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A PROSPECTIVE OBSERVATIONAL STUDY ON DRUG UTILIZATION EVALUATION OF CORTICOSTEROIDS IN A TERTIARY CARE TEACHING HOSPITAL, DAVANAGERE

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ABSTRACT

Background: Corticosteroids are renowned for their anti-inflammatory, anti-proliferative and immuno-suppressive actions; However, their illegitimate use can manifest catastrophic effects. **Objective:** To carry out the DUE of corticosteroids in a tertiary care teaching hospital**. Methodology:** A Prospective Observational study was carried out on 150 patients for six months in the medicine department of Chigateri District Hospital, Davanagere, Karnataka; subjects were enrolled based on inclusion criteria after obtaining informed consent; And the details were collected using a data collection form. **Results**: Among 150 subjects [93 and 57 females], (n=30,20%) were smokers. Most of the subjects belonged to the age group of 61-70 (n=60, 40%). A major percentage of prescription belonged to Pulmonology Department (n=102, 68%), followed by Neurology (n=10, 6.66%), Rheumatology (n=10, 6.66%), Hepatology (n=9, 6%), Nephrology (n=9, 6%), and Cardiology(n=2, 1.34%) and n=112, 59.89% of them were prescribed using their brand name. Short acting agent Hydrocortisone (n=69, 36.89%), was the commonly prescribed drug followed by Dexamethasone, Budesonide, Methylprednisolone and Prednisolone. Intravenous administration (n=134, 70.90%) was predominant than, inhalation (n=37, 19.58%) and oral (n=18, 9.52%). TDS 95 (57.93%) was the frequently observed frequency of administration followed by BD (n=34, 20.74%). 90 prescriptions were with interactions; which included moderate (n=273, 60.40%), minor (n=153, 33.84%) and major (n=26, 5.76%). **Conclusion**: A rational prescription pattern was

observed in the case of most steroids, although some factors like drug administration time and tapering caused mild deviations; the involvement of a clinical pharmacist can effectively improve the safety and efficacy of the drug; by early detection and prevention of drug-related adverse events and thus, enhancing health-related outcomes.

KEYWORDS: Corticosteroids, Drug utilization Evaluation, informed consent.

INTRODUCTION

Corticosteroids are produced in the adrenal cortex and belongs to a class of drugs called steroids, they are released as a response to adrenocorticotropic hormone (ACTH) and are regulated by hypothalamic corticotrophin releasing hormone (CRH). They have metabolic (glucocorticoid) as well as electrolyte regulating (mineralocorticoid) activity.[1] Glucocorticoids like Cortisol affect carbohydrate, fat, and protein metabolism along with anti-inflammatory, immunosuppressive, anti-proliferative and vasoconstrictive effect. Mineralocorticoids such as aldosterone involved in electrolyte and water balance by modulating ion transport in the renal tubules of kidney. Glucocorticoid have proved to be extremely effective in treatment of acute and chronic inflammatory diseases, due to this property these drugs are being prescribed widely by physicians. It is most frequently prescribed for patients with respiratory conditions such as asthma, COPD, allergic rhinitis, rheumatoid arthritis, inflammatory bowel disease, rejection of organ transplant and shock symptoms, also used as replacement therapy in Addison`s disease. The ability of corticosteroids to acts on different target tissues and exert biological responses depends in most cases on the presence of the glucocorticoid receptor (GR).[2] Due to its wide range of therapeutic uses, there is a possibility of induction of a large number of adverse events like Hypothalamic-pituitary-adrenal axis suppression, glaucoma, changes in bone mineral density, cataracts and psychiatric effect. So rational use of corticosteroid is really crucial. There is a need of DUE study of corticosteroid because misuse of corticosteroids is becoming a wide spread phenomenon. Despite their beneficial effects, long term oral or parenteral use of these agents is associated with various adverse drug reactions.[3] DUE is a systematic, authorized, structured, ongoing review of health care provider prescribing, pharmacist dispensing and patient use of medication. The goal of a DUE is to support the most effective and optimal medication therapy and ensure that drug therapy requires the current standards of treatment.

METHODS AND MATERIALS

Study Procedure: A total of 150 subjects receiving corticosteroids were included in a prospective observational research carried out in the General medicine department of Chigateri District hospital Davanagere for a period of six months. The ethical committee clearance was obtained from institutional ethics committee of SCS college of pharmacy. A set of inclusion criteria were carried out to conduct the study such as patients prescribed with atleast one corticosteroid, subjects of either sex above the age of 18 years, who were admitted in General medicine department. Patients who were pregnant or who do not require hospital stay were excluded from the study. Informed consent was taken from enrolled patients. A well designed data collection form was filled out with all the necessary information.

Data Analysis: The collected data were analyzed for evaluating the drug utilization pattern for ensuring the rationality of drug therapy and to identify possible drug interactions in the patients who were admitted in the medicine department. Data are analyzed using Microsoft excel and results are presented in tables.

