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A clinico-etiological study of Cutaneous Adverse Drug Reactions in Tertiary Care Centre

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Abstract
Aims & Objectives*: To find out the incidence of Cutaneous Adverse drug reactions in outdoor and indoor patients and observe different clinical patterns of cutaneous eruptions and identify the offending drug.* ***Materials and Methods****: This is an observational study done over a period of 1 year (Jan. to Dec.2020) in department of Dermatology, RIMS Ranchi with sample size of total 183 patients (96 females, 87 males). The diagnosis of the ADRs was done by establishing the drug use with the help of history and improvement of mucocutaneous lesions after stoppage of offending drugs and reappearance of reactions after reexposure.* ***Results****: In this study out of total 183 cases, patients presented with Contact dermatitis (97, 53%), Exfoliative dermatitis (19, 10.38%), Fixed drug eruptions (17, 9.28%), SJS-TEN (9, 4.92%), Erythema multiforme (9, 4.92%), Maculopapular rash (8, 4.37%), Ichthyosis (5, 2.73%), Urticaria (4, 2.18 %), angioedema (3, 1.64%), Aphthous mucositis (3,1.64%), DHS (3, 1.64%), Teratogenicity (2, 1.1%), Lipodystrophy due to steroid inj. (2, 1.1%), Ochronosis (1, 0.55%), Cut. Vesiculobullous eruptions d/t NBUVB (1, 0.55%). In this study, the incidence of ADRs was found to be 10.35/1000 total dermatological cases with max. cases found in the age group of 46-65 years (34.42 %). Mild predominance of ADRs was seen in females as compared to males (F:M – 1.1:1). Antimicrobials have been implicated as the major causative factor (40%) for ADRs among systemic drugs and among topicals, major causative factor were topical steroids (94.89%).* ***Conclusion****: With the number of marketed drugs increasing every year, it is very much important to have an in-depth understanding of their possible adverse reactions and this is possible only when the physician is trained adequately and is actively looking for any ADR. So, anticipating, preventing, recognizing, and responding to ADRs should be the prime concern of the physicians to minimize the incidence of ADRs.*

Key Words*: Cutaneous Adverse Drug Reactions, Contact Dermatitis, Exfoliative Dermatitis, SJS-TEN, Antimicrobials, NSAIDS, Topical Steroids.*

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I. Introduction:

Adverse drug reaction is a *response to a drug which is noxious and unintended which occurs either at a dose normally used in humans for prophylaxis / diagnosis /therapy of disease / for the modifications of physiological functions or for pathological states of the recipient, or with overdosage, misuse or abuse of drugs.* Adverse drug reactions (ADRs) are important cause of morbidity, hospitalization, increased health expenditure and even death. The Cutaneous reactions are the most common manifestations of ADRs ranging from maculopapular rashes, Fixed drugs eruptions, SJS- TEN, Erythema multiforme, exfoliative dermatitis. In diagnosing a cutaneous eruption that may be an adverse drug reaction, it is important to decide whether the eruption is due to the disease, primarily due to the drug, or due possible to an interaction between the disease and the drug.

Many drug reactions are due the augmented effects which are predictable and related to their pharmacological actions, while some are bizarre, due to chronic use or due to delayed effect of stored concentration. Drug provocation challenge test is one approach to detect the effect due to the corresponding drug. Other methods include patch test, prick test and intradermal test. Some eruptions can be diagnosed as an effect either of disease or of drug use by histopathology and in vivo tests.

II. Aims and objectives:

To find out the incidence of cutaneous adverse drug reactions in outdoor and indoor patients in Dermatology department of Tertiary care hospital and observe different clinical patterns and investigate the offending drug.

III. Materials and Methods:

This is a prospective observational study done over a period of 1 year (Jan. to Dec.2020). There was total 183 patients (96 females, 87 males). The diagnosis of the ADRs was done by establishing the drug use with the help of history, temporal association of offending drugs with ADR, morphology of lesions, improvement of mucocutaneous lesions after stoppage of offending drugs and reappearance of reactions after reexposure.

Inclusion criteria: All age group patients, all patients presenting to the dermatology OPD and IPD with cutaneous manifestations after drug consumption and those referred from other departments were included in this study. Referrals and OPD patients when necessary were hospitalized for further management.

