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### RESEARCH ARTICLE

## EVALUATION OF CORTICOSTEROID UTILIZATION PATTERN IN TERTIARY CARE HOSPITAL, DEHRADUN.

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##### Key words:-

Corticosteroids, Anti-inflammatory, immunosuppressive, adverse drug reaction, drug interaction.

#### Abstract

**Background:** Corticosteroids are widely used as potent anti-inflammatory and immunosuppressive drugs to treat a wide range of diseases. This study evaluates the rational use of corticosteroid amongst hospitalized patients.

**Objectives:** To investigate the utilization and evaluation pattern of corticosteroids in various department of tertiary care hospital.

**Methodology:** A prospective observational study was conducted on 90 patients receiving corticosteroids in the various departments of ShriMahantIndiresh Hospital, Dehradun, Uttarakhand. Patients receiving corticosteroid therapy were included in the study, exclusion of those patients who were of age less than 18, patients with psychiatric disease and those patients not willing to sign on inform consent form.

**Result:** The study involved 90 patients to evaluate the appropriate use of corticosteroids. Majority of patients were of age group >60 years, followed by 41-50 years, 51-60 years, 31-40 years, 18-30 years respectively. Majority of corticosteroids were prescribed to females than males. Prednisolone was the mostly used corticosteroid (34.40%) followed by hydrocortisone (18.9%), budesonide (14.4%), methylprednisolone (11.1%), dexamethasone (11.1%), deflazacort (5.6%) and prednisone (4.4%). Total 16 ADRs were detected in the study. Total 24 drug interactions were found in 90 prescription, the majority of drug interactions were moderate 15 (62.50%) followed by major 5 (20.83%) and minor 4 (16.67%).

**Conclusion:** There was lack of appropriate guidelines for use of corticosteroids and drug interaction reporting, which could be considered an emerging scope of pharmacy. Commonly geriatric population was more prone to diseases, for which steroids were used.

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#### Introduction:-

Glucocorticoids are widely used as potent anti-inflammatory and immunosuppressive drugs to treat a wide range of diseases. However, they are also associated with a number of side effects.<sup>1</sup> Glucocorticoids are used as replacement therapy in adrenal insufficiency as well as for the management of various dermatologic, ophthalmologic, rheumatologic, pulmonary, hematologic, and gastrointestinal disorders. In the field of respiratory, systemic corticosteroids are used for the treatment of acute exacerbations of chronic obstructive pulmonary disease (COPD) and severe, uncontrolled asthma, as well as for inflammatory parenchymal lung diseases such as hypersensitivity

pneumonitis and immune mediated vasculitis.<sup>2</sup> Oral corticosteroids become important part of therapy regimens for a diverse variety of conditions. Despite their efficacy, they are associated with a wide variety of adverse events.<sup>3</sup> There has been increasing concern regarding the safety of corticosteroids, as a large number of patients are prescribed these drugs for long-term prophylactic treatment. There are different areas of concern with regard to systemic side effects, HPA-axis suppression, glaucoma, changes in bone mineral density and cataracts, psychiatric effects.<sup>4</sup>

Since the discovery of corticosteroids most areas of clinical practice have been influenced by these compounds. Sometimes their use has been soundly based on rational principles supported by adequate clinical trials, but often they have been used without any evidence for their efficacy. As a result of their mode of action and their use in such a wide range of diseases, no class of drugs has ever come closer than corticosteroids to the universal healer, so avidly sought by medieval physicians.<sup>5</sup> The present study has been to get overview of the current trends of corticosteroids utilisation in health care centre and to facilitate rational use of drugs in population. Corticosteroids have multiple uses so its utilisation also depends upon the condition and doses. This study focuses on the current practice followed by medical practitioners and the uses of drug.

A systematic review is performed in US to find incidence and US costs of corticosteroid-associated adverse events. In this study psychiatric events, infections, gastric conditions, and fractures were the most frequently reported corticosteroid-associated AEs. Corticosteroid-associated AEs reported to occur at an incidence >30% were sleep disturbances, lipodystrophy, adrenal suppression, metabolic syndrome, weight gain, and hypertension. Incidence of vertebral fractures was 21% to 30%. The literature reported 1-year per-patient costs of up to \$26,471.80 for nonfatal myocardial infarction, and per-event costs as high as \$18,357.90 for fracture. Based on the findings from this review, systemic corticosteroids are a common cause of AEs that may increased the cost of the treatment.<sup>6</sup>

Due to the wide range of therapeutic uses of corticosteroids there is large number adverse events induced by the use of the corticosteroids like HPA-axis suppression, glaucoma, changes in bone mineral density and cataracts, psychiatric effects. So the rational use of corticosteroid is very important.

