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Study on Drug Utilization Evaluation of Corticosteroids in a Tertiary Care Teaching Hospital

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ABSTRACT

Steroids are widely prescribed and used by practitioners due to powerful anti-inflammatory and immunosuppressive actions. So, care should be exercised in the rational selection of steroids¹. Hence this study was aimed to evaluate the utilization of corticosteroids with the secondary objective to assess co-prescription with corticosteroids, the nature and severity of adverse drug reactions and drug-drug interactions, with an intention to prevent the inappropriate use of corticosteroids. A prospective observational study was carried out in 215 In-patient from various departments of the hospital during 6 months period and subjected to statistical analysis. Out of 215 In-patients, 145 were male and 70 were female, in which most of the patients (22.7%) belongs to age group of 51-60 years. The major complaints were respiratory tract disorders (about 48%) and most of the patients (82%) were prescribed single corticosteroids as monotherapy (42.3%, budesonide) in same or different dosage forms. The commonly used route of administration was inhalation (48%) and is co-prescribed with antibiotics (19.5%). The average number of drugs prescribed was 7.16 drugs per prescription. The mean duration of corticosteroids use was 3.20 ± 1.98 days. The incidence of drug interactions observed were higher (78.6%), with most of them were moderate interactions. The ADR observed with study population were few and minor. The study concluded that, the prescription of corticosteroids is found to be rational except for drug interactions and dosage regimen. Hence the involvement of clinical pharmacists in clinical practice helps to increase proper usage of corticosteroids and optimum outcome.

Keywords: Corticosteroids, Drug Utilization, Dug-Drug Interactions, Adverse Drug Reaction.

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INTRODUCTION

Now-a-days the prescribing pattern is changing and it has become just an indication of medicine with some instruction of doses without considering its rationality. It has been frequently observed that doctors are adopting polypharmacy, promoting unnecessary use of tonic and other drugs under the sales influence of drug companies and overlooking drug interactions. This has resulted in increased adverse drug effects and cost of treatment². Drug utilization research is an essential part of pharmacoepidemiology as it describes the extent, nature and determinants of drug exposure. Drug use is a complex process. In any country a large number of socio-economic factors contribute to the ways drugs are used. Drug utilization evaluation can be used for the description of drug use pattern; early signals of irrational use of drugs; interventions to improve drug use; quality control cycle; continuous quality improvement. The principal aim of drug utilization research is to facilitate the rational use of drugs in populations³. Worldwide, many studies on drug utilization have been performed and the collected data were used to⁴:

- Constitute guidelines for improving drug utilization patterns,
- Enable suitable modifications in prescription of drugs to increase the therapeutic benefit and decrease the adverse effects,
- Identify problems related to drug use such as poly pharmacy and drug-drug interaction,
- Implement economic aspects at all stages in the chain of drug use,
- Assist the prescribing physician to achieve rational and cost-effective medical care and
- Implement standards of medical treatment at all levels in the health care system.

Corticosteroids are adrenal steroids, divided into two types based upon their physiological effects such as a) Glucocorticoids & b) Mineralocorticoids. Corticosteroids are usually given for 1 of 3 reasons; 1) suppression of inflammation, 2) Replacement therapy and 3) Suppression of immune response. They are widely used either by systemic or topical route⁵. Oral corticosteroids have been widely used in medical practice for over 50 years and play major role in the treatment of chronic diseases like asthma, COPD, inflammatory joint disorders and other diseases affecting GIT & CNS. However, glaucoma, cataract, osteoporosis are the most serious complications of oral therapy⁶. Topical corticosteroids, which were introduced in late 1950s, have revolutionized the practice of dermatology and still constitute one of the largest group of drug used in treatment of psoriasis, urticaria, dermatitis, otitis externa etc. even though have prevalence to develop ADRs such as hypersensitivity, tachyphylaxis and increase susceptibility to bacterial and fungal infection^{7,8,9}. For successful treatment with corticosteroids, key factors to be considered are

accurate diagnosis, selecting the correct drug, keeping in mind the potency, delivery vehicle, frequency of use, duration of treatment and adverse drug effects, and proper patient counseling. To achieve this, there is need to monitor, evaluate and therapeutically analyze the prescribing pattern of corticosteroid drugs. Such analysis will not only improve the standards of medical treatment at all levels in health system, but will also help in the identification of problems related to drug use such as polypharmacy, Drug-Drug interactions and Adverse Drug Reactions⁷. The ultimate goal in corticosteroids therapy is to use the safest and least number of drugs in order to obtain the best possible effect in the shortest period at reasonable cost. The pattern of corticosteroids use in hospital setting monitored intermittently, will analyze their rationality and to offer feedback and/or suggestions to drug prescribers so as to enable and effect suitable modifications in prescribing pattern to increase the therapeutic benefits and reduce adverse effects. The ultimate outcome of the study will be a message to the prescribing doctor to achieve rational medical care⁸.

