



Original Article

Assessment of Prescription Pattern and Monitoring Adverse Drug Reactions of Corticosteroid Usage in a Teaching Hospital

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A B S T R A C T

Received: 13 Mar 2016
Accepted: 19 Apr 2016**Objective:** To analyze the prescription pattern and to monitor the adverse drug reactions due to corticosteroid usage**Materials and Methods:** A prospective observational study was conducted at the medicine and pediatric in-patient department of Basaveshwara medical college hospital and research centre Chitradurga for a period of six months. Data on prescription pattern of corticosteroids and adverse drug reactions from the patients and their representatives was collected and assessed by following Naranjo's scale and Hartwig's scale. The data was analyzed descriptively.**Results:** During the study period, a total of 110 prescriptions were collected. Out of these 54% were males and 46% were females. By analyzing the prescriptions, Budesonide (51%) was the most prescribed corticosteroid followed by Dexamethasone (27%), Hydrocortisone (17%), Prednisolone (3%), and Deflazacort (2%). Corticosteroids were prescribed more in respiratory diseases (61.82%). Common adverse drug reactions (ADRs) observed with corticosteroids were eye pain, numbness in arms, increased appetite, Cushing's syndrome, edema in both legs and weight gain. These ADRs comes under possible & probable category as per Naranjo's scale and mild & moderate as per Hartwigs scale.**Conclusion:** The present study reveals that the most prescribed corticosteroid was Budesonide followed by Dexamethasone, Hydrocortisone, Prednisolone and Deflazacort. Out of the several adverse drug reactions reported as a consequence of the corticosteroid usage, the present study reported six adverse drug reactions.**Keywords:** Prescription Pattern, Adverse Drug Reaction, Corticosteroids, Budesonide

1. INTRODUCTION

Drugs play an important role in protecting, maintaining and restoring health. Prescription writing is a science and art, as it conveys the message from the prescriber to the patient.¹ Irrational prescription of drugs is common in clinical practice.² The patterns of drug use in a hospital setting need to be monitored intermittently in order to analyze their rationality and to offer

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feedback and suggestions to drug prescribers so as to enable and effect suitable modifications in prescribing pattern to increase the therapeutic benefits and reduce adverse effects.³

According to World Health Organization (WHO), an adverse drug reaction (ADR) is defined as “a response to a drug which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy for a disease and for the modification of function excluding failure to accomplish the intended purpose”. Adverse drug reactions are one of the major causes of morbidity and account for nearly 5% of all hospital admissions all over the world.⁴

Systemic as well as topical corticosteroids have one of the wide spectrum of medical uses for their anti-inflammatory and immunosuppressive properties. They have the potential to cause dramatic improvement in many severe diseases as well as to produce equally dramatic adverse effects if not properly used. The use in nonendocrine diseases is empirical and palliative, but may be life saving.⁵

By quantifying the morbidity associated with the use of corticosteroids, this study should help rationalize their long term use.⁶ Since no systematic study has been done so far to monitor ADRs of corticosteroids⁷, the present study was conducted to monitor ADRs occurring during use of corticosteroids. Further, causality and severity assessment of ADRs, which reflects the association of the drug with the adverse effects, was done for confirmatory purposes. We wanted to know the frequency of ADR and were interested to find out whether new and/or life-threatening ADRs were reported. A great deal of work still needs to be done so that the pathogenesis of such adverse events can be clearly determined and effective therapeutic interventions devised.⁸ To the best of our knowledge, less systematically analyzed data are

available on the drug use pattern in corticosteroids. Hence, the present study was undertaken in patients under corticosteroid treatment for analyses of prescription pattern and adverse events.

2. MATERIALS AND METHODS

A prospective observational study was conducted at Basaveshwara Medical College Hospital & Research Centre, Chitradurga, Karnataka, India. The patients admitted in Medicine and Pediatric Departments of the hospital who were prescribed with corticosteroids during the study period were included the study. In the study population, patients were classified into four categories according to age group (20years, 21-40years, 41-60years and >60years). A data collection form that carries demographic details of the patients like age, sex, diagnosis, prescription pattern and scores of ADR assessing scales was prepared.

This study was approved by the “Institutional Human Ethical Committee” of the S.J.M College of Pharmacy, Chitradurga. (SJMCP/IEC/543B/2014-15 Date-13/10/2014). The data was entered in Microsoft Excel-2007 version and the results were analyzed using Statistical Package for Social Services (SPSS 19.0). Descriptive Method was used for analysis.

3. RESULTS

Data from a total of 110 patients were collected during the study period 59 were males and 51 females. Out of this, 52 were from >60years, 33 from 41-60years, 19 from 21-40years and 6 patients from 20years. In the study population, majority of patients had lower respiratory tract infection (LRTI) (20%) followed by anaemia, chronic obstructive pulmonary disease, asthma and many other diseases. Table 1 represents the percentage of diseases that were collected during the study period.

