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RESEARCH ARTICLE
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PRESCRIPTION PATTERNS AND SAFETY EVALUATION OF CORTICOSTEROIDS IN A TERTIARY CARE SETTING, NORTH INDIA

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Abstract:
Corticosteroids are widely used in various medical conditions due to their potent anti-inflammatory and immunosuppressive properties. However, their long-term use can lead to significant adverse effects. This study aimed to evaluate the prescription patterns and safety of corticosteroids in a tertiary care setting.
Objectives: To assess prescription patterns and safety evaluation of drugs in patients using different corticosteroids.
Material & Methods: An observational prospective study was conducted by the Department of Pharmacology in L.L.R.M Medical College, Meerut, UP. Data were collected from admitted patients. Inclusion criteria encompassed patients prescribed corticosteroids, while exclusions involved those with incomplete medical records, critically ill, pregnant, and non-consenting patients.
Results: The study included 165 patients, with a mean age of 39.85 ± 11.15 years. The demographic analysis revealed a male predominance (61.21%). The most prescribed corticosteroids were methylprednisolone, hydrocortisone and dexamethasone; primarily administered intravenously (65.83%). The average number of drugs per prescription was 8.95 with corticosteroids at 1.21 per prescription.
Conclusion: The study revealed that corticosteroids were commonly prescribed for respiratory and rheumatologic conditions. The most frequently prescribed corticosteroid was methylprednisolone. The findings suggest that corticosteroids are effective in managing various conditions, but their use requires careful consideration of risks and benefits.

Keywords: Prescription patterns, Safety evaluation, Corticosteroids

INTRODUCTION:

Corticosteroids are a class of steroid hormones that are widely used in medicine due to their potent anti-inflammatory and immunosuppressive properties. They are used to treat a variety of conditions, including respiratory diseases, rheumatologic disorders, and allergic reactions.

The World Health Organization (WHO) in 1997 defined drug utilization as the marketing, distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social, and economic consequences. Drug utilization research is an essential part of pharmacoepidemiology and Pharmacoeconomics as it describes the extent, nature, and determinants of drug exposure. [1, 2]

Corticosteroids (CS) are potent anti-inflammatory and immunosuppressive drugs, widely used to treat variety of diseases, [3] like replacement therapy in adrenal insufficiency and of various dermatologic, ophthalmologic, rheumatologic, pulmonary, hematologic, and gastrointestinal conditions. They are also used to treat acute exacerbations of chronic obstructive pulmonary disease (COPD) and severe, uncontrolled asthma, as well as inflammatory parenchymal lung diseases such as hypersensitivity pneumonitis and immune-mediated vasculitis. [4]

Despite their efficacy, corticosteroids are linked to a wide range of adverse effects. As a greater number of patients are prescribed corticosteroids for long-term prophylaxis so there has been growing concern about their safety. [5] Long-term systemic (oral or parenteral) use of these agents is associated with well-known adverse events (AEs), such as osteoporosis and fractures, adrenal suppression, hyperglycemia and diabetes, cardiovascular disease (CVD) and dyslipidemia, dermatological and gastrointestinal (GI) events, psychiatric disturbances, and immunosuppression. Corticosteroids can cause serious side effects that mimic Cushing's disease due to their potent effect. Systemic corticosteroids are a common cause of adverse effects that may increase the treatment cost. [6]

The usefulness of corticosteroids is limited by their severe adverse effects, despite their high potency. Corticosteroids side effects appear related to both their average dose and cumulative duration.[7] Although adverse effects are not restricted to greater doses and long-term usage, they are more prevalent at these levels. Ninety percent of patients who take these medications for more than sixty days develop side effects.[8]

However, the long-term use of corticosteroids can lead to significant adverse effects, such as osteoporosis, diabetes, hypertension, and adrenal suppression. Therefore, it is essential to evaluate the prescription patterns and safety of corticosteroids in a tertiary care setting to ensure their rational use. With this background, present study was planned with aim to assess prescription patterns and safety evaluation of drugs in patients using different corticosteroids.