MATERIALS AND METHOD

Study Design

It was a prospective observational study

Study setting

The study was conducted in the various departments of Navodaya Medical College, Hospital and research center, Raichur, Karnataka, after obtaining the ethical clearance.

Study period

The study was conducted over a period of six month from November 2014 to April 2015.

Study criteria

Inclusion criteria

In-patients prescribed with corticosteroids from General Medicine, Orthopedic, ICU &Emergency, Pediatrics, Post-Operative and Pulmonary Medicine.

Exclusion Criteria:

The patients from departments other than mentioned in inclusion criteria.

Source of Data

The data was collected from various sources such as patient's case reports, laboratory data, treatment charts and patient interview/patient care taker interview using specially designed data collection form.

Study protocol

Patient who met the study criteria were included in the study. Demographics, lab data, diagnosis and treatment chart were noted. All the cases were reviewed prospectively and monitored

extensively, the pattern of corticosteroids uses like their category, indication, rationality of the prescription (number of corticosteroids, appropriateness of dose, dosage form, and duration of therapy) and number of drugs in prescriptions. Drug-drug interactions were checked by using MICROMEDEX software, DRUG.COM and STOCKLEY book as well as ADRS found were recorded and reported.

Statistical Analysis

Data was analyzed using descriptive statistics namely total numbers, percentage, mean and standard deviation wherever applicable.

RESULTS AND DISCUSSION

As per demographic data obtained, out of the total 215 In-patients, 64.4 % were male and 32.6 % were female. This data showed that commonly male population are more prone to diseases, for which steroids are used. A maximum of around 23 % belonged to age group of 51-60 years followed by around 22 % from the age group of more than 60 years. It shows that corticosteroids are mainly used in old age groups. However around 16 % of the In-patients belonged to pediatrics group of 0-10 years. The mean age of the in-patients was 42.5 ± 1.81 and 38.59 ± 0.94 years in males and females respectively (Table 1).

Table 1: Age Wise Distribution

Age Group (years)	Male	Percentage (%)	Female	Percentage (%)	Total	Percentage (%)
In-Patients (N=215)						
0-10	23	5.5	12	5.5	35	16.2
11-20	7	2.7	6	2.7	13	6.0
21-30	8	2.3	5	2.3	13	6.0
31-40	16	4.1	9	4.1	25	11.6
41-50	23	4.6	10	4.6	33	15.3
51-60	32	7.9	17	7.9	49	22.7
>60	36	5.1	11	5.1	47	21.8

Out of 215 In-patients, majority were from General Medicine (43.7%), Pediatrics (17.2%) and Pulmonary Medicine department (14.4%).(Figure 1) The major clinical complaints of these patients were related to respiratory tract i.e. COPD (20.9%), LRTI (11.1%), TB (9.3%) and Pneumonia (7.9%). (Table 2)

Table 2: Disease Associated with Study Population

Disease	No. of Patients	Percentages (%)
In-Patients (N=215)		
COPD	45	20.9
LRTI	24	11.1

TB	20	9.3
Pneumonia	17	7.9
HTN with fever	11	5.1
Asthma	11	5.1
Bronchitis	8	3.7
Nephritis	6	2.7
Anemia	6	2.7
Meningitis	6	2.7
Spondylitis	6	2.7
Arthritis	6	2.7
Fracture	5	2.3
Infection	5	2.3
UTI	4	1.8
DM with HTN	3	1.3
AGE	3	1.3
Hepatitis	2	0.9
Psoriasis	2	0.9
Miscellaneous	25	11.6