In the study population, a total of 140 corticosteroids were prescribed. Among those 51% were Budesonide, followed by Dexamethasone (27%) Hydrocortisone

(17%), Prednisolone (3%) and Deflazacort(2%). In anaemic patients, Dexamethasone was prescribed mostly followed by Budesonide, and in asthma patients Budesonide was the most prescribed corticosteroid followed by Hydrocortisone. In COPD and LRTI majority were prescribed with Budesonide, followed by Hydrocortisone. Table 2 explains the diseases with the prescribed corticosteroids.

Table 1: Distribution According to Disease

DISEASE	% of Patients
Anaemia	19%
Asthma	12%
COPD	18%
LRTI	20%
Other diseases (chronic renal failure, nephrotic syndrome, cancer in larynx, pulmonary tuberculosis, acute gastroenteritis, Cushing's syndrome, upper respiratory tract infection etc.)	

Table 2: Distribution According to Disease Vs Drugs

DISEASES	Budeso- nide	Dexa- methason	Hydro- cortisone	Predni- solone	Deflaza- cort	Total
Anaemia	1	20	1	-	-	22
Asthma	13	1	4	-	2	20
COPD	19	2	5	-	-	26
LRTI	20	1	6	-	-	27
Others	18	14	8	4	1	45
Total	71	38	24	4	3	140
% of Drug	51%	27%	17%	3%	2%	100%

In the study population, 75% were prescribed with corticosteroid as monotherapy, 22% with two corticosteroids and remaining 3% with three corticosteroids, which is represented in Table 3.

Table 3: Distribution According to Number of Corticosteroid per Prescription

Number of Corticosteroid Per Prescription	% of Prescription
1 corticosteroid	75%
2 corticosteroids	22%
3 corticosteroids	3%

Table 4: Distribution According To Drug Vs ADR

Suspected Drugs	ADR Experienced	Percentage
Deflazacort	Edema In Both Legs	25%
	Weight Gain	25%
Prednisolone	Eye Pain	25%
	Numbness In Arms	
	Increased Appetite	
	Cushing's Syndrome	25%

During the study period, a total of six ADRs were observed in four patients. Out of them, two were Deflazacort induced edema in both legs & weight gain and remaining were Prednisolone induced eye pain, numbness in arms, increased appetite & Cushing's syndrome. The results are presented in table 4.

The ADRs have been assessed for causality by using Naranjo's probability scale and severity using Hartwig's scale. In the documented ADRs, 1 was possible and 3 were in probable category. No definite and doubtful ADRs were observed. According to Hartwig's scale, 1 was Mild and 3 were in Moderate category. No severe ADRs were observed. The results are summarized in table 5.

Table 5: Causality and Severity assessment of ADRs

Naranjo's causality assessment scale	Number of ADR	% of ADR	Hartwig's severity assessment scale	Number of ADR	% of ADR
Doubtful (0)	0	-	Mild (Level 1 & 2)	1	25%
Possible (1-4)	1	25%	Moderate (Level 3 & 4)	3	75%
Probable (5-8)	3	75%	Severe (Level 5, 6 & 7)	0	-
Definite (>9)	0	-			

4. DISCUSSION

Prescription writing is a science and an art, as it conveys the message from the prescriber to the patient.² Steroids are associated with numerous side effects that lead to increased patient morbidity and mortality. The incidence and economic aspects of steroid-related side effects have not been quantitatively assessed.⁹

Previous studies showed that, common ADRs observed with inhaled steroids were Sore throat, Dysgeusia, Hoarseness of voice, Hyperpigmentation of face, Glossitis etc. As per the Naranjo's scale, the total score for these ADRs with inhaled steroids ranged from 5 to 8, which fell in the 'probable' category.¹⁰ The major adverse effects of glucocorticoids on the cardiovascular system include dyslipidemia and hypertension.¹¹ The

cumulative incidence of fractures since the time of diagnosis was 23% for patients taking oral corticosteroids. They also reported a significant increase in cataracts.⁶

In the present study, we used the hospital case sheets for the analysis of prescription pattern, and collected the details of ADRs from the patient and their representatives. We conclude that, Budesonide was the most prescribed corticosteroid and the least prescribed was Deflazacort. A total of six ADRs were observed in four patients. Those were edema in legs, weight gain, Eye pain, Numbness in arms, Increased appetite and Cushing's syndrome. As per the Naranjo's scale, the total score for these ADRs ranged from 1 to 4 & 5 to 8, which fell in the 'possible' & 'probable' categories respectively and according to Hartwig's severity scale, the ADRs were under 'mild' & 'moderate' categories.

5. CONCLUSION

This study provides the information regarding the prescription pattern of corticosteroids and the ADRs which can be caused due to the use of these drugs. In this study, the most prescribed corticosteroid was Budesonide and the ADRs found to be were edema in legs, weight gain, Eye pain, Numbness in arms, Increased appetite and Cushing's syndrome. Unnecessary use of corticosteroids in patients may leads to decrease their quality of life and long term use will leads to more severe ADRs. Similar studies need to be conducted in more patients and for longer duration of time to establish these findings.

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