RESULTS

Basic Demographic Details of the subjects

In our study the majority of the subjects belonged to the age group 61-70 (n=60, 40%) among which (n=36, 24%) were males and (n=24, 16%) were females. Out of total subjects 20% were smokers and 80 % were non-smokers.

Table 1: Basic demographics of the subjects.

AGE	GENDER	
	MALE	FEMALE
20-30	8 (5.33%)	6 (4.0%)
31-40	17 (11.33%)	5 (3.33%)
41-50	9 (6%)	7 (4.66%)
51-60	13 (8.66%)	10 (6.66%)
61-70	36 (24%)	24 (16%)
71-80	10 (6.66%)	5 (3.33%)
Total (N)	**93 (62%)**	**57 (38%)**
SOCIAL HABITS	**NO. OF PATIENTS**	
Smokers	30 (20%)	
Non smokers	120 (80%)	
Total (N)	150 (100%)	

Department wise distribution of corticosteroids

A major percentage of prescription belonged to Pulmonology Department (n=102, 68%), followed by Neurology (n=10, 6.66%), Rheumatology (n=10, 6.66%), Hepatology (n=9, 6%),

Nephrology (n=9, 6%), and the least were observed in Cardiology department (n=2, 1.34%).

Table 2: Department wise distribution of corticosteroids.

DEPARTMENT	NO. OF PATIENTS(N)	PERCENTAGE (%)
Pulmonology	102	68
Hepatology	9	6
Nephrology	9	6
Neurology	10	6.66
Cardiology	2	1.34
Rheumatology	10	6.66
Others	8	5.34

Distribution according to Brand and Generic name

As shown in the table (n=112, 59.89 %) drugs were prescribed by brand name and (n=75, 40.10 %) were prescribed in their generic name**.** Hydrocortisone was the most frequently prescribed drug using their Brand name (n=38, 20.32%%) followed by dexamethasone (n=29, 15.50 %), budesonide (n=28, 14.97 %), prednisolone (n=8,4.27 %) and methyl prednisolone (n=9, 4.81%).

Table 3: Distribution according to Brand and Generic name.

Drug	Drug type		No. of drugs(n)
	Brand	Generic	
Hydrocortisone	38	31	69
Dexamethasone	29	27	56
Prednisolone	8	5	13
Methylprednisolone	9	5	14
Budesonide	28	7	35
Total	**112(59.89%)**	**75(40.10%)**	**187**

Drug Utilization Pattern of Corticosteroids and their route of administration

In our study, Intravenous Hydrocortisone (n=69, 6.89%) was the predominantly prescribed drug followed by Dexamethasone (n=56, 29.94%), Budesonide (n=37, 19.58%), Methylprednisolone (n=14, 7.49%) and the least prescribed was Prednisolone (n=13, 6.95%).

Table 4: Drug Utilization Pattern of Corticosteroids and their route of administration.

DRUG	ROUTE			FREQUENCY
	IV	ORAL	INHALATION	
Hydrocortisone	69 (36.51%)	0	0	69
Dexamethasone	53 (28.04%)	3 (1.58%)	0	56
Prednisolone	2 (1.05%)	11 (5.82%)	0	13
Methylprednisolone	10 (5.30%)	4 (2.11%)	0	14
Budesonide	0	0	37 (19.58%)	37
Total(N)	**134(70.90%)**	**18(9.52%)**	**37 (19.58%)**	**189**

Steroid classification based on duration of action.

Out of 187 corticosteroids prescribed, majority was short acting [Hydrocortisone (n=69, 36.90%)] followed by intermediate acting [Prednisolone (n=13, 6.96%) and Methyl prednisolone (n=14, 7.49%)] and Long acting [Dexamethasone (n=56, 29.94%)]. The least among the list was [Budesonide (n=35, 18.71%)].

Table 5: Steroid classification based on duration of action.

Classification	Drug	No. of Drugs (n)	Percentage (%)
Short acting	Hydrocortisone	69	36.90
Intermediate acting	Prednisolone	13	6.96
	Methylprednisolone	14	7.49
Long acting	Dexamethasone	56	29.94
Inhalation	Budesonide	35	18.71
	Total (N)	**187**	**100**

Frequency of administration of corticosteroids

Out of 187 corticosteroids prescribed, 108 (57.76%) were prescribed in TDS, 39 (20.86%) were prescribed in BD, 16 (8.56%) prescribed as STAT, 9 (4.81%) prescribed in QID, 14 (7.48%) prescribed in OD, and 1 (0.53%) were indicated as SOS .

Table 6: Frequency of administration of corticosteroids.