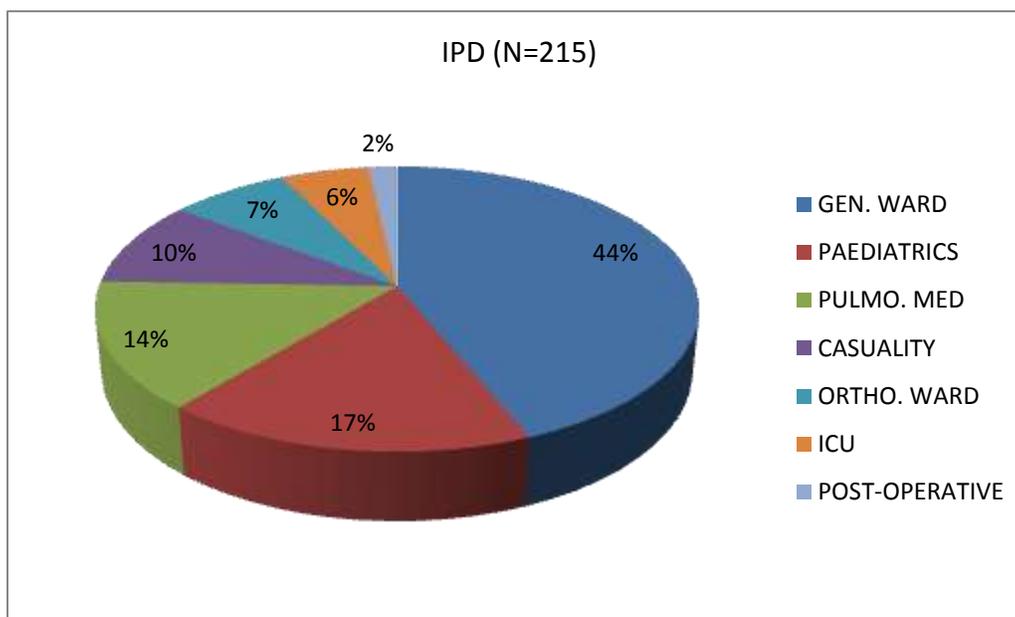


Figure 1: Ward Wise Distribution

Majority of in-patients were prescribed with potent class of corticosteroids (81.5%) (Figure 2). The most widely prescribed corticosteroids were budesonide (42.3%), followed by dexamethasone (33.7%) (Table 3). The duration of treatment with corticosteroids was mainly found to be four days (20.9%), followed by three days (18.1%) and two days (15.3%) (Table 4). The mean duration of corticosteroids use was 3.20 ± 1.98 in days. Among various dosage forms of steroids use, nebulization was most widely/ frequently used (46.9%), followed by injection (37.2%) and tablets (13.4%) (Table 5).

