



A STUDY OF ADVERSE DRUG REACTIONS IN PATIENTS REPORTING IN DEPT OF DERMATOLOGY IN A TERTIARY HEALTH CARE CENTER OF CENTRAL INDIA.

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ABSTRACT **Objective-** To monitor the most common manifestation of adverse drug reactions (ADR) and most common drug responsible for ADR among patients presenting in department of dermatology of a tertiary healthcare centre of central India.

Method- A total of 200 patients of ADRs were recruited in a period of December 2015 to November 2016. Diagnosis of ADR made by consultant of dermatology department. All the information collected and recorded according to CDSCO, ADR form. Causality was assessed according to WHO-UMC causality scale. Data analyzed by percentage method.

Result- In this study 18 cases were probable and 182 cases were certain, among total 200 cases of ADRs. Maximum ADR (39%) reported from age group of 21 to 30 years, Male: Female is 1.24:1. The most common manifestation of ADR is Tinea incognita 53%, followed by topical steroid damaged face (TSDF) 38%. Topical steroids were most offending drug (90.5%) followed by NSAIDs (5.5%) and oral antimicrobials (3%).

Conclusion- This study is a small attempt to know the clinical spectrum of ADR occurrence. So that we can analyze the cause of ADR occurrence whether it is under reporting or irrational prescribing. The patients need to be aware of hazards of irrational use of drugs, simultaneously clinician should be motivated for prompt reporting of ADRs.

KEYWORDS : ADR, Dermatology, Tinea incognita, TSDF

INTRODUCTION-

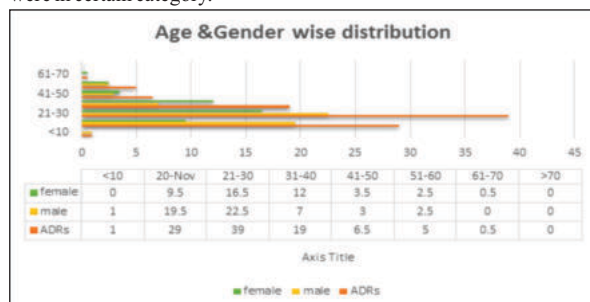
In world about 3-5% hospital admissions are due to adverse drug reactions^[1]. About 5 to 9 % of all hospital costs are due to ADRs^[2]. In India pharmacovigilance is struggling to make an impact as still ADRs are underreported though not underdiagnosed. This creates difficulty in collecting data and hence, lack of knowledge and awareness regarding these ADRs can go a long way even up to failure to make appropriate policies. Every hospital needs to have its local data as there are various factors for manifestations of these and also, hospital policies can be modified according to local needs. This prompted us to monitor the ADR profile of drugs used by patients presenting in a dermatology department of a tertiary care teaching institute.

MATERIALS AND METHODS-

ADRs were diagnosed by consultant of Dermatology department. Spontaneous reporting of data was followed by principal investigator collecting the data. A total of 200 patients were included in the study during the period of December 2015 to November 2016. The data was recorded as per recent version of standard ADR form obtained from Central Drug Standard Control Organization (CDSCO) website. The causality assessment was done using WHO-UMC causality scale^[3]. In case of combination preparations causality assessment was done for most offending component suggested by consultant Dermatology. In this study rechallenge was not done because of safety concerns of the patient.

RESULTS-

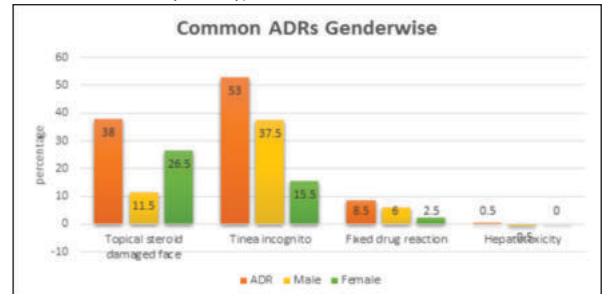
According to WHO -UMC scale out of 200 cases included in the study, 18 cases fell in the category of being probable and 182 cases were in certain category.



Pic 1- Age & Gender Wise Distribution

Inference-

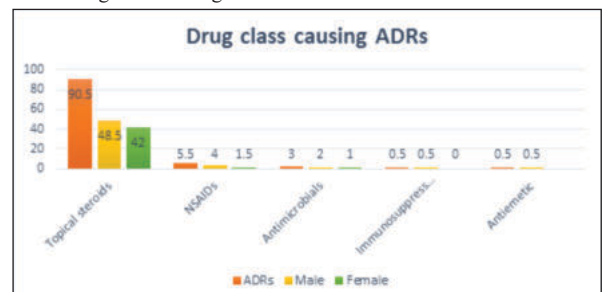
Maximum ADR (39%) were reported from age group of 21 to 30 years, followed by age group 11 to 20 (29%) and 31 to 40 (19%) years. Elderly and children were least affected. Males (55.5%) are affected more than females (44.5%), Male: Female=1.24:1



Pic 2: Common ADRs gender wise

Inference- The most common manifestation of ADR is Tinea incognita 53%, followed by topical steroid damaged face (TSDF) 38%.