There is a need of DUE study of corticosteroids because misuse of corticosteroids is becoming a widespread phenomenon. Despite their beneficial effects, long-term systemic (oral or parenteral) use of these agents is associated with well known adverse events (AEs) including osteoporosis and fractures, adrenal suppression (AS), hyperglycemia and diabetes, cardiovascular disease (CVD) and dyslipidemia, dermatological and GI events, psychiatric disturbances and immunosuppression. The potent effect of corticosteroids can result in serious side effects, which mimic Cushing's disease.

### **Material and Method:-**

A prospective observational study was conducted to evaluate drug utilization pattern of corticosteroids. Patients prescribed with corticosteroids in various departments were interviewed randomly. The name, dose, dosage, frequency, side effects and adverse drug reaction of drugs were noted of the patients who prescribed corticosteroids.

#### **Study Site:**

The study was carried out in various departments of Tertiary Care Hospital in Deharadun.

#### **Inclusion criteria:**

- Inpatients prescribed with corticosteroids.
- Patients of either gender.
- Patients above 18 years of age.

#### **Exclusion criteria:**

- Patients below 18 years of age.
- Patients treated on outpatient basis.
- Patients under critical condition and requiring critical care stay.
- Lactating and nursing mothers.
- Patients not willing to sign inform consent form.

**Sources of Data:**

- Inpatient profile form
- Patient history record.
- Laboratory data record.
- Verbal communication with patients.

**Statistical analysis:** Statistical analysis was conducted descriptively by using SPSS 21 software.

**Duration of study:** The study was conducted for a period of 6 month after obtaining IEC clearance.

**Collection of data:** The data was collected using suitably designed data collection form.

**Results:-****Demographic details of subjects**

All subjects satisfy the inclusion and exclusion criteria were included as the study population. Total 90 inpatient subjects prescribed corticosteroids were included in the study.

Subjects were categorised according to gender and out of 90 subjects 40 (44.44%) were male and 50 (55.56%) were female. According to age group distribution 8 subjects were in age group of 18-30 years, 11 subjects were in age group of 31-40 years, 18 subjects were in age group of 41-50, 15 subjects were in age group of 51-60 and 38 subjects were in age group above 60 years, the mean age of population was  $54.47 \pm 15.08$  (Mean $\pm$ SD) and the range of ages was between 18-60> years old. 67 (74.44%) subjects were married and 23 (25.56%) were unmarried. When distributed according to employment status, out of 90 subjects most of them were unemployed 38 (42.22%), in unorganised sector 15 (41.11%), in government sector 15 (16.67%) as shown in table 1.

**Table 1:-**Demographic details of subjects

<b>Gender</b>	<b>No. of subjects</b>	<b>Percentage %</b>
Male	40	44.44
Female	50	55.56
<b>Age</b>	<b>No. of subjects</b>	<b>Percentage %</b>
18-30	8	8.89
31-40	11	12.22
41-50	18	20.00
51-60	15	16.67
60>	38	42.22
<b>Age ranges</b>	<b>Mean age <math>\pm</math> SD</b>	
18-60>	$54.47 \pm 15.08$	
<b>Marital status</b>	<b>No. of subjects</b>	<b>Percentage %</b>
Married	67	74.44
Unmarried	23	25.56
<b>Occupation</b>	<b>No. of subjects</b>	<b>Percentage %</b>
Government	15	16.67
Unorganised	37	41.11
Unemployed	38	42.22

**Prescribing pattern of corticosteroids**

Prednisolone was prescribed in 31 (34.9%) prescription followed by hydrocortisone in 17 (18.9%), budesonide in 13 (14.4%), dexamethasone in 10 (11.1%), methylprednisolone in 10 (11.1%), deflazacort in 5 (5.6%) and prednisone in 4 (4.4%) respectively as shown in fig.1.

