlap syndrome (ACOS).
- Patients prescribed inhaled corticosteroid-containing therapy.
- Patients willing to provide written informed consent.

2.3.2. Exclusion Criteria

- Pregnant and lactating women.
- Patients with incomplete clinical records or those lost to follow-up.

2.4. Sample Size

A total of 60 patients fulfilling the eligibility criteria were enrolled using convenience sampling during the study period.

2.5. Data Collection

Data were collected using a predesigned and validated patient data collection form. The following information was recorded:

- Demographic characteristics (age, gender, body weight)
- Clinical diagnosis
- Comorbid conditions
- Prescribed inhaled corticosteroid regimen
- Type of inhaler device
- ICS-LABA combinations
- Inhaler technique assessment
- Pulmonary function test findings
- Adverse drug reactions
- Compliance with GOLD and GINA recommendations

Patient interviews, prescription reviews, medical records, and pulmonary function test reports were used as sources of data.

2.6. Drug Utilization Evaluation

Drug utilization evaluation was performed by assessing the prescribing pattern of inhaled corticosteroids according to established treatment guidelines.

- The following parameters were evaluated:
- Frequency of various inhaled corticosteroids prescribed.
- Distribution of ICS-LABA combinations.
- Adherence of COPD prescriptions to GOLD recommendations.
- Adherence of asthma prescriptions to GINA recommendations.
- Distribution of inhaler devices.
- Patient inhaler technique before and after pharmacist counselling.
- Occurrence of adverse drug reactions related to inhaled corticosteroids.

2.7. Patient Counselling

All enrolled patients received individualized counselling from the clinical pharmacist regarding the correct use of inhaler devices. Demonstration of inhaler technique was provided, followed by return demonstration by the patient. The inhaler technique was reassessed during follow-up to evaluate the effectiveness of pharmacist intervention.

2.8. Outcome Measures

The primary outcome was the evaluation of the utilization pattern of inhaled corticosteroids among patients with chronic lung diseases.

- Secondary outcomes included:
- Assessment of adherence to GOLD and GINA treatment guidelines.
- Evaluation of inhaler technique before and after counselling.
- Identification of adverse drug reactions associated with inhaled corticosteroid therapy.

2.9. Statistical Analysis

Collected data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were presented as frequency and percentage. Descriptive statistics were used to summarize demographic characteristics and prescribing patterns. The paired t-test was used to compare inhaler technique scores before and after pharmacist counselling. A p-value <0.05 was considered statistically significant.

2.9.1. Ethical Considerations

The study was conducted after obtaining approval from the Institutional Ethical Committee of KVM College of Pharmacy, Cherthala. Written informed consent was obtained from all study participants before enrolment. Patient confidentiality and anonymity were strictly maintained throughout the study in accordance with the principles of the Declaration of Helsinki.

3. Results and discussion

A total of 60 patients with chronic lung diseases receiving inhaled corticosteroid therapy were included in the study. The drug utilization pattern was evaluated based on demographic characteristics, disease distribution, prescribing pattern of inhaled corticosteroids, adherence to standard treatment guidelines, inhaler device utilization, inhaler technique assessment, and adverse drug reactions.

3.1. Demographic Characteristics of the Study Population

The demographic profile of the study participants, including age distribution, gender distribution, and other baseline characteristics, is presented in Table 1.

Table 1 Demographic characteristics of the study participants.

Characteristic	Category	Frequency (N)	Percentage (%)
Age	≤50	10	16.7
	51–60	7	11.7
	61–70	24	40.0
	>70	19	31.6
Body Weight(Kg)	≤50	4	6.7
	51–60	24	40.0
	61–70	19	31.7
	>70	13	21.6
Disease By Gender	COPD Male	17	65.38
	COPD Female	16	47.05
	ASTHMA Male	8	30.78
	ASTHMA Female	17	50.00
	ACOS Male	1	3.84
	ACOS Female	1	2.95

The majority of participants were older adults, with most patients aged 61–70 years. COPD was more prevalent among males, whereas asthma showed a relatively higher proportion among females. These findings are consistent with the epidemiology of chronic respiratory diseases, where COPD is more common in older individuals due to cumulative exposure to smoking and environmental pollutants.

3.2. Distribution of Chronic Lung Diseases

The distribution of patients according to the diagnosis of chronic lung diseases, including COPD, asthma, and asthma-COPD overlap syndrome (ACOS), is illustrated in Figure 1.

