

## Original Research Article

# Pharmacovigilance of corticosteroids in dermatological diseases

Narotham Reddy\*, S. Parveen, Allahuddin Syed

Department of Dermatology, Rajiv Gandhi Institute of Medical Sciences, Kadapa, Andhra Pradesh, India

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### \*Correspondence:

Dr. Narotham Reddy,

E-mail: [kavalakuntlanarothamreddy@gmail.com](mailto:kavalakuntlanarothamreddy@gmail.com)

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## ABSTRACT

**Background:** The aim of the study was to conduct the monitoring, detection, assessment and prevention of corticosteroid induced adverse drug reactions in dermatological diseases.

**Methods:** Patient demographic details, past medical, medication history, lab investigations, allergic history were collected patient were followed and data collected every 1 month from the day of patient recruitment. The 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> follow ups were done, analysis of ADRs was done by using scales at each follow-up. In statistical analysis, data was articulated in percentage. A prospective, interventional study were designed.

**Results:** In present study, author have recruited 40 subjects of which authors categorized ADRs based on different systems. In that 14 (56%) ADRs were identified in cardiovascular system and it was the majorly affected organ system followed by endocrine system 4 (16%). In 40 patients, 25 patients developed ADRs. In these male patients was 14 (56%) and female patients was 11 (44%). In 25, the majorly developed ADR was hypertension 13 (52%) followed by DM 4 (16%). In all ADRs majorly developed due to use of Prednisolone 17 (42%). The developed ADRs majorly in the age group of 41-50 (48%) years followed by 31-40 (16%) and 51-60 (16%).

**Conclusions:** The study found that incidence of ADRs in males was higher than that of the females. Prednisolone was the most common drug associated with the ADRs. Majority of reported ADRs were managed by giving suitable interventions and most of the patients recovered after management.

**Keywords:** Cardiovascular system, Corticosteroids, Hypertension, Pharmacovigilance, Prednisolone

## INTRODUCTION

Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines.<sup>1-3</sup>

The present study aims was to identify and characterize the pattern of ADRs (adverse drug reactions) due to corticosteroids in tertiary care teaching hospital and analyze and reported them. This information may be

useful in identifying and minimizing preventable ADRs, at the same time it may help clinicians to tackle with ADRs more efficiently.<sup>4,5</sup> The skin, also known as the cutaneous membrane, covers the external surface of the body and was the largest organ of the body in both surface area and weight.<sup>6</sup> Glucocorticoids dramatically relieve itching, pain and inflammation in allergic and other dermatoses.

To minimize systemic effects, topical steroid was preferred. Systemic steroid therapy is needed in severe conditions like exfoliative dermatitis, dermatomyositis, pemphigus etc, psoriasis, keloids and hypertrophic scar

are sometimes treated by intralesional injection of steroids.<sup>7,8</sup> There are two main forms glucocorticoids and mineralocorticoids.

The actions of glucocorticoids include gluconeogenesis, fat deposition, sodium retention, decreased protein synthesis and decreased immune response. Examples of glucocorticoids include cortisol hydrocortisone), prednisolone and dexamethasone. Initially, a higher dose of corticosteroids will be given to gain control of the skin disease. Once improvement was seen, the dose will be reduced gradually. For some skin conditions, a low dose of systemic corticosteroids may be needed for a long duration of time (months to years) to control the skin disease.<sup>9,10</sup>

## METHODS

A prospective, interventional study was performed for a period of 6 months in general medicine department at Rajiv Gandhi Institute of Medical sciences, a south Indian tertiary care teaching Government hospital Kadapa and got ethical approval from the IEC (Rc.No.4226/Acad.2015). A total of 60 study populations were taken and patients were enrolled based on inclusion and exclusion criteria by using study materials like specially designed patient data collection form, informed consent form and specially designed laboratory investigation and interpretation form. Both males and females of age group between 10 to 80 years subjects who were diagnosed with skin diseases and on treatment with systemic and topical corticosteroids, Patients who were coming to the dermatology for regular checkups/follow ups.

### Inclusion criteria

Patients who had been hospitalized due to dermatological ADR (adverse drug reaction). The patients who were willing to participate in the study were under inclusion criteria.

