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Adverse Drug Reactions Associated with Inhaled Corticosteroids: A Community-Based Case Study

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Abstract
Inhaled corticosteroids (ICS) are widely prescribed for asthma and chronic obstructive pulmonary disease (COPD) due to their proven efficacy in controlling airway inflammation. Despite their therapeutic benefits, adverse drug reactions (ADRs) related to ICS use in community settings are underreported. This observational study, conducted among 250 patients in the Thiruvalla, Mallappally, and Kozhencherry taluks of Pathanamthitta district, Kerala, aimed to identify and assess the spectrum of ADRs associated with ICS use. Among the study population, 144 patients (57.6%) experienced at least one ADR, while 106 (42.4%) did not report any adverse effects. The most commonly used ICS was budesonide. The most frequent ADRs included oropharyngeal issues (89.58%), weight gain (23.2%), elevated blood sugar levels (85.42%), infections (41.6%), and ocular changes (17.3%). This study emphasizes the need for close monitoring of ICS therapy, especially in long-term users, and calls attention to the potential for systemic effects even with inhaled formulations.

Keywords: Inhaled Corticosteroids, Adverse drug reactions, oropharyngeal candidiasis, Chronic obstructive pulmonary disease, Pharmacovigilence

Introduction

Inhaled corticosteroids (ICS) are the cornerstone in the management of persistent asthma and moderate-to-severe COPD. They are known to effectively suppress airway inflammation, enhance patient quality of life, and reduce the frequency of exacerbations. When used correctly, ICS deliver anti-inflammatory effects directly to the lungs with fewer systemic complications than oral corticosteroids. However, long-term or high-dose use of ICS, particularly without proper administration technique or preventive measures (e.g., mouth rinsing), can lead to both localized and systemic adverse effects. [1]

While oropharyngeal candidiasis and hoarseness are well-documented local effects, emerging data suggest that ICS can also contribute to systemic effects such as hyperglycemia, weight gain, adrenal suppression, infections, and ocular complications, especially when used in high doses or over prolonged periods. Despite the increasing use of ICS in the general population, studies documenting ADRs in non-hospitalized, community-based populations remain sparse. [2,3]

This study was undertaken to assess the prevalence and spectrum of adverse drug reactions associated with inhaled corticosteroids in a community setting in Kerala.

Case Report

A cross-sectional observational study was conducted in Thiruvalla, Mallappally, and Kozhencherry taluks of Pathanamthitta district, Kerala, involving 250 patients prescribed inhaled corticosteroids. The study population comprised individuals of varied ages from 15-84 years and respiratory diagnoses, predominantly asthma and COPD. The most commonly used ICS was **budesonide**, often in combination with long-acting beta-agonists (LABAs).

Out of 250 patients:

- **144 patients (57.6%)** experienced at least one adverse drug reaction (ADR)
- **106 patients (42.4%)** reported no ADRs

Among those with ADRs (n = 144), the frequency of specific adverse effects was as follows:

These adverse effects were documented through direct patient interviews, review of clinical history, and self-reported symptoms.

ADVERSE REACTION	FREQUENCY	PERCENTAGE	WHO-UMC CAUSALITY ASSESSMENT	RAWLINS &THOMPSON CLASSIFICATION	HARTWIG'S SEVERITY ASSESSMENT
Oropharyngeal candidiasis	129	89.58%	Probable	Type A	Mild (Level 1)
Weight gain	36	23.20%	Possible	Type A	Mild (Level 2)
Elevated blood sugar levels	19	13.1%	Probable	Type A	Moderate (Level 3)
Elevated blood pressure	19	13.1%	Possible	Type A	Mild to Moderate (Level 2–3)
Increased infections	60	41.6%	Probable	Type A	Moderate (Level 3)
Ocular complications	25	17.3%	Possible	Type B	Moderate (Level 4a)
Skin integrity issues (Skin thinning)	13	9.0%	Probable	Type A	Mild (Level 2)
Gastrointestinal disturbances	7	5.0%	Possible	Type A	Mild (Level 1)