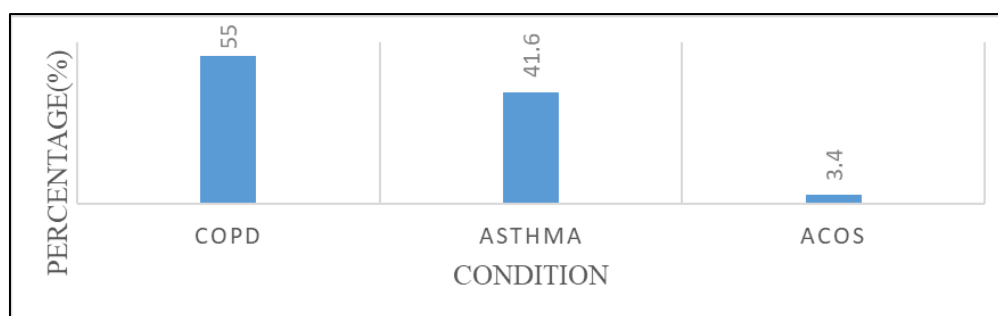


Figure 1 Distribution of chronic lung diseases.

COPD was the most common chronic lung disease observed, followed by asthma and ACOS. Similar findings have been reported in previous drug utilization studies conducted in tertiary care hospitals, reflecting the increasing burden of COPD among the elderly population.

3.3. Pattern of Inhaled Corticosteroid Utilization

The utilization pattern of inhaled corticosteroid-containing medications prescribed during the study period is presented in Table 2.

Table 2 Drug utilization pattern of inhaled corticosteroid preparations.

Brand name	Generic name	Frequency (n)	Percentage (%)
Foracort	Formoterol Fumarate+ Budesonide	15	25.00
Formonide Forte		7	15.00
Formonide		9	11.66
Budamate		3	5.00
Odihaile	Vilanterol + Fluticasone furoate	9	15.00
Seroflo	Salmeterol + Fluticasone propionate	11	18.33
Trimium	Tiotropium bromide + Formoterol fumerate + Ciclesonide	4	6.66
Triohale		2	3.35

Budesonide-based inhalers, particularly ICS-LABA combinations, were the most frequently prescribed medications. Combination therapy is preferred because it improves symptom control, reduces exacerbations, and enhances treatment adherence compared with inhaled corticosteroid monotherapy.

3.4. Utilization of ICS-Based Combination Therapy

The prescribing pattern of inhaled corticosteroid-based combination therapies, including ICS-LABA formulations, is presented in Table 3.

Table 3 Utilization pattern of ICS-containing combination therapies.

Most frequently prescribed combination of ICS	FREQUENCY (n)	PERCENTAGE (%)
BUDESONIDE + LABA	34	62.96
FLUTICASONE + LABA	20	37.04

Budesonide-LABA combinations accounted for the majority of prescriptions, indicating adherence to current evidence-based recommendations. These combinations are commonly prescribed due to their proven efficacy and safety in the management of asthma and selected COPD patients.

3.5. Adherence to Standard Treatment Guidelines

The appropriateness of inhaled corticosteroid prescribing according to the Global Initiative for Asthma (GINA) and Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines is summarized in Table 4.

Table 4 Adherence of inhaled corticosteroid prescriptions to GOLD and GINA guidelines.

Disease	Guideline	Adherent	Non adherent
COPD	GOLD	27 (81.8%)	6 (18.2%)
ASTHMA	GINA	23 (92.0%)	2 (8.0%)
ACOS	GOLD	2 (100%)	0 (0%)

Most prescriptions adhered to GOLD and GINA recommendations, demonstrating rational prescribing practices. High guideline adherence indicates appropriate selection of inhaled corticosteroid therapy according to disease severity and clinical indications.

3.6. Assessment of Inhaler Technique

The assessment of patients' inhaler technique before and after pharmacist counselling is presented in Table 5.

Table 5 Assessment of inhaler technique before and after pharmacist counselling.

Score	Inhaler technique compliance (Before counselling)		Mean $\pm$ SD	Inhaler technique compliance (After counselling)		Mean $\pm$ SD	Mean difference
	f	%	6.57 $\pm$ 1.20	f	%	7.53 $\pm$ 0.50	0.96
1	0	0		0	0		
2	0	0		0	0		
3	0	0		0	0		
4	4	6.7		0	0		
5	8	13.3		0	0		
6	13	21.7		0	0		
7	20	33.3		28	46.66		
8	15	25.0		32	53.34		

A significant improvement in inhaler technique was observed after pharmacist counselling. This finding highlights the important role of clinical pharmacists in educating patients, improving medication use, and optimizing treatment outcomes.

3.7. Adverse Drug Reactions Associated with Inhaled Corticosteroids.

The adverse drug reactions observed among patients receiving inhaled corticosteroid therapy are presented in Figure 2.