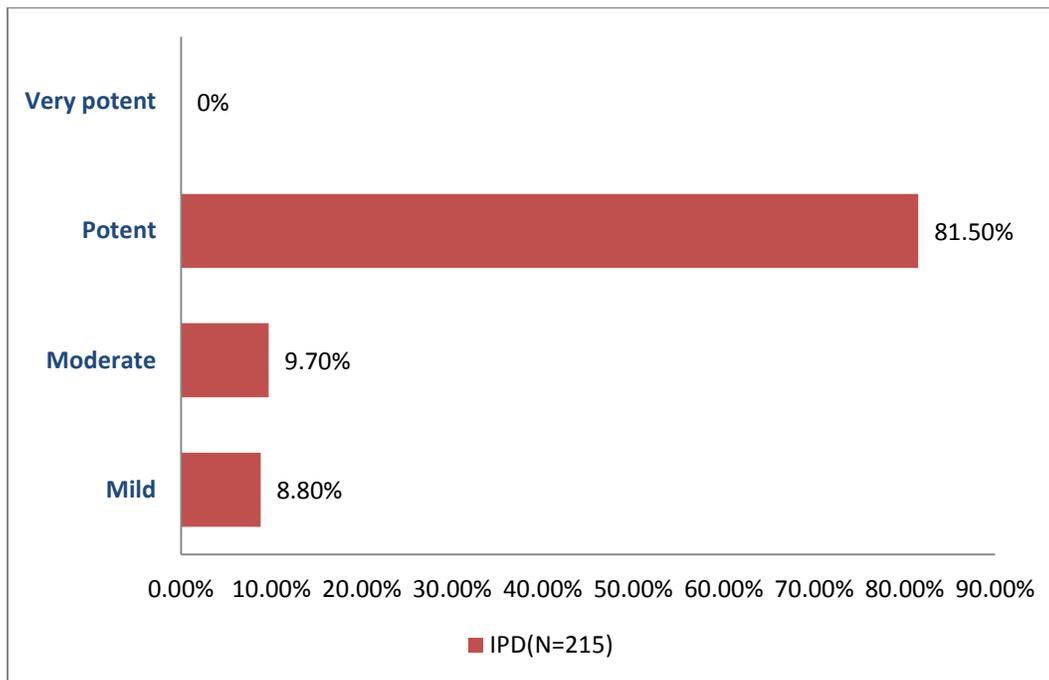


Figure 2: Class of Corticosteroids Prescribed

Table 3: Individual Corticosteroids Prescribed

Corticosteroids	No. of Patients	Percentages (%)
In-Patients (N= 215)		
Budesonide	91	42.3
Dexamethasone	73	33.9
Prednisolone	17	7.9
Hydrocortisone	14	6.5
Fluticasone	8	3.7
Deflazacort	7	3.2
Methyl Prednisolone	2	0.9
Formetrol	2	0.9
Beclomethasone	1	0.4

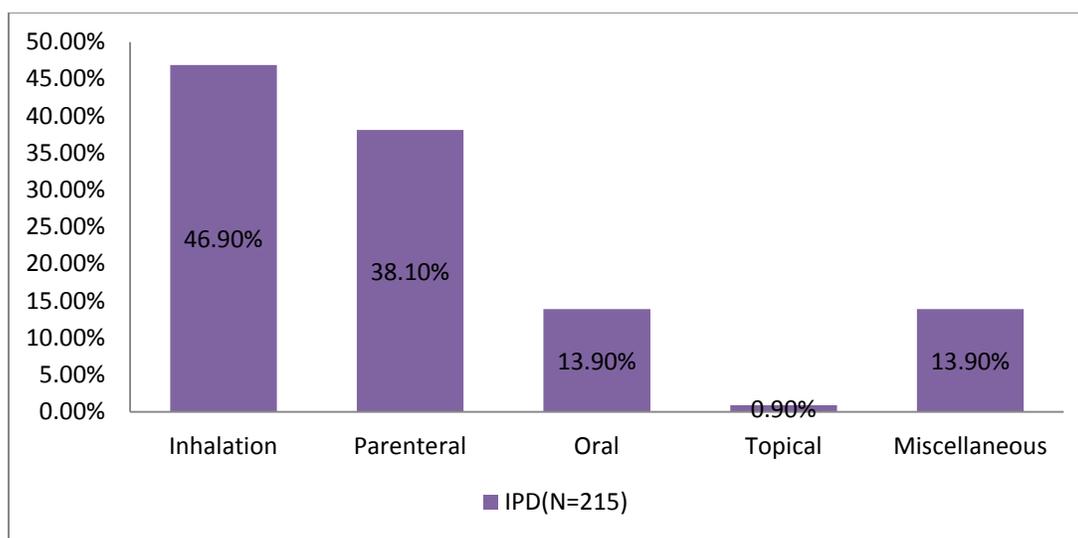
Table 4: Duration of Treatment with Corticosteroids

Duration (in days)	No. of Patients	Percentages (%)
In-Patients (N=215)		
1	19	8.8
2	33	15.3
3	39	18.1
4	45	20.9
5	31	14.4
6	11	5.1
7	13	6.0
8	6	2.7
9	6	2.7
10	3	1.3
>10	9	4.1

Table 5: Dosage Form of Corticosteroids Prescribed

Dosage form	No. of Patients	Percentages (%)
In-Patients (N=215)		
Inhalation	101	46.9
Injection	80	37.2
Tablet	29	13.4
Infusion	2	0.9
Topical (in any)	2	0.9
Syrup	1	0.4

Among 215 in-patients, 178 patients (82.79%) were prescribed with single corticosteroids and remaining patients were given combination of corticosteroids through same or different routes. (Figure 3) The most widely used combination was dexamethasone + budesonide (9.3%), followed by hydrocortisone + budesonide (3.7%), for greater potency and efficacy in treatment of respiratory tract disorders.(Table 6).

**Figure 3: Route of Administration of Corticosteroids****Table 6: Different Combination of Corticosteroids Prescribed**

Combination of corticosteroids prescribed	No. of patients	Percentage (%)
In-Patients (N=215)		
Dexamethasone + Budesonide	20	9.3
Hydrocortisone + Budesonide	8	3.7
Hydrocortisone + Dexamethasone	3	1.3
Deflazacort + Dexamethasone	2	0.9
Prednisolone + Fluticasone	1	0.5
Prednisolone + Hydrocortisone	1	0.5
Prednisolone + Deflazacort	1	0.5
Budesonide + Deflazacort	1	0.5

Most of the In-patients received more than 3 drugs (96.3%) and 15.7% of patients received 10 or more than 10 drugs.(Table 7) The average number of drugs prescribed was 7.16 drugs per prescription. These results indicate high incidence of polypharmacy, which may be due to the patient's expectation and demand of quick relief, incorrect diagnosis and the influence of the lucrative promotional programs of the drug companies.