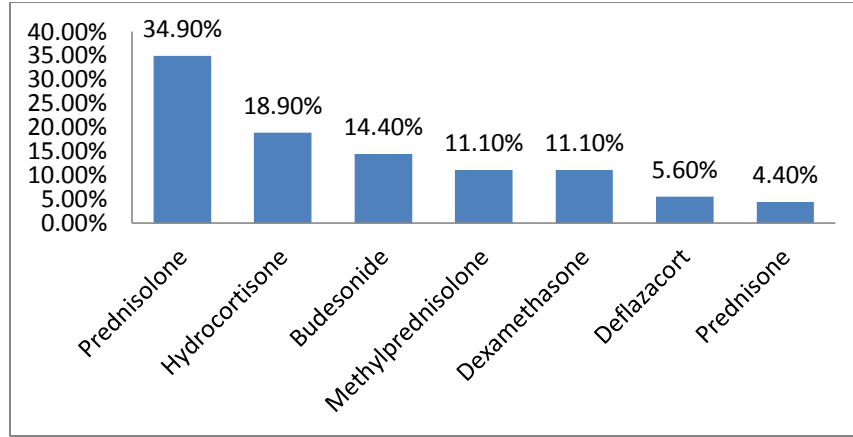


Fig.1:-Representing the prescribing pattern of corticosteroids.

**Dosage form used in study**

The most preferred route of administration of corticosteroid was oral (47.8%), IV (37.8%) and inhaler (14.4%) respectively as shown in fig.2.

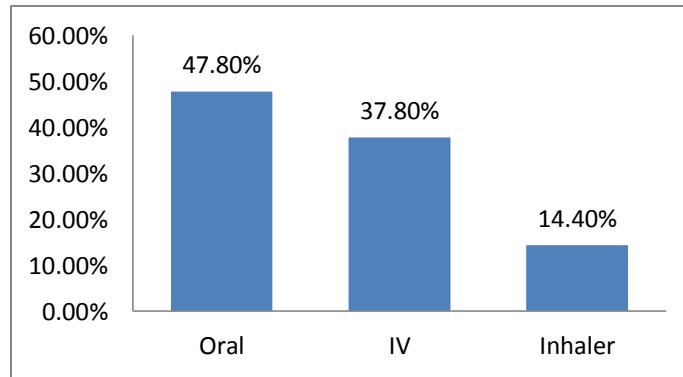


Fig.2:-Representing the dosage form of corticosteroids.

**Distribution of diseases treating with corticosteroids**

Corticosteroids were used in COPD (17.78%), ulcerative colitis (3.33), TB (3.33%), RA (11.11%), osteoarthritis (4.44%), meningitis (3.33%), CKD (7.78%), liver cirrhosis (2.22%), ILD (4.44%), gout (2.22%), bronchial asthma (11.11%), hepatitis (2.2%) and other conditions (26.67%) respectively as shown in fig.3.

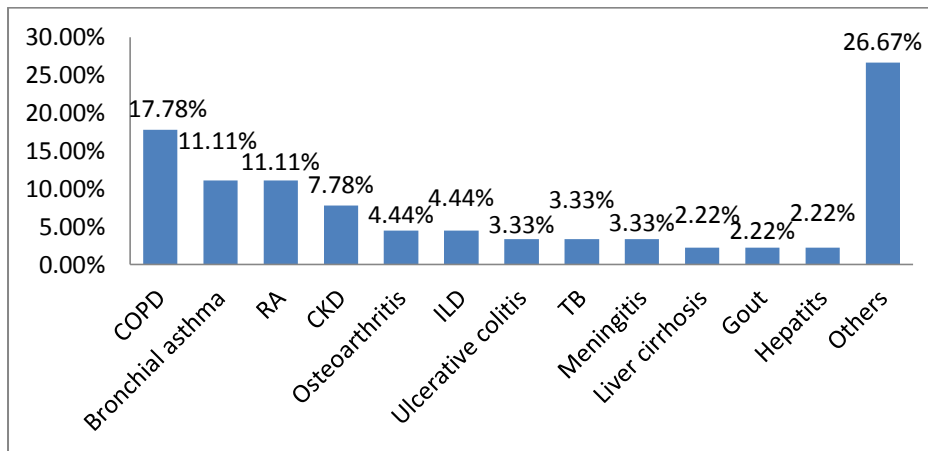
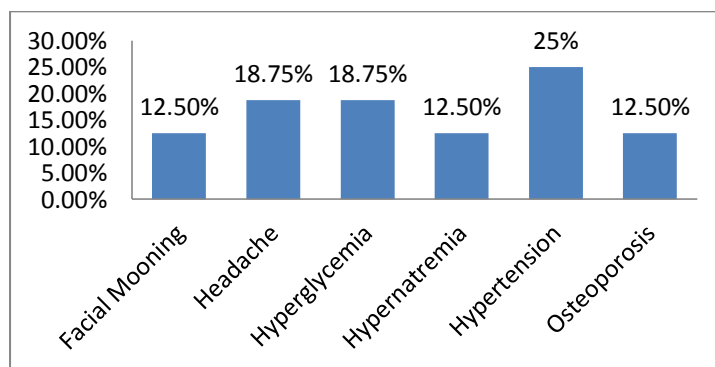