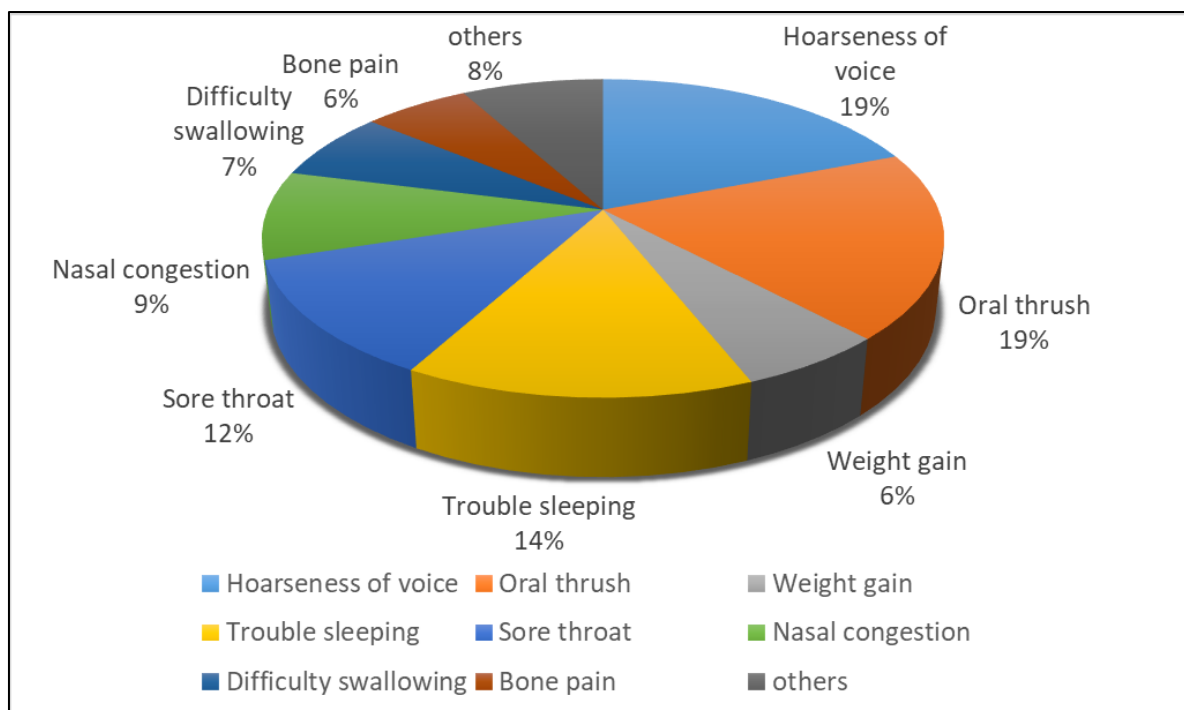


Figure 2 Distribution of adverse drug reactions.

Adverse drug reactions were infrequent and predominantly mild. Hoarseness of voice and oral candidiasis were the most commonly reported events, which are recognized local adverse effects of inhaled corticosteroids. Proper inhaler technique and mouth rinsing after inhalation may reduce their occurrence.

3.8. Overall Interpretation

The findings of the present study indicate that inhaled corticosteroids were predominantly prescribed as ICS-LABA combination therapy, with budesonide-based formulations being the most frequently utilized. Prescribing practices showed high adherence to GOLD and GINA recommendations, indicating rational use of inhaled corticosteroids in chronic lung disease management. Pharmacist-led counselling significantly improved inhaler technique, while adverse drug reactions were infrequent and predominantly mild.

The study provides real-world evidence on prescribing practices in a tertiary care hospital and highlights the importance of routine Drug Utilization Evaluation (DUE) in promoting evidence-based prescribing. However, the findings should be interpreted considering the single-centre design, relatively small sample size, and short study duration. Larger multicentre studies with longer follow-up are recommended to further evaluate long-term clinical outcomes and prescribing trends.

4. Conclusion

The present prospective observational study evaluated the drug utilization pattern of inhaled corticosteroids (ICS) among patients with chronic lung diseases in a tertiary care hospital. The findings showed that ICS were predominantly prescribed as fixed-dose combinations with long-acting β_2 -agonists (LABAs), with budesonide-based ICS-LABA combinations being the most frequently utilized. Prescribing practices demonstrated high adherence to the recommendations of the Global Initiative for Asthma (GINA) and the Global Initiative for Chronic Obstructive Lung Disease (GOLD), indicating rational use of inhaled corticosteroids in the study setting.

Pharmacist-led counselling significantly improved patients' inhaler technique, highlighting the important role of clinical pharmacists in optimizing inhaled therapy. Adverse drug reactions were infrequent, predominantly mild, and mainly localized, with hoarseness of voice and oral candidiasis being the most commonly reported events.

Overall, the study demonstrates that regular Drug Utilization Evaluation (DUE) is an effective approach for monitoring prescribing practices, promoting adherence to evidence-based treatment guidelines, and improving medication safety.

and therapeutic outcomes in patients with chronic lung diseases. Continued prescription audits and patient education on correct inhaler technique are recommended to further enhance the quality of respiratory care.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare that there are no financial or non-financial conflicts of interest regarding the publication of this research.

Statement of ethical approval

The study was conducted after obtaining approval from the Institutional Ethics Committee of KVM College of Pharmacy, Cherthala, Kerala, India. The research was performed in accordance with the ethical principles outlined in the Declaration of Helsinki.

Statement of informed consent

Written informed consent was obtained from all study participants prior to enrolment.

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Data availability statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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