### Exclusion criteria

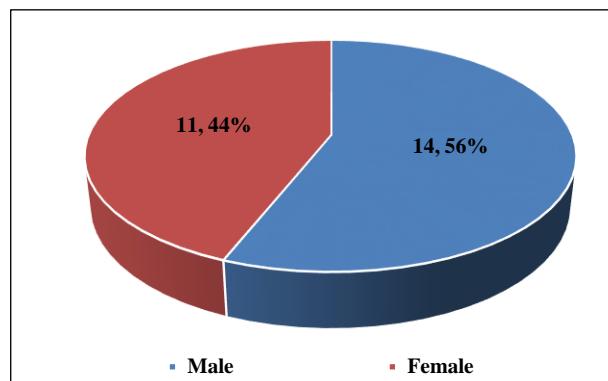
The other drug induced skin diseases, patients with alcoholic and smoking abuse, pregnant and lactating women, patients with renal impairment, patients having past history of hypertension, diabetics mellitus, Gastric ulcers (before using corticosteroids) were excluded.

Obtained informed consent form and recruited patients as per eligibility criteria. Patient demographic details, past medical, medication history, family history, lab investigations, allergic history were collected patient data was collected like RBS (random blood sugar) levels, Blood pressure, serum electrolytes (systemic steroids) and hypersensitivity reactions (topical steroids) patients were followed and data collected every 1 month from the

day of patient recruitment. The 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> follow ups were done.

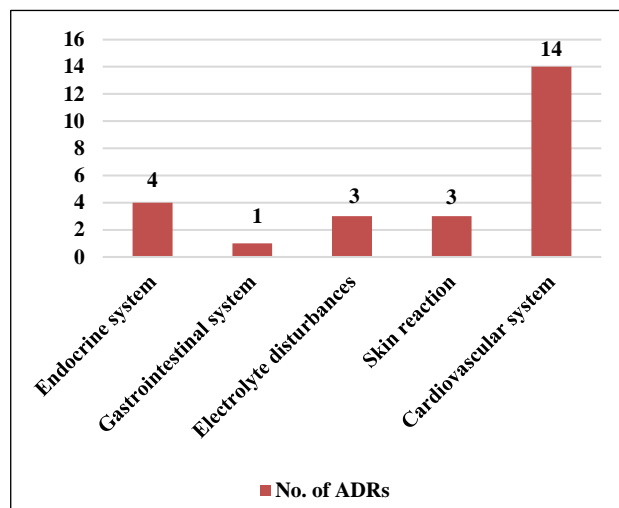
## RESULTS

Authors distributed all 40 patients according to their gender. In these patients 25 patients developed ADRs. In these male patients was 14 (56%) and female patients was 11 (44%), results were shown in Figure 1.



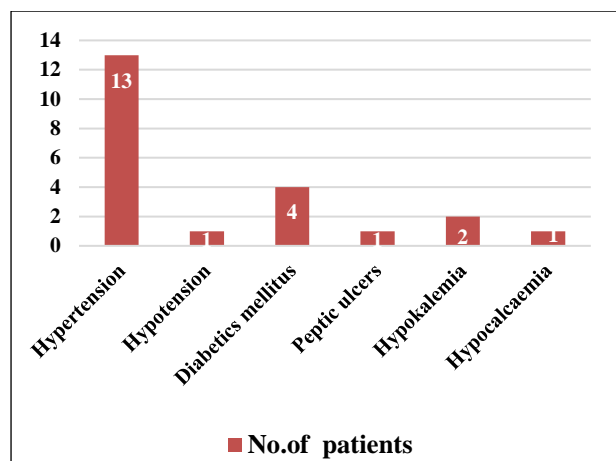
**Figure 1: Distribution of patients based on gender.**

Authors categorized ADRs (adverse drug reaction) based on different systems. In that 14 (56%) ADRs were identified in cardiovascular system and it is the majorly affected organ system followed by endocrine system 4 (16%), gastrointestinal system 1 (4%), electrolyte disturbances 3 (25%) and skin reactions 3(25%) And the results were shown in Figure 2.



**Figure 2: Distribution of ADRs based on different systems.**

In 40 patients 25 patients were developed ADRs. In these hypertension in 13 (52%) patients, hypotension in 1 (4%), diabetics mellitus in 4 (16%), peptic ulcers in 1 (4%), hypokalemia in 2 (8%), hypocalcemia 1 (4%) and the results were shown in Figure 3.



**Figure 3: Distribution of ADRS based on diseases.**

A total of 4 corticosteroids were prescribed in 40 patients. Alone prednisolone was prescribed for 17 patients, in that 8 (47%) were males and 9 (53%) were females. Dexamethasone for 6 patients, in that 5(83%) were males and 1 (17%) female. Onit-betamethasone for 7, in that 5 (71%) males and 2 (29%) females. In combination of both drugs onit-betamethasone and prednisolone 3, in that 1 (33%) male and 2 (66%) females. Combination of dexamethasone and onit-betamethasone was 4, in that 4 (100%) were males. Combination of prednisolone and dexamethasone were 3 among them 3 (100%) were females and the results were shown in Table 1.

**Table 1: Patients based on treatment.**

Treatment	Male	Female	Total
Prednisolone	8 (47%)	9 (53%)	17
Dexamethasone	5 (83%)	1 (17%)	6
Onit-betamethasone	5 (71%)	2 (29%)	7
Onit -betamethasone and prednisolone	1 (33%)	2 (66%)	3
Dexamethasone and onit -betamethasone	4 (100%)	-	4
Prednisolone and dexamethasone	-	3 (100%)	3
Total n= 40 (100%)			n=40

## DISCUSSION

Corticosteroids were the most common medicaments used to reduce inflammation in inflammatory conditions, suppress the immune system in immunological disorders and replace hormones in the body in hormonal insufficiency conditions. Corticosteroids were proven to be very effective in these conditions which led to popularity and widespread usage of this group of drugs among physicians in different specialty, though corticosteroids had outstanding therapeutic benefits, they may also produce some unwanted or undesirable effects.<sup>11</sup> This was the need of the hour to monitor adverse effects of corticosteroids during the treatment of

these different conditions. The present study was intended to investigate adverse drug effects of corticosteroids oral and topical preparation in the Department Dermatology in a Tertiary Care Hospital Rajiv Gandhi institute of Medical science at Kadapa. In present study authors had recruited 40 subjects of which authors categorized ADRs based on different systems. In that 14 (56%) ADRs were identified in cardiovascular system and it is the majorly affected organ system followed by endocrine system 4 (16%). In 40 patients 25 patients developed ADRs. In present study 40 patients with 25 suspected adverse drug reactions were screened and enrolled for the study based on previously discussed inclusion and exclusion criteria. It was similar to the observation done by Gohel D et al.<sup>12</sup> Evaluation Of dermatological adverse drug reaction. In the outpatient Department Of Dermatology at a Tertiary Care Hospital” where they had reported that 28 (54.90%) males and 23 (45.09%) females.<sup>12</sup> Present study had been supported by Acharya T et al.<sup>2</sup>

Pharmacovigilance study Of adverse cutaneous drug reactions In A Tertiary Care Hospital (2013)” where they had reported that 58.3% of the ADRs had occurred in the age group of 35-60 years and it is similar to present study that majority of ADRs developed in the age group of 41-50 (48%).<sup>13</sup> Present study was supported by Petkova V et al.<sup>14</sup> Analysis Of the adverse drug reactions Of some corticosteroids (2012)”. where they reported that glucocorticoids were the class of drugs causing highest number of ADRs and it is similar to present study that was 17 (42.5%) ADRs by use of glucocorticoids.<sup>14</sup>

The Limitations of this study were to patients regular follow up (some patients were not coming), Sample patient’s size is very less (40 patients), limited study period (6 months). Ethical approval and consent to participate. Approval to conduct this study was obtained from the Rajiv Gandhi institute of medical sciences (RIMS) Govt. Hospital, IEC (Rc.No.4226/Acad.2015). Permission to conduct this study was also obtained from the Director of Hospital RIMS.

## CONCLUSION

The present study made observations on the suspected adverse drug reaction (ADRs) in a tertiary care hospital. The study found that incidence of ADRs in males was higher than that of the females. The most age group which was more prone for corticosteroid related ADRs among the adults were significantly higher when compared with geriatrics and pediatrics. Prednisolone was the most common drug associated with the ADRs. Cardiovascular system was the most commonly affected organ system due to ADRs. Among the reported ADRs, hypertension was the majorly developed ADR. Majority of reported ADRs were managed by giving suitable interventions and most of the patients recovered after management.

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*Ethical approval: The study was approved by the Institutional Ethics Committee (Rc.No.4226/Acad.2015).*

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