Frequency of Administration	No. of corticosteroids (n)	Percentage (%)
OD	14	7.48
BD	39	20.86
TDS	108	57.76
QID	9	4.81
STAT	16	8.56
SOS	1	0.53
Total (N)	**187**	**100**

Severity Distribution of Interactions

In our study total of 452 interactions were found, which included moderate (n=273, 60.40%), minor (n=153, 33.84%) and major (n=26, 5.76%) interactions.

Table 7: Severity Distribution of Interactions.

Interactions	Frequency(n)	Percentage (%)
Minor	153	33.84
Moderate	273	60.40
Major	26	5.76
Total (N)	**452**	**100**

DISCUSSION

Corticosteroids are of great value in treating a wide spectrum of inflammatory and autoimmune conditions, thus periodic reassessment of prescriptions and rational drug prescription is necessary to increase the therapeutic efficacy.

During the study period, a total of 150 subjects were enrolled from various departments of medicine ward of the tertiary care teaching hospital. Most findings of our study correlate with the findings of earlier study which were conducted both in India and other countries. During the study 93 (62%) of the male patients were found to have prescribed with corticosteroid, which was more than females 57 (38%). Among those patients non-smoker's (80%) were more in number as compared to smokers (20%) as depicted by Aryal A et al[4] in their study conducted at Bangalore, Karnataka. Most of the patients belonged to the age group of 61-70 (40%), which was similar to result depicted in study conducted by Pandey M et al[5] at Punjab, India.

While analyzing department wise corticosteroids prescription, Pulmonology department 102 (68%) was the first among them followed by Rheumatology 10 (6.66%), Neurology10 (6.66%), Hepatology 9 (6%), Nephrology 9 (6%) and Cardiology 2 (1.34%) which was depicted in the study conducted by Unissa MS et al [6] at Hyderabad, Telangana.

While studying the prescription pattern, 107 prescriptions were found with single corticosteroid, 41 with two corticosteroids and 2 were with multiple corticosteroids as depicted in study conducted by Dr. Priyanka S et al [7] at Hyderabad, Telangana. 56.57% of corticosteroid was prescribed in their brand name and 43.42% were prescribed in their generic name, which was similar to DUE conducted by Chowdhury HM et al [8] at Suryapet, Telangana. In our study Short acting corticosteroids 69 (36.90%) were the most frequently prescribed followed by long acting 56 (29.94%), Inhalation 35 (18.71%) and Intermediate acting 27 (14.45%). The duration of corticosteroid was found to be a predominant in short acting agent, that seems to be an opposition to the result concluded by Aryal A et al [9] at Bangalore,

Karnataka. The reason behind this was that in our hospital much more symptomatic treatment condition was seen during the study period.

During the analysis of route of administration, Intravenous 134 (70.90%) was found to be highest followed by inhalation 37 (19.58%) and oral 18 (9.52%) as depicted in study conducted by Rajesham VV et al[1] at Hyderabad, Telangana.

A total of 187 corticosteroids were there in 150 prescriptions, in that TDS 108 (57.76%) was the most frequently prescribed frequency of administration, followed by BD 39 (20.86%), STAT 16 (8.56%), OD 14 (7.48%), QID 9 (4.81%) and SOS 1 (0.53%) which was contradictory to the study conducted by Chowdhury HM et al [8] at Suryapet, Telangana. The reason for the contradiction is that in our study, Hydrocortisone is prescribed frequently, which is administered by slow intravenous injection. The dose for this injection can vary from 100 to 500 mg. This dose can be repeated 3 or 4 times in 24 hours depending upon the condition being treated and response of the patient.

In order to improve the therapeutic efficacy and quality of life of the patient, it is essential to review the prescriptions and to find out possible drug interactions and thereby reducing the probability of having an adverse event. In this study out of 150 prescriptions 90 were found with interactions and 60 were without interactions. In 90 prescriptions with interactions 60.40% were moderate followed by 33.84% minor and 5.76% major, which was also depicted in study conducted by Dabral A et al[3] at Dehradun.

The goal of the corticosteroid therapy is usually to reduce symptoms to a tolerable level. Total suppression of symptoms may require excessively large doses and these may lead to serious adverse reactions. Indications for their clinical use should be clear cut as possible.

CONCLUSION

The current study primarily examined how well the corticosteroids were being used. Supremacy of corticosteroid use was perceived in male subjects belongs to the age group of 61 to 70 years. The predominance of respiratory diseases was found for which hydrocortisone was preferred often in a frequency of thrice daily. Although the majority of the drugs were prescribed rationally, educational and managerial approaches are needed to overcome the unwanted effects of corticosteroids. As the majority of study subjects belong to the elderly population, there is a need for proper treatment guidelines; taking into consideration patient

specific parameters which will improve therapeutic efficacy. Proper counseling is necessary for conveying proper instructions, thereby reducing the chances of treatment failures. Thus the involvement of clinical pharmacist is highly advised for the prevention and early detection of adverse events, thereby ensuring drug safety and improved patient care.

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CONFLICT OF INTEREST

All the authors declare no conflict of interest

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