Table 7: Incidence of Polypharmacy

No. of drug per prescription	No. of Patients	Percentages (%)
In-Patients (N= 215)		
3	8	3.7
4	11	5.1
5	34	15.8
6	40	18.6
7	30	13.9
8	33	15.3
9	25	11.6
10	16	7.4
11	13	6.0
12	4	1.9
13	1	0.7

Concurrent drugs distribution shows that, among 215 in-patients, antibiotics (19.5%) were most frequently administered, followed by acid suppressants (15.2%) and bronchodilators (10.1%).(Table 8) This analysis showed that antibiotics and bronchodilators were most prescribed systemic agents because of disease prevalence with related symptoms of LRTI.

Table 8: Con-current Drugs Prescribed with Corticosteroids

Drug category	No. of Patients	Percentages (%)
In-Patients (N=215)		
Antibiotics	201	19.5
Acid suppressants	156	15.2
Bronchodilators	104	10.1
Anti-pyretics	91	8.8
Electrolytes	80	7.7
Multivitamins	65	6.3
Expectorants	63	6.1
NSAIDs	56	5.4
Anti-hypertensives	31	3.0
Diuretics	27	2.6
Anti-emetics	26	2.6
Anti-allergics	26	2.6
Hypoglycaemics	15	1.4
Anti-amoebics	15	1.4
Anti-malarials	11	1.0

Opioid analgesics	8	0.8
anti-depressants	8	0.8
Anti- tubercular	7	0.6
Miscellaneous	42	4.0

Among in-patients, the incidence of drug-drug interaction was observed in 169 prescriptions (78.6%). Among these 169 prescriptions, the total number of drug-drug interactions with corticosteroids was found to be 194, of which 171 are moderate and 23 are major interactions. The possible reason for high incidence of drug-drug interactions may be multiple complaints or incorrect diagnosis or polypharmacy (Table 9). The ADR observed with study population were few and minor i.e., hypertension (2.4%) and joint pain (0.6%) (Table 10)

Table 9: Drug-Drug Interaction Observed

Ward	No. of Patients	No. of prescription with interaction (%)	No. of total interaction with corticosteroids	No. of Moderate Interaction	No. of major interaction
In-Patients (N=215)					
General medicine	94	73(33.9%)	92	83	9
Pulmonary med.	31	24(11.2%)	19	19	0
Paediatrics	37	23(10.6%)	33	28	5
Orthopaedics	16	13(6.0%)	13	13	0
Emergency & causality	21	17(7.9%)	17	15	2
ICU	12	10(4.6%)	12	7	5
Post-operative	4	4(1.8%)	8	6	2
Total	215	169 (78.6%)	194	171	23

Table 10: ADRs Observed with Corticosteroids

Adverse drug reaction	No. of Patients	Percentages (%)
In-Patients (N=215)		
Hypertension	4	2.4
Joint pain	1	0.6

CONCLUSION

In the present study, the prescription of corticosteroids is found to be rational except for drug interactions and dosage regimen. However there was a lack of appropriate guidelines and drug interaction reporting is emerging scope of pharmacy should be considerable. Commonly pediatric and geriatric population was more prone to diseases, for which steroids are used. Hence close observation is required. To ensure safe, effective and well balanced therapeutic management with corticosteroids, both patients and prescribers should be more aware of the appropriate dose, dosage regimen, drug-drug interactions, frequently occurred ADRs and overall guidelines for

corticosteroids prescribing. Hence the involvement of clinical pharmacists in clinical practice helps to increase proper usage of corticosteroids and optimum outcome.

LIMITATION

- The study was conducted for a short period (6 months) which can be extended.
- The study was conducted in seven different wards which can be extended to other departments like ENT, surgery etc.

FUTURE DIRECTION

Drug use evaluation helps us to understand how and why drugs are used, so that drug use and health outcome can be improved. It can play a key role in helping the healthcare system to understand, interpret and improve the prescribing, administration and use of medications.

- Repeated monitoring of drug usage combined with regular feedback to the prescribers is essential. Measures to facilitate and encourage rational prescribing among the students and prescribers should be undertaken.
- Pharmacoeconomic studies can be conducted to promote safe and cost effective use of corticosteroids.

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