Exclusion criteria: Patients with other skin diseases, hepatic and renal diseases, pregnancy and lactation, incomplete h/o drug intake or disease after unknown drugs were excluded from this study.

IV. Results:

In this study out of total 183 cases, patients presented with maximum cases of Contact dermatitis(97, 53%), followed by Exfoliative dermatitis(19, 10.38%), Fixed drug eruptions(17, 9.28%), SJS-TEN(9, 4.92%), Erythema multiforme(9, 4.92%), Maculopapular rash(8, 4.37%), Ichthyosis(5, 2.73%), Urticaria(4, 2.18 %), angioedema(3, 1.64%), Aphthous mucositis(3, 1.64%), DHS(3, 1.64%), Teratogenicity(2, 1.1%), Lipodystrophy due to steroid inj.(2, 1.1%), Ochronosis(1, 0.55%), Cut. Vesiculobullous eruptions d/t NBUVB (1, 0.55%). The distributions of adverse drug reactions percentage is given in the fig. 1. The drugs most commonly responsible for ADRs among systemic drugs were antimicrobials (34, 40 %) (fig.2.), followed by nonsteroidal anti-inflammatory drugs (NSAIDs) (10, 11.76%) (fig.3.), anti- convulsants (8, 9.41 %) (fig.4.) and Other drugs (33, 38.82 %) (fig.5.). Maximum incidences of Exf.dermatitis, SJS-TEN, FDE and maculopapular rash were seen to be associated with antimicrobials.

Cutaneous ADRs due to topical drugs (fig.6.) were found to be total of 98 cases including Contact dermatitis due to permethrin (4, 4.08%), Steroid dermatitis (93, 94.89 %), ochronosis due to Hydroquinone (1, 1.02 %). Steroid dermatitis included steroid acne (13, 13.26 %), tinea incognito (79, 80.61 %), scabies incognito (1, 1.02 %).

V. Discussion:

In this study, the incidence of ADRs was found to be 10.35/1000 of total dermatological OPD and IPD cases, which is higher than the study by *Thakkar et. al.* (4.5/1000), with max. cases found in the age group of 46-65 years (34.42 %) (Table no. 1.). Mild predominance of ADRs was seen in females as compared to males (F:M – 1.1:1). This difference may be due to the fact that the females may be more conscious of any minor cutaneous reactions and report it, while males tend to ignore or not notice minor cutaneous reactions. Antimicrobials have been implicated as the major causative factor (40%) for ADRs among systemic drugs and among topicals, major causative factor were topical steroids (94.89%). NSAIDs were the second leading cause (11.76 %) of ADRs in this study. The study by *Sharma et al*. reported NSAIDS as a cause of ADRs in 18 % of patients.