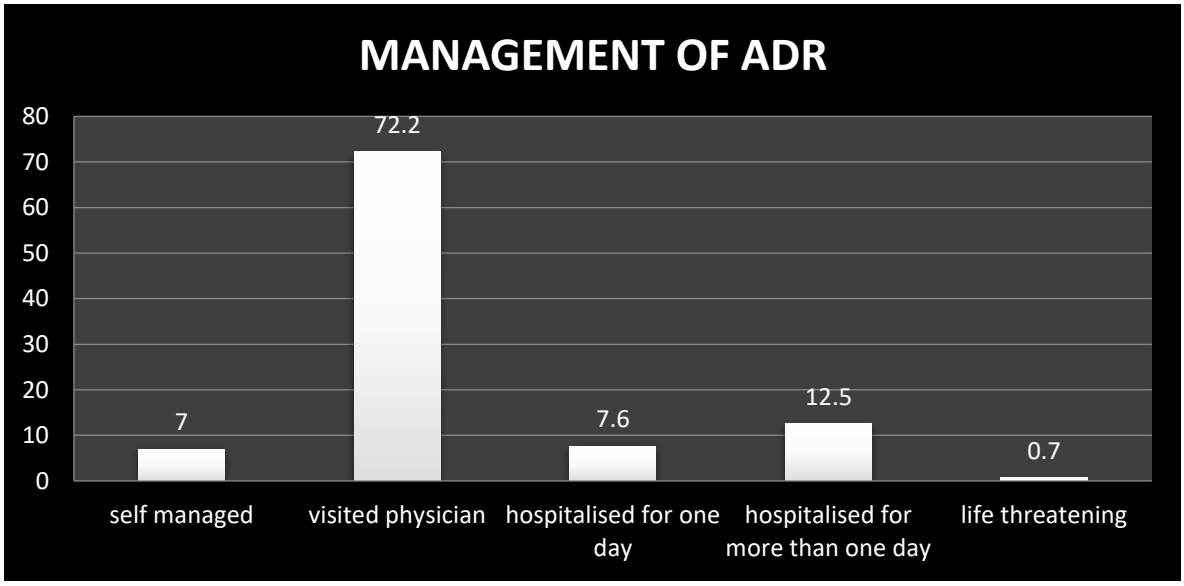
Central nervous system effects	25	17.67%	Possible	Type B	Mild to Moderate (Level 2–3)

PROPOSED REASON FOR ADR

PROPOSED REASON FOR ADR	FREQUENCY	PERCENTAGE
Irregularity in visiting physician	67	46.5
Prolonged use	21	14.6
Overdose	1	0.7
Overdose + Irregularity in visiting physician	1	0.7
Overdose + Prolonged use	1	0.7
Prolonged use + Irregularity in visiting physician	53	36.8
Total	144	100

The proposed reason for ADR among Corticosteroid users. The data shows that 0.7% of ADRs were attributed to overdose, 37.5% to prolonged use, 46.5% to irregularity in visiting a physician, 0.7% to overdose + irregularity in visiting physician, 0.7% to overdose +prolonged dose , 13.9% to prolonged use+ irregularity in visiting physician

MANAGEMENT OF ADR



Management of ADR among inhaled corticosteroid users. The data shows that 7% of users managed their ADRs on their own, while 72.2% visited a physician for treatment. A small percentage, 7.6% required hospitalized for one day, and 12.5% were hospitalized for more than one day. Only 0.7% of cases were classified as life threatening.

Discussion

ADR of ICS from this study of 250 patients it was found that 57.6% of patients(144) suffered from ADR

and the total number of ADR was found to be 557 , among which oropharyngeal effects such as oropharyngeal candidiasis were the most common followed by diabetes mellitus, infections, CNS side effects, weight gain, muscles and joints pain, fatigue , cataract, hypertension, skin brusing and thinning, GI problems. In relation to the the study conducted by **Dhruti Pandya** on "Systemic Effects of ICS showed ICS affected HPA axis , eyes, skin, and immunity including an increase risk of pneumonia". Another study conducted by **Wenli Shang et al** on "the safety of long term use of inhaled corticosteroids in patients with asthma: A systematic review and meta analysis" showed that long term use of inhaled corticosteroids resulted in oropharyngeal candidiasis and dysphonia. [4,5]