MATERIAL AND METHODS:

This prospective observational study was conducted on patients who received corticosteroids in the medicine department of a tertiary care hospital, L.L.R.M Medical College, Meerut, UP.

Patients of either Sex and 18-60 years of age and both genders who received corticosteroids for more than a week were included in the study after taking written informed consent. Patients with incomplete or missing records were excluded. The collected data include demographic details, diagnosis, type and dose of corticosteroid, duration of treatment and adverse effects.

On considering inclusion and exclusion criteria a total of 165 study subjects were selected for the present study. Prescription of each study subject were collected and further studied for prescription of corticosteroids. All basic details of patient and prescribed corticosteroids were collected and recorded using a structured data collection sheet. The data of present study has been recorded and after its proper validation checked for errors, coding and data compilation and segregation were done in MS excel. Statistical Package for the Social Sciences (SPSS) software version 23.0 (SPSS1 Inc., Chicago, IL, USA) was used for statistical analysis.

RESULTS

A total of 165 patients were included in the study, with a mean age ± S.D. was 39.85 ± 11.15. The most common conditions for which corticosteroids were prescribed were respiratory diseases (40%) followed by rheumatologic disorders (30%). The demographic analysis revealed a male predominance (61.21%). [Table 1, Figure 1]

Table 1: Distribution of Age and Gender of study patients

Variables	Age Interval (Years)	Frequency (n = 165)	Percent (%)
Age	**Up to 24 Years**	**48**	**29.09**
	25-40 Years	**35**	**21.21**
	41-50 Years	**32**	**19.39**
	Above 50 Years	**50**	**30.30**

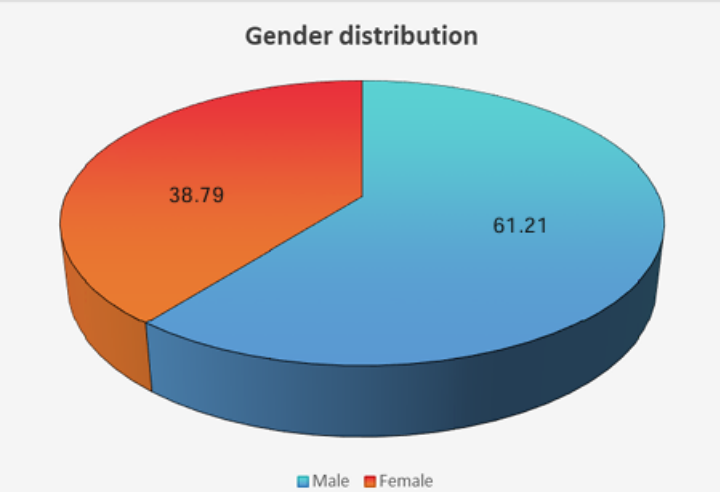

Figure 2: Distribution of Gender of study patients

On considering prescribed corticosteroids by generic classes, most commonly prescribed corticosteroids were inj. Methylprednisolone 61 (30.65%) followed by inj. Hydrocortisone 39 (19.6%) and inj. Dexamethasone 31 (15.58%), primarily administered intravenously (65.83%). Other prescribed corticosteroids were oral Prednisolone 35 (17.59%) and inhalational Budesonide 33 (16.58%). [Table 2]

Table 2: Distribution of prescribed corticosteroids in study subjects

Types of Corticosteroids	Frequency	Percentage
Inj. Methylprednisolone	61	30.65%
Inj. Hydrocortisone	39	19.60%
Inj. Dexamethasone	31	15.58%
Tab. Prednisolone	35	17.59%
Inhalation Budesonide	33	16.58%

On considering various routes of administration of prescribed corticosteroids, the most common route for administration was intravenous route in 131 (65.83%), oral route of administration in 35 (17.59%) and respiratory/inhalational route in 33 (16.58%). [Table 3]

Table 3: Distribution of prescribed corticosteroids by Route

Route	Frequency	Percentage
Intravenous	131	65.83%
Oral	35	17.59%
Inhalational	33	16.58%