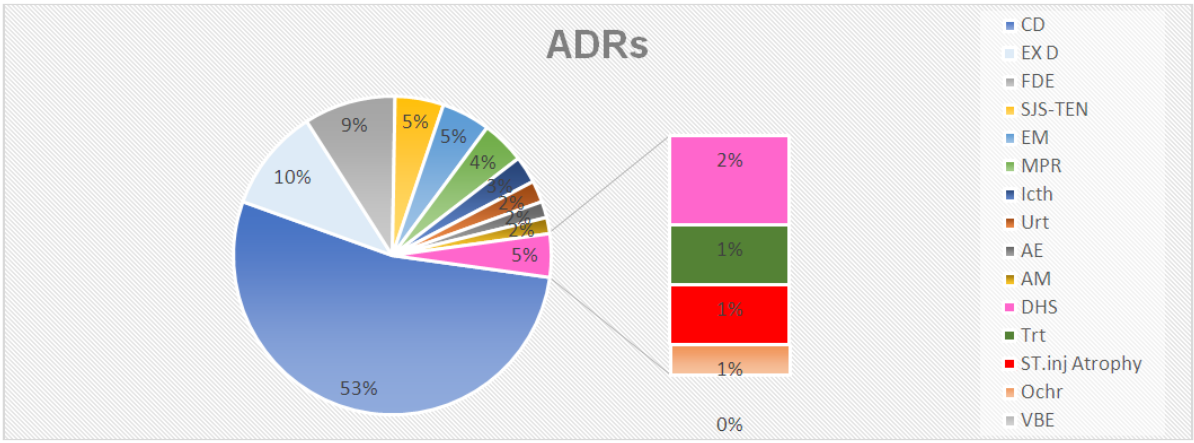


Fig. 1

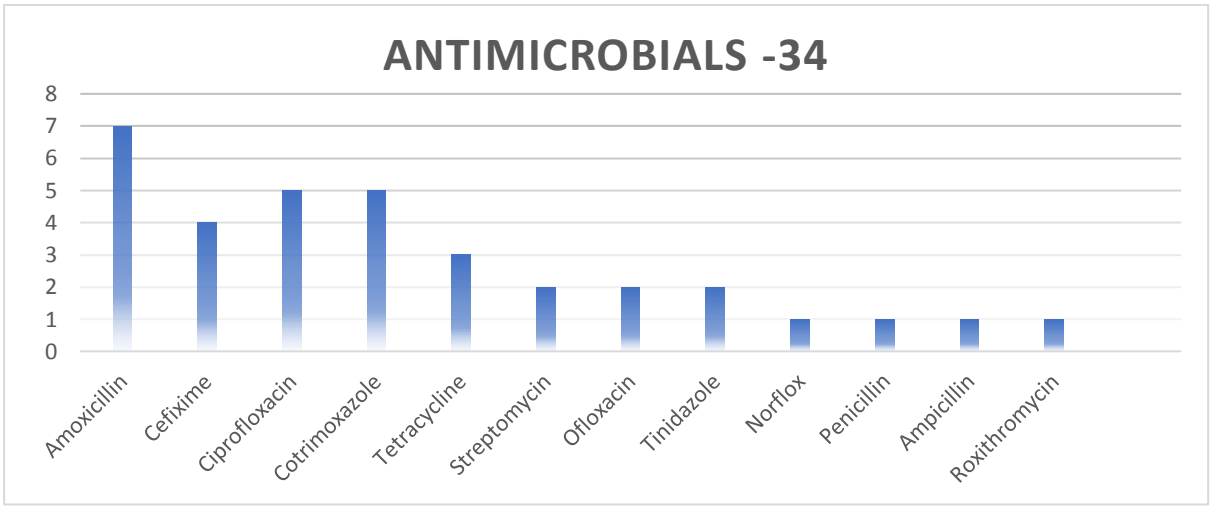


Fig.2.

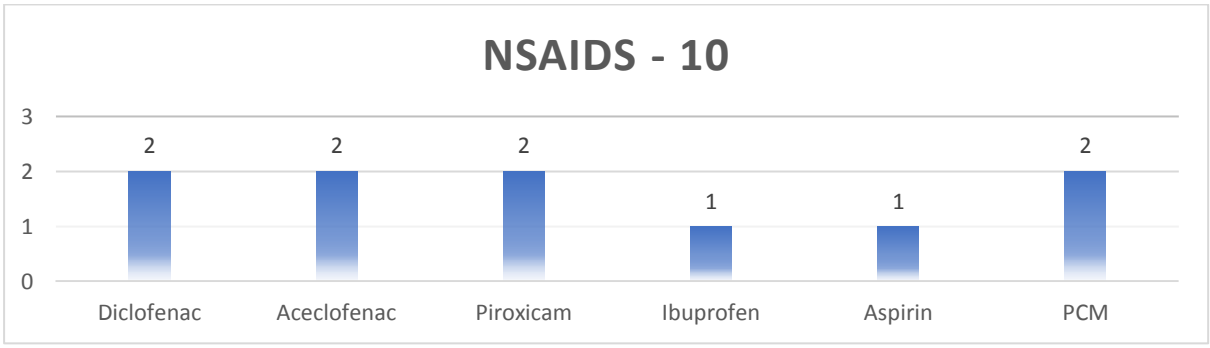


Fig.3.