- Out of 144 patients who suffered from ADR , 129 patients had oropharyngeal side effects such as dysphonia, pain while swallowing, white lesions on tongue , difficulty in speaking and oral thrush. These ADR had occurred due to improper inhalation technique , not rinsing mouth properly.
- Regarding diabetes mellitus ,123 patients showed increase in blood sugar level which is similar to the study conducted by Sammy Suissa on" Inhaled corticosteroids and the risks of diabetes onset and progression" which gives the conclusion that the use of inhaled corticosteroids increased the rate of diabetes and progression by 34%. The risk was highest with the highest doses, equivalent to fluticasone 1000 µg per day or more.[6]
- From our data we found that infections ,gastric disorders ,skin integrity accounts 41.6% 5.5% and 9 % which is similar to the study conducted by Willy Fonscea on "Inhaled drug therapy associated adverse reactions in obstructive respiratory diseases :A review of a decade of reporting to the Portuguese Pharmacovigilance system"61 .According to the study the most common ADRs reported with ICS and ICS/LABA inhalers were "General disorders and administration site conditions" and "Respiratory, thoracic and mediastinal disorders" followed by "skin and subcutaneous tissue disorders" respectively.[7]
- From the study we found that from 144 people who suffered from ADR about 58 people (23.20%) suffered from increase in weight gain .In relation to the study conducted by **Jenifer Han et al** "Effect of inhaled corticosteroid use on weight (BMI) in pediatric patients with moderate to severe asthma",they revealed a notable yearly rise of 0.369 kg/m2 in BMI for individuals receiving high dose steroids while those in the low dose group also experienced weight gain even though it is at a lesser rate of 0.195 kg/m2.62 .[8]
- Regarding cataract out of 144 who had experienced ADR 25 people (17.3%) had cataract. According to the study conducted by R G Cumming et al on "Use of inhaled corticosteroids and the risk of cataracts "which concluded that the use of inhaled corticosteroids is associated with development of posterior subcapsular and nuclear cataracts. [9]

PROPOSED REASON FOR ADR : From our study we found that 0.7% of ADRs were attributed to overdose, 37.5% to prolonged use, 46.5% to irregularity in visiting a physician, 0.7% to overdose + irregularity in visiting physician, 0.7% to overdose +prolonged dose , 13.9% to prolonged use+ irregularity in visiting physician . From the study conducted by **Ashwaghosha Parthasarathi** on "Local adverse drug reaction in ambulatory asthma patients treated with inhaled corticosteroids An experience from south Indian teaching hospital" showed that Despite their doctor's advice to stick to their usual ICS dosage, two out of every five patients who reported ADRs reduced or skipped doses due to discomfort. ADRs to ICS were found to be associated with three risk factors: using budesonide, age more than 41, and using MDI without a spacer.

Conclusion

This community-based study reveals a significant occurrence of adverse drug reactions among patients using inhaled corticosteroids, with over half of the users reporting at least one ADR. While oropharyngeal candidiasis remain the most common and manageable, systemic effects such as hyperglycemia, infections, and fatigue should not be underestimated.

Budesonide 400 mcg was the most often utilized ICS, especially for people 65 to 74 years old. The majority of ICS users were female. Oropharyngeal candidiasis were the most commonly found adverse drug reaction (ADR)in the study population, underscoring the need for improved management and preventative measures for these particular side effects.

The majority of ADRs were most Probably Preventable, according to the Schumock and Thornton scale. Its is used to assess the preventability of ADRs.The proposed reason for the occurrence of ADR was irregularity in visiting physician and the patients managed the ADR by visiting physician. This research highlights how improving clinical procedures, patient education, and guideline adherence can lower the occurrence of adverse drug reactions. The study concludes by highlighting the potential for reducing preventable ADRs through improved healthcare practices, the necessity of targeted interventions to improve patient knowledge and management of ICS therapy, and the significance of monitoring for specific ADRs, particularly oropharyngeal candidiasis. The study suggest that people using inhaled corticosteroid must be given with proper administration techniques and in case of oropharyngeal candidiasis preventable treatment measures can be suggested by the healthcare professionals like use of antifungal medications.

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