Fig.3:-Representing the percentage diseases treated with corticosteroids.

**ADRs due to corticosteroids**

Total 16 (17.78%) ADRs were detected in the study due to corticosteroid use, facial mooning was detected in 2 (12.50%), headache in 3 (18.75%), hyperglycemia in 3 (18.75%), hypernatremia in 2 (12.5%), hypertension in 4 (25%) and osteoporosis in 2 (12.50%) as shown in fig.4.



**Fig.4:-**Representing the ADRs due to corticosteroid use.

**Causality assessment of ADRs according to Naranjo scale**

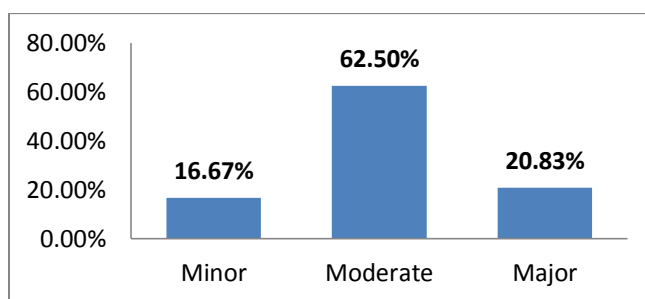
Out of 16 ADRs 7 (43.75%) were probable and 9 (56.25%) were possible according to Naranjo causality assessment scale as shown in table 2.

**Table 2:-**Causality assessment of ADRs by Naranjo scale

Causality Assesment by Naranjo scale	No. of ADRs	Percentage %
Probable	7	44
Possible	9	56

**Drug interactions with corticosteroids**

Total 24 drug interactions were found in 90 prescription, the majority of intractions were moderate 15 (62.50%) followed by major 5 (20.83%) and minor 4 (16.67%) respectively as shown in fig.5.



**Fig.5:-**Representing drug interactions with corticosteroids.

**Discussion:-**

The data was subjected to descriptive analysis using SPSS 21 and Microsoft Excel. 90 subjects were included who were prescribed with corticosteroids and admitted to the various inpatient departments of tertiary care hospital. Demography, corticosteroid used, route of administration, dose, dose frequency, dosage form of corticosteroids, condition for use, drug interactions and ADRs subsequent to use of corticosteroids were studied.

This study included 90 subjects out of which 50 (55.6%) were female and 40 (44.4%) were male. In age wise distribution, 8 (8.89%) subjects prescribed with corticosteroid in age group 18-30 years, 11 (12.22%) subjects in 31-40 years, 18 (20%) in 41-50 years, 15 (16.67%) in 51-60 years and 38 (42.22%) in above 60 years. The mean age of subjects was  $54.47 \pm 15.08$ . In this the prescribing of corticosteroids were increasing as the age group increased. The number of married subjects 67 (74.44%) were more than unmarried subjects 23 (25.56%). There were 57.78% employed subjects and 42.22% unemployed subjects in the study. These factors were comparable with the studies of

Overman A. Robert *et al.*<sup>7</sup> who found that mean age of subjects was 56.5 (54.4-58.7) years. Women (53.3%; 95% CI 47.2–59.4) represented a larger proportion of oral glucocorticoid users than men. When stratified by sex, oral glucocorticoid use was reported by 1.3% (95% CI 1.0 –1.5) of women and 1.2% (95% CI 1.0 –1.4) of men. When stratified by sex and age, the prevalence rates were between 0.5% and 3.5%. Greatest use by sex and age was reported in men ages  $\geq 80$  years (3.5%; 95% CI 2.3–4.7) and women ages 70–79 years (2.7%; 95% CI 1.7–3.7) and Curtis R Jeffery *et al.*<sup>8</sup> who found that mean age of subjects was 53 $\pm$ 14 years. The percentage of female (71%) was more than male subjects. Percentage of married and employed subjects was 67% and 56% respectively. In another study by Laugesen Kristina *et al.*<sup>9</sup> in which the annual prevalence of systemic GC prescription users was higher among women than among men with a prevalence ratio of 1.11 (95% CI 1.11 to 1.11) and prevalence ranging from 3.3% to 3.7% in women and 2.7% to 3.1% in men. The prevalence of prescription users increased substantially with age. Thus, persons aged 40–64 were more than 10 times as likely and persons aged 80+ were more than 25 times as likely to receive GC treatment than those aged below 19 years. This shows that with increase in age number of diseases increases and due to which use of corticosteroid was increases with age.