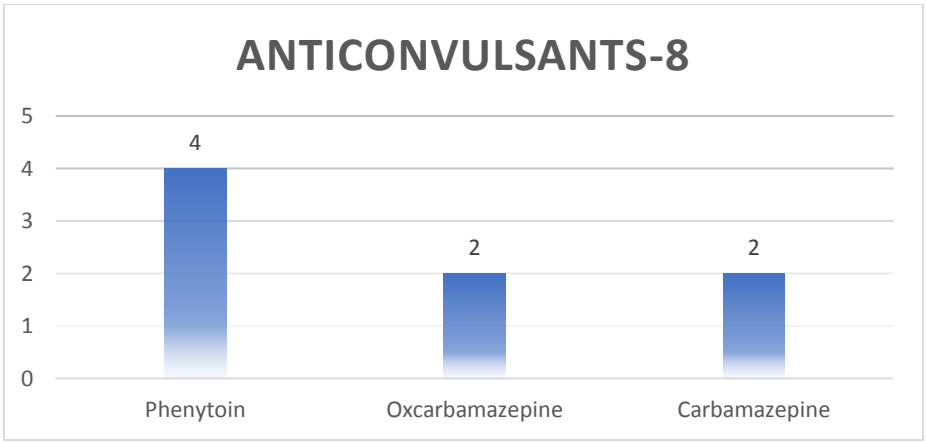


Fig.4.

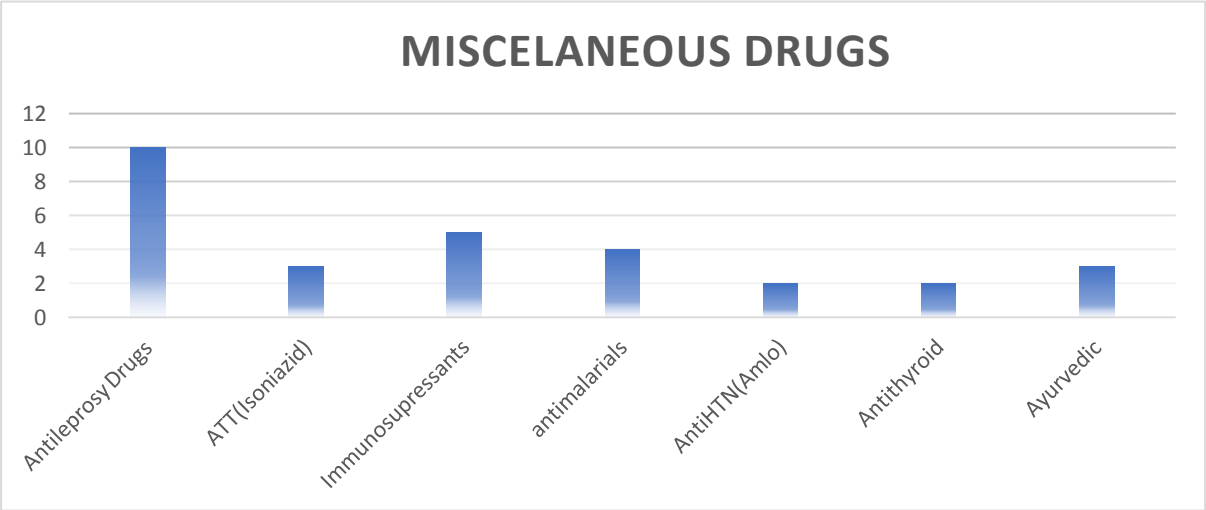


Fig.5.

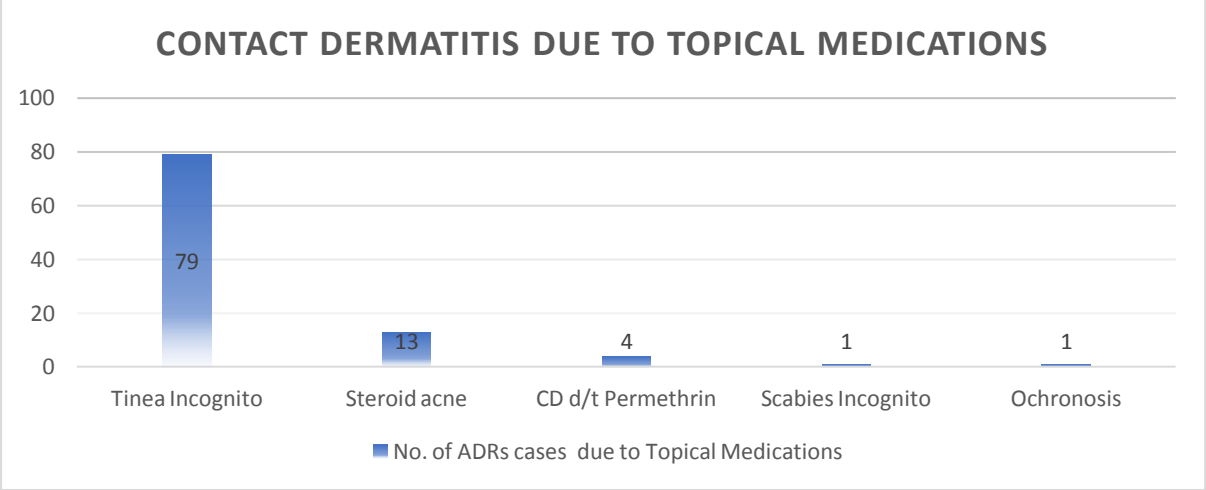


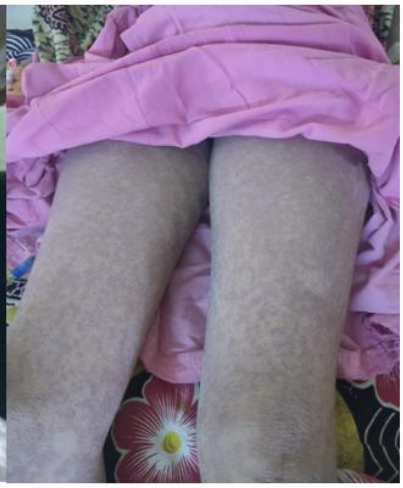
Fig.6.

Age Group (years)	number of cases	%
Paediatric (0-18)	5	2.73
Young Adult (19-30)	30	16.39
Mid- Adult (31-45)	48	26.23
Older adult (46-65)	63	34.42
Elderly (>65)	37	20.23

Table 1. Age wise distribution of ADRs

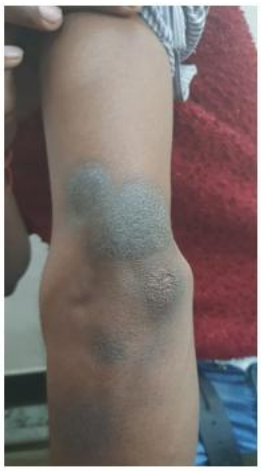
Clinical Pictures of various Cutaneous Adverse Drug reactions:

SJS-TEN



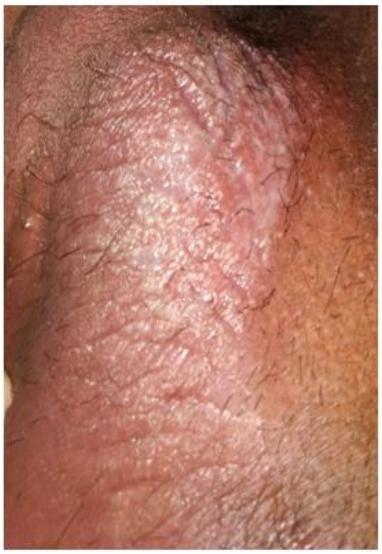
Maculopapular Rashes

Exfoliative Dermatitis

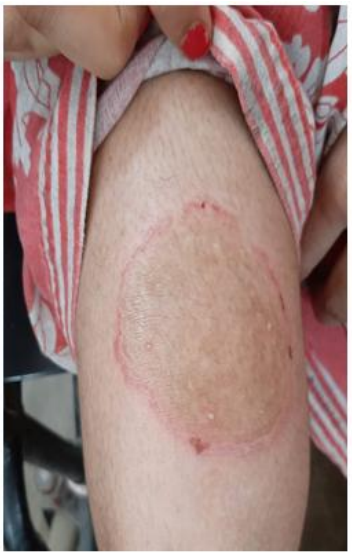


FDE to Aceclofenac

Contact Dermatitis
due to Permethrin



Steroid Dermatitis



Tinea Incognito

VI. Conclusion

ADRs are potentially avoidable causes for seeking medical care. They increase the burden of work and can be fatal at times. Increase in cases of ADRs may be due to over the counter sell of medicines, increasing no. of quacks, common person's negative perception of allopathy.

With the number of marketed drugs increasing every year, it is very much important to have an in-depth understanding of their possible adverse reactions and this is possible only when the physician is trained adequately and is actively looking for any ADRs. So, anticipating, preventing, recognizing, and responding to ADRs should be the prime concern of the physicians to minimize the incidence of ADRs. The offending drugs should be mentioned in the medical card of the patients as a precautionary measure to avoid future ADRs.

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