The safety of prescribed corticosteroids among study patients was assessed by using Naranjo Adverse Drug Reaction Probability scale. Among 165 study patients, ADRs due to prescribed corticosteroids was seen in 34 (22.6%) cases. ADRs were detected in the study due to prescribed corticosteroids were nausea/vomiting in 4 (11.76%), headache in 9 (26.5%), hyperglycemia in 10 (29.4%) and gastric upset in 11(32.3%) patients. Most common ADR was seen as gastric upset 11(32.3%). For causality assessment of ADRs, according to Naranjo causality assessment scale out of these 34 reported ADRs 14 (41%) ADRs were probable and 20 (59%) were possible as shown in table 4 and figure 4.

Table 4: Causality assessment of ADRs by Naranjo causality assessment scale

Scale	No. of ADRs	Percent (%)
Probable	14	41%
Possible	20	59%

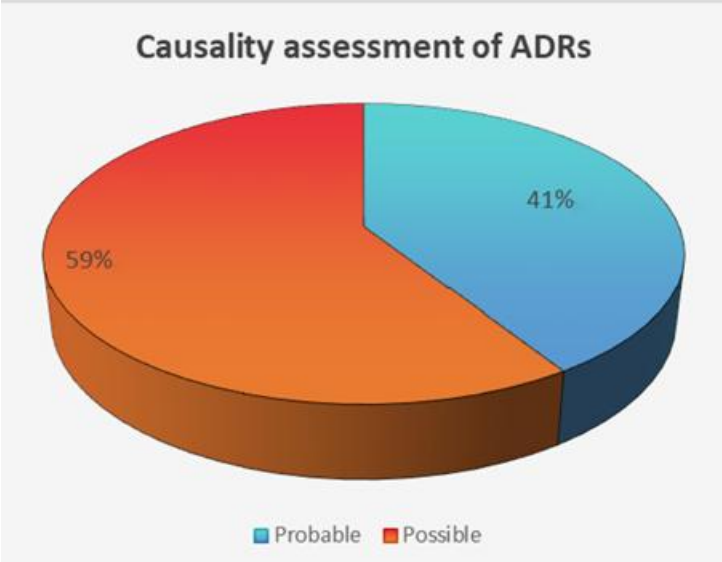

Table 4: Causality assessment of ADRs by Naranjo scale

DISCUSSION:

The study highlights the common use of corticosteroids in respiratory and rheumatological conditions. Prednisolone was the most frequently prescribed corticosteroid, which is consistent with other studies. The study also reveals that adverse effects are common with corticosteroid use; particularly osteoporosis, diabetes and hypertension.

In our study, most of the study patients were in late age group of 50 and above years (30.3%) and Similarly, In study by Curtis R Jeffery et al. [10] the study population with older mean age of 53±14 year and 56.5 (54.4-58.7) years. There was male predominance over female (61.21% Vs 38.79%) in our study. Nerukar et al. [11] and Saravanakumar et al. [12] showed a higher male preponderance. Reason for this finding may be either due to variation in demographic situation and common diseases in local area or study sample increases the chance of male patients to be recruited more.

In present study, the average number of drugs per prescription was found 8.95 and average number of corticosteroids was found 1.21. These findings were higher than the WHO recommendations (optimal value 1.6-1.8) and suggested a trend towards polypharmacy. [13] It is preferable to keep the number of drugs per prescription as low as possible to avoid an increased risk of adverse effects and drug interactions, thereby minimizing the cost of drug therapy. Our study findings were similar to studies conducted by Bhuvana et al. [14] and Padma et al.[15] In contrast, Purushotham et al. [16] in his study stated that the average number of drugs per prescription was 2.09, while In Gambre R et al. [17] study a prescription of GC per prescription was 1.11.