Pic 3: Drug class causing ADRs



Inference-

Topical steroids were most offending drug (90.5%) followed by NSAIDs (5.5%) and oral antimicrobials (3%).

DISCUSSION-

In our study 18 cases of ADRs were in probable category following WHO causality scale guidelines, all of them having temporal

relationship between drug intake and ADR occurrence, their occurrence cannot be explained by underlying disease or other drugs and rechallenge was not done. On the other hand, 182 cases were in certain category. This finding is in contrast to study conducted by Zinnat Ara Begum *et al.* where they reported all the ADRs of Probable category.^[4]

The certain cases were due to topical steroid application resulting into manifestations of Tinea Incognito and Topical steroid damaged face (TSDF). These two manifestations occur secondary to steroid application.

In our study we reported maximum number of ADRs in 21-30 years of age group (39%) this finding is consistent with study by Rohini Sharma *et al.*^[5] and study by Bharani Kalpna *et al.*^[6]

The next commonest age group affected is 11 to 20 years (29%), this finding is in contrast to studies by Rohini Sharma *et al.*^[5] and Bharani Kalpna *et al.*^[6], where they found 31-40 years of age group as second most commonly affected, while in our study this age group constitute third commonest category. Under 10 years of age group only 2 cases (1%) were found, this may be due to inaccessibility to the OTC drug and lack of self-medication which are the major cause of ADRs. The least number of ADRs were reported in age group above 60 years (0.5%). This finding is similar to study conducted by Rohini Sharma *et al.*^[5]

In our study there were 55.5% male affected compared to 44.5% female affected. This finding is similar to study by Rohini Sharma *et al.*^[5] where as in contrast to this study Amrinder R *et al.* reported maximum ADR in females (54.2%)^[7] and Bharani Kalpna *et al.* reported 143 cases in females and 88 cases in males.^[6]

The most common manifestation of ADRs reported in dermatology department were Tinea Incognito (53%) followed by Topical Steroid Damaged Face (TSDF) (38%).

In TSDF, consultant included acneiform eruptions, depigmentation, thinning of skin, hairy growth on female face.

This finding is in contrast to study conducted by Rohini Sharma *et al.*^[5] who reported fixed drug reaction as the most common cutaneous adverse drug reaction. This is the third commonest manifestation of ADRs (8%) in our study.

Tinea incognito was more common in males (37.5%) than in females (15.5%).

TSDF is more common in female patient (26.5%) than in males (11.5%) this is because females are probably more conscious for good look and fair skin.

Among fixed drug reactions (FDRs) most of the cases were due to NSAIDs (5.5%) followed by oral antimicrobials (3%). Among NSAIDs, paracetamol was found to be most offending, while ibuprofen and nimesulide were next to it. While doxycycline, ciprofloxacin, cefpodoxime peroxitil and antiemetic domperidone were other incriminated drugs in causing FDRs.

The most offending drug responsible for maximum ADRs were belonging to topical steroids accounting for 90.5% of cases. Among topical steroids most offending agent was betamethasone. This finding is similar to study by Ratan J. Lihite *et al.*^[8] and Malladi Pavani.^[9] The other less common topical steroids were beclomethasone (3.5%) and cortisone (0.5%).

The next category of drugs causing ADRs were belonging to NSAIDs (5.5%). This finding is consistent with studies by Zinnat Ara Begum *et al.*^[4], Rohini Sharma *et al.*^[5] and Amrinder R *et al.*^[7] Paracetamol, ibuprofen and nimesulide were common NSAIDs. These were taken for relief of headache, fever, pain in legs and knees, subsequently developed FDRs.

The oral antimicrobials which include doxycycline, ciprofloxacin, cotrimoxazole-trimethoprim, cefepodoxime peroxitil constitute third common class of drugs causing ADRs in our study. While this class of drugs were most commonly involved in studies by Zinnat Ara Begum *et al.*^[4], Rohini Sharma *et al.*^[5], Bharani Kalpna *et al.*^[6] and Amrinder R *et al.*^[7]

Immunosuppressant (methotrexate) and antiemetic (domperidone) were least commonly implicated drugs in our study, each one was responsible for single case of ADRs. Methotrexate was responsible for hepatotoxicity (deranged LFT) and immunosuppression while domperidone was causing FDR according to consultant.

CONCLUSION-

Timely identification and management of ADRs can save patient from unnecessary sufferings and expenses. For this adequate knowledge of manifestations of ADRs and offending drug is necessary. Prompt reporting of ADR by clinician and awareness of patients regarding ADR occurrence also help in reducing the incidences of ADRs.

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