Our finding that prednisolone was the most frequent corticosteroid prescribed (34.9%) followed by hydrocortisone (18.9%), budesonide (14.4%), dexamethasone (11.1%), methylprednisolone (11.1%), deflazacort (5.6%), and prednisone (4.4%) was consistent with the finding of Laugesen K, *et al.*<sup>9</sup> who reported that 50% of the total corticosteroid prescription were for prednisolone and Overman R, *et al.*<sup>7</sup> who reported that prednisolone was the oral corticosteroid most commonly prescribed.

Oral route (47.8%) is the most preferred route of administration followed by IV (37.8%) and inhaler (14.4%) which is not consistent to the study of Thakur P.K, *et al.*<sup>10</sup> in which inhalation (46.9%) was the most preferred route of administration followed by injection (37.2%), oral (13.4%), infusion (0.9%), topical (0.9%), syrup (0.4%). This can be due to the difference in the inclusion criteria of the study.

In our study corticosteroids were used in COPD (17.78%), ulcerative colitis (3.33), TB (3.33%), RA (11.11%), osteoarthritis (4.44%), meningitis (3.33%), CKD (7.78%), liver cirrhosis (2.22%), ILD (4.44%), gout (2.22%), bronchial asthma (11.11%), hepatitis (2.2%) and other conditions (26.67%) which was consistent to the study by Thakur P.K, *et al.*<sup>10</sup> in which the major clinical complaints were related to respiratory tract i.e. COPD (20.9%), LRTI (11.1%), TB (9.3%) and pneumonia (7.9%). COPD was the diagnosis for which most of the corticosteroid was prescribed.

In 90 prescriptions total 24 interactions were found out of which 4 (16.67%) were minor, 15 were (62.50%) moderate and 5 (20.83%) were major. Mostly moderate interactions were found in the study which was consistent with the study of Kumar S, *et al.*<sup>11</sup> who found that 80% of the interactions were moderate, 13% were major and 55.8% were contraindicated interactions subsequent the use of corticosteroids in his study.

16 ADRs were found in this study due to corticosteroids use. Facial mooning was detected in 2 (12.50%), headache in 3 (18.75%), hyperglycemia in 3 (18.75%), hyponatremia in 2 (12.5%), hypertension in 4 (25%) and osteoporosis in 2 (12.50%). By using Naranjo causality assessment scale 9 ADRs were possible and 7 ADRs were probable. Our study was consistent with the study of Treadwell.B, *et al.*<sup>12</sup> who found that corticosteroid causes hypertension, facial mooning, osteoporosis in the subjects who were on corticosteroid therapy. Also Clore J, *et al.*<sup>13</sup> in his study found that Glucocorticoid-induced hyperglycemia is common in patients with and without diabetes. The odds ratio for new-onset diabetes mellitus in patients treated with glucocorticoids ranges from approximately 1.5 to 2.5.

### Conclusion:-

Prescription pattern of corticosteroids was not found to be rational as the number of drug interactions was high. There was a lack of appropriate guidelines and drug interaction reporting is emerging scope of pharmacy should be considerable. Commonly geriatric population was more prone to diseases, for which steroids were used. Hence close observation is required. To ensure safety, effectiveness and well balanced therapeutic management with corticosteroids, both patients and prescribers should be more aware of the appropriate dose, dosage regimen, drug-drug interactions, ADRs and overall guidelines for corticosteroids prescribing. Hence, the clinical pharmacist can perform potential role in health care system in assisting physician in altering the number of medications taken, the number of doses taken, improving the patient medication adherence, preventing the adverse drug reactions, drug-drug interactions, in patient counselling, improve the health related quality of life and decreasing the health care cost of the patient.

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**Conflict Of Interest:-**

The authors declare no conflict of interest.

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