In our study it was found that most of the physicians prescribed corticosteroids by their generic names, out of total 199 prescribed corticosteroids 59.79% were prescribed as generic names, which is low. In contrast to our study, Kumar et al. [18] and Ankit P et al. [19] where 100% brand names usage was reported and all the drugs were prescribed by brand name and none of the drugs were prescribed by generic name. In our study most commonly, prescribed corticosteroids were injectable and these were inj. Methylprednisolone (30.65%) followed by inj. Hydrocortisone (19.6%) and inj. Dexamethasone (15.58%).
Oral Prednisolone (17.50%) and inhalational Budesonide (16.58%) were other prescribed corticosteroids. However, according to Biswas NR et al. [20] rational use of drugs can help to reduce the incidence of adverse effects. In Adhikari K et al. [21] study, the usage of Dexamethasone and Fluocinolone was higher than other prescribing corticosteroids. In Shende M et al. [22] study in the general medicine ward, dexamethasone was given to 63.8% of patients, followed by hydrocortisone (32.8% of patients) and prednisolone (3.4% of patients). In dermatology department out of 51 drugs, betamethasone was given to 1.9% of patients. Dexamethasone was prescribed most frequently, while hydrocortisone was used as a short acting and prednisolone as an intermediately acting corticosteroid.

In present study ADRs due to prescribed corticosteroids was seen in (22.6%) cases. Most common ADR was seen as gastric upset (32.3%). Other ADRs were Nausea/vomiting (11.76%), Headache (26.5%), Hyperglycemia (29.4%). In Makbul Hussain Chowdhury et al. [23] study, 34 ADRs were found due to corticosteroids use, out of those facial puffiness (11.76%), headache (14.70%), hypernatremia (14.70%), hyperglycemia (17.64%), hypertension (26.47%) and osteoporosis (14.70%). By using Naranjo causality assessment scale 14 ADRs were probable and 20 ADRs were possible. Similarly, our study was consistent with the study of Treadwell. B. et al.[24] and Kumar S et al.[25] who found that corticosteroid causes hypertension, facial mooning, osteoporosis in the subjects who were on corticosteroid therapy.

Unissa SM et al. [26], found 10 ADRs due to corticosteroids use, of which facial mooning was detected in 2, headache in 3, hyperglycemia in 1, hypertension in 3 (25%) and osteoporosis in 1 (12.50%). The study of Treadwell.B, et al [24] who found that corticosteroid causes hypertension, facial mooning, osteoporosis in the subjects who were on corticosteroid therapy. Also Clore J, et al. [27] found that Glucocorticoid-induced hyperglycemia is common in patients with and without diabetes. Several studies have reported that transient increases in serum glucose are associated with acute inflammatory processes and endothelial dysfunction in both diabetic and non-diabetic patients. [28] These findings suggest that corticosteroids are effective in managing various conditions, but their use requires careful consideration of risks and benefits.
The key strength of this study is its novel approach to study drug utilization, prescribing pattern, and safety of different corticosteroids. The study has some limitations, including its study design and limited sample size. Further prospective studies with larger sample sizes are needed to confirm the findings. Our study was a single hospital based observational study and findings cannot be generalized as this was not a population-based study. The sample size and the target population selected for the study was limited. We suggest further studies on a broader based and a more representative sample size using sophisticated methodology in order to generalize the results.

CONCLUSION

The study concludes that corticosteroids are commonly prescribed in a tertiary care setting for various conditions. The study revealed that corticosteroids were commonly prescribed for respiratory and rheumatologic conditions. The findings suggest that corticosteroids are effective in managing various conditions, but their use requires careful consideration of risks and benefits. However, their use requires careful monitoring of adverse effects, particularly osteoporosis, diabetes, and hypertension. Healthcare professionals should be aware of the potential risks and benefits of corticosteroids and use them judiciously.

RECOMMENDATIONS:

Healthcare professionals should carefully evaluate the risks and benefits of corticosteroids before prescribing them.

- Patients receiving long-term corticosteroid therapy should be monitored regularly for adverse effects.
- Measures should be taken to prevent osteoporosis in patients receiving corticosteroids, such as calcium and vitamin D supplements.
- Further studies are needed to evaluate the long-term safety of corticosteroids in various medical conditions

Conflict of Interest: None
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