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Research Article

STUDY OF CUTANEOUS ADVERSE DRUG REACTIONS IN A TERTIARY CARE TEACHING HOSPITAL

***Vijaykumar Lakshman Lamani, Jagdishchandra S. Ratnakar, Basavaraj C. Kotinatot and Aruna Bhushan**
Department of Pharmacology, Belgaum Institute of Medical Scienes, Belgaum, Karnataka, India
**Author for Correspondence*

ABSTRACT
Cutaneous adverse drug reactions (CADRs) constitute a major clinical problem in terms of human suffering and increased healthcare costs. A wide spectrum of cutaneous manifestations ranging from maculopapular rash to severe toxic epidermal necrolysis (TEN) can be produced by different classes of drugs. Some severe CADRs may result in serious morbidity and even death. Although many a times, presentation is too trivial and benign, the early identification of the condition and culprit drug earliest holds the keystone in management and prevention of more severe CADRs. It is also a fact that in the present world, almost every day a new drug enters market, therefore, a chance of a new drug reaction manifesting somewhere in some form in any corner of world is unknown or unreported. Therefore, not only the dermatologists, but all practicing physicians should be familiar with these conditions to diagnose them early and to be prepared to handle them adequately.

Keywords: *Cutaneous Adverse Drug Reactions, Stevens–Johnson Syndrome, Toxic Epidermal Necrolysis, Causality Assessment, Nevirapine*

INTRODUCTION
Cutaneous drug reactions are one of the most common types of adverse reaction to drug therapy, almost any drug can induce skin reactions. An adverse cutaneous reaction caused by a drug is any undesirable change in the structure or function of the skin, its appendages or mucous membranes, and it encompass all adverse events related to drug eruption, regardless of the etiology (Nayak and Acharjya, 2008).

Although most drug-related skin eruptions are not serious, some are severe and potentially life-threatening conditions like angio-oedema, erythroderma, Stevens–Johnson syndrome and toxic epidermal necrolysis. Comprehensive information regarding their incidence, severity and ultimate health effects are often not available as many cases go unreported.

The present study is designed to obtained information about drug induced cutaneous adverