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A PROSPECTIVE STUDY TO EVALUATE THE ADVERSE DRUG REACTION DURING CORTICOSTEROID THERAPY IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

INTRODUCTION: Corticosteroids plays an important role in the management of inflammatory disease, autoimmune disorders and tissue transplantation. It produces many adverse reactions. We planned a study to evaluate the adverse drug reaction following corticosteroid therapy. **MATERIALS AND METHODOLOGY**:100 corticosteroids treated patients were enrolled, in that 75 patients were from Rheumatology OPD and rest from dermatology OPD who were taking corticosteroids for rheumatoid arthritis and chronic eczema for more than 6 months, patient aged between 15 -70 years diagnosed as rheumatoid arthritis and eczema on oral and topical corticosteroid treatment for more than 6 months were included in the study.

RESULTS: Most common adverse effects in oral corticosteroid population were 46.7% with hypertension, 24% with hyperglycemia, 16% with cushingoid feature were observed with causality score 7, 13.3% with peptic ulcer disease and the causality score was 6. In topical corticosteroid population 60% with hyperglycemia, 40% with cushingoid feature, hypertension, peptic ulcer disease were not reported. This indicates oral and topical corticosteroids were the probable cause of these adverse events. **CONCLUSION:** In our study we found that the most common adverse effects of oral and topical corticosteroids, were more for those who take these preparation for more than six months. The most common adverse effects observed in oral corticosteroid preparations was hypertension followed by hyperglycemia, cushingoid feature & peptic ulcer disease. For topical corticosteroid preparation the most common adverse effects were hyperglycemia followed by cushingoid feature.

KEYWORDS: Adverse drug reaction, corticosteroid, cushingoid feature, hyperglycemia, eczema, rheumatoid arthritis.

INTRODUCTION

All medicines carry some risk of harm and it is important to monitor their effects, both intended and unwanted, so that good evidence is available to base an assessment of risk versus effectiveness or risk versus benefit. Medicines are important aspect in clinical practice, that are designed to improve the health of target population. During the course of treatment drug prescribed to patients produce certain effects other than the desired or expected effects, these issues concern both to the physician and the patient by spiraling costs of medical treatments and also cause a great deal of morbidity and mortality.

Adverse drug reactions are noxious, unintended, and undesirable effects that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis and treatment. Adverse drug reactions constitute a major clinical problem in terms of human suffering and increased health care costs. It has been reported that the incidence of adverse drug reaction is much more in geriatric, paediatric and female patients. Female are more susceptible to gastrointestinal and cutaneous allergic adverse drug reactions, it has been estimated that 83% of adverse drug reactions in male and 93% of adverse drug reactions in female are dose related.[1,2,3,4,5]

Research findings estimate a 6.5% prevalence of adverse drug events. 1% of these adverse drug event resulted in patient death, 12% in life danger, 30% in serious illness, 60% – 70% of adverse drug events are preventable, this calls urgent need to reinforce the monitoring of adverse reactions to drugs, which can lead to reduction in incidence of adverse drug reactions. Early identification of unexpected adverse drug reactions and their risk factor is essential, so that the medicines can be used in an effective manner with the least chance of harm.[6]

Pharmacovigilance is an important tool in the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problems, thereby it improves public health and safety in relation to the use of medicines and communicate the findings in a timely manner. This tool contributes to assessment of benefit, harm, effectiveness and risk of medicines, leading to prevention of harm and maximization of benefit. Aim of the pharmacovigilance is to improve patient care and safety in relation to the use of medicines

and all medical and paramedical interventions. It also encourage the safe, rational and more effective (including cost effective) uses of medicines.[7]

Corticosteroids are 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 are proven to be very effective in these conditions which led to popularity and widespread usage of these group of drugs among physicians in different speciality, though corticosteroids have outstanding therapeutic benefits, they may also produce some unwanted or undesirable effects.[8] The present study is intended to investigate adverse drug effects of corticosteroids oral and topical preparation

MATERIALS AND METHODS

Study was conducted at Sri Ramachandra medical college hospital porur, Chennai. A prospective non blinded observational study was conducted over a period of 6 months. Approval of the institutional human ethics committee was obtained. Total of 100 patients with 15–70 years of age were enrolled in this study, among them 75 patients from rheumatology OPD and 25 patients from dermatology OPD who were taking oral corticosteroid (T.prednisolone 10mg) for rheumatoid arthritis[9] and for chronic eczema who were taking topical corticosteroid (betamethasone dipropionate 0.05%)[10] for more than 6 months were included in this study. Patients with diabetes mellitus, hypertension, peptic ulcer disease, hormonal disturbances, renal and hepatic insufficiency and pregnant women were excluded from the study. All the out patients were assessed for ADRs during the study period. In the suspected cases past medical or medication history of patients were collected. Patients were interviewed and their medical records were reviewed. The suspected ADRs were carefully analyzed and documented. All relevant data including all drugs the patients received prior to the onset of the reaction, their respective dosage, route of administration with frequency, date of onset of reaction and the patient allergy status were noted. Evaluation of the ADE reports for causality assessment to confirm ADRs. The causality relationship between the ADR and the suspected drug therapy was assessed using the naranjo probability scale.[11]

RESULTS

In a total of hundred patients 75 patients were taking oral prednisolone,25 patients on topical corticosteroids.

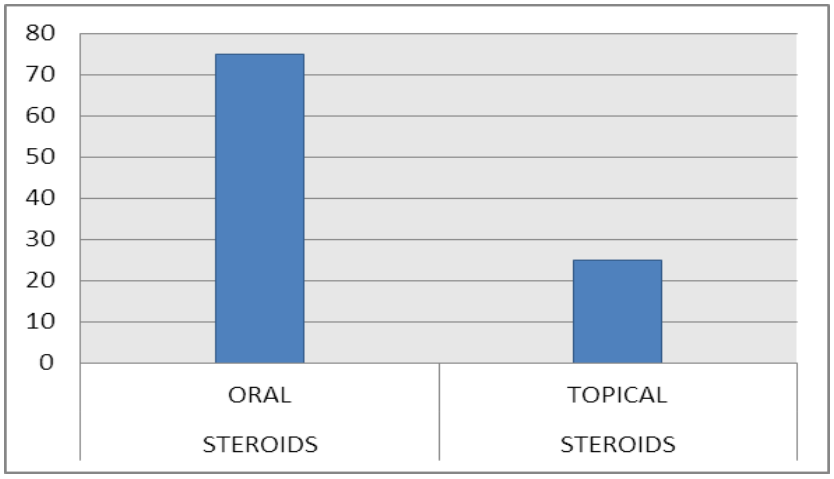


Figure 1: Distibution Of Oral And Topical Corticosteroid

The gender wise distribution of the patients taking oral prednisolone (corticosteroid) for the indication of rheumatoid arthritis were 27 male ,female patients were 48.women were more commonly affected than men. The gender wise distribution of the patients taking topical corticosteroids (betamethasone dipropionate 0.05%) for eczema were 14 male patients and female patients were 11.Chronic eczema was more common in men than in women. The age distribution of the patients was 21 patients were within the age group of 15–40 years, 66 patients were within the group of 41 - 65 years, 13 patients were more than 65 years.

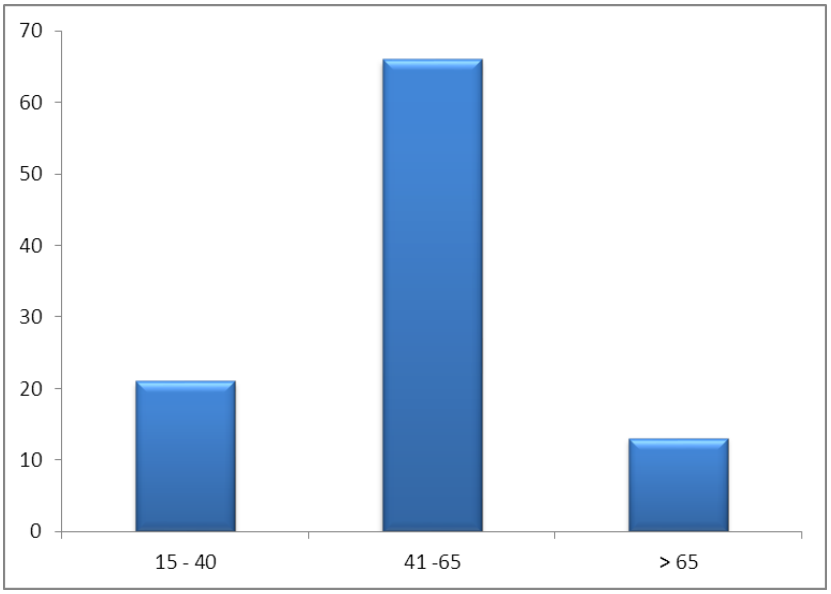


Figure 2: Age Distribution

Most common adverse effect was hypertension that is 46.7%, followed by hyperglycemia 24%, cushingoid feature 16% and 13.3% of patients with peptic ulcer disease in patients treated with oral prednisolone while common adverse effect was hyperglycemia that is 60%

followed by cushingoid feature 40%, hypertension and peptic ulcer disease in patients treated with topical corticosteroid.

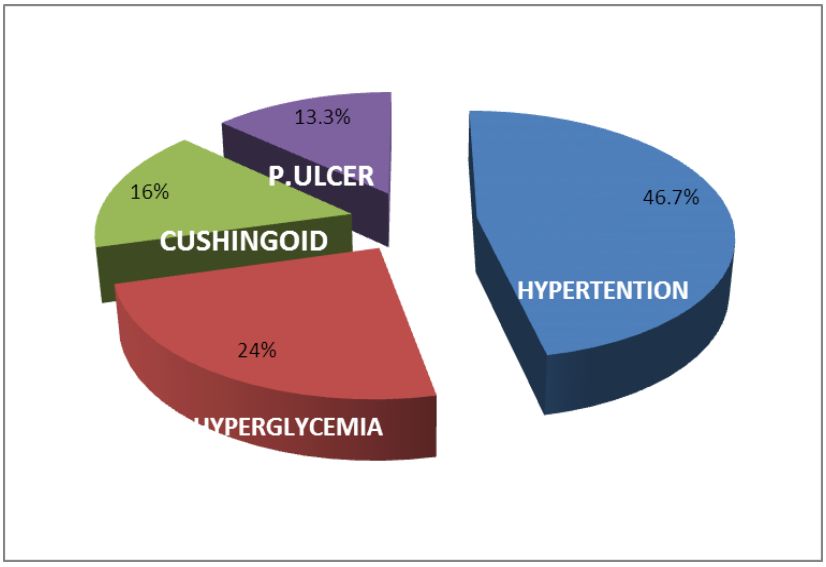
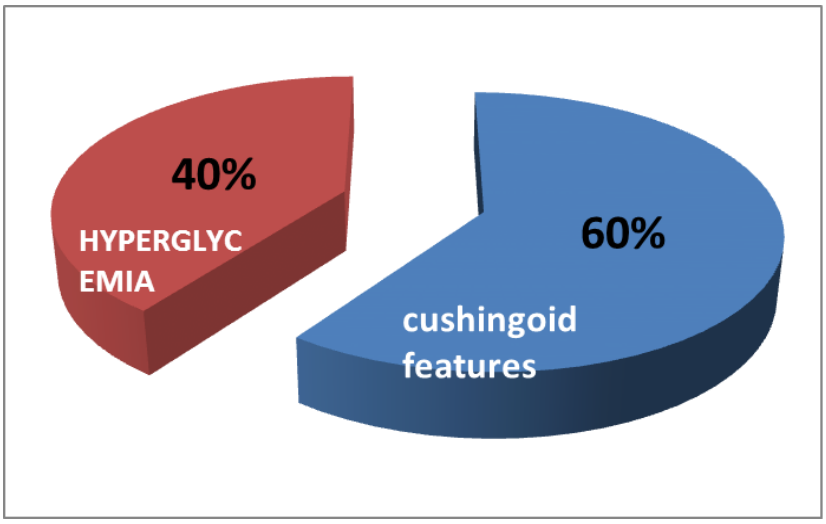


Figure 3: Adverse Effect On Oral Corticosteroids Therapy



Fiigure 4: Adverse Effect On Topical Corticosteroid Therapy

Naranjo Score of both oral and topical corticosteroid induced adverse drug reaction was used to assess severity and we found that Hypertension, Hyperglycemia, Cushingoid feature causality score was 7 while Peptic ulcer disease causality score was 6.This indicates oral and topical corticosteroids were the probable cause of these adverse events.

DISCUSSION AND CONCLUSION

Corticosteroid induced adverse events were studied in hundred patients of 15 – 70 years age group who are suffering from Rheumatoid arthritis and chronic eczematous conditions.

Adverse events like hypertension, hyperglycemia, cushingoid feature & peptic ulcer disease were seen in both oral prednisolone & topical corticosteroid preparations. In our study there was no radiological evidence of osteoporosis in the long term treatment of oral and topical corticosteroids. Incidence of adverse events in oral prednisolone preparation groups were hypertension (46.7%) followed by hyperglycemia (24%), cushingoid feature (16%) then peptic ulcer disease (13.3%). So the more common adverse events observed in oral corticosteroid preparation in descending order were hypertension, hyperglycemia, cushingoid feature, and peptic ulcer disease with causality score of seven (Hypertension, hyperglycemia, cushingoid feature) and six for peptic ulcer disease which indicates that the oral steroid preparation were the probable cause for these adverse effects. Incidence of adverse events in topical corticosteroid (betamethasone dipropionate 0.05%) were Hyperglycemia (60%) followed by cushingoid feature (40%). So the more common adverse events in topical corticosteroid preparation were Hyperglycemia followed by cushingoid feature with causality score of seven, that is the topical corticosteroids were the probable cause of these adverse effects. Similar study was conducted by H.C. Smyllie and C.K. Connolly under 'Incidence of serious complications of corticosteroid therapy in respiratory disease' this is a retrospective survey of patients in the Brompton Hospital. In this study 550 patients treated with corticosteroids. Overall incidence of side effects were cushingoid feature 29% followed by peptic ulcer disease 4.2%,hypertension 4%,hyperglycemia 1.63%.[12]

In our study hypertension and hyperglycemia dominates over the other adverse effects and cushingoid feature is comparatively less. This may be due to the differences in the racial, constitutional and other contributory factors in the Indian population. Glucocorticoids are used widely in the treatment of a variety of rheumatic disorders and are the mainstay in the treatment of more serious inflammatory rheumatic diseases. In our study the outcome shows that the most common adverse effects of oral and topical corticosteroids, were more for those who take these preparation for more than six months in cases of Rheumatoid Arthritis and Eczema.

The most common adverse effects observed in oral corticosteroid preparations were hypertension followed by hyperglycemia, cushingoid feature & peptic ulcer disease. For topical corticosteroid preparation the most common adverse effects were hyperglycemia followed by cushingoid feature. In Indian Population the incidence of hypertension and

hyperglycemia were more common and the cushingoid feature appears to be less when compared to the studies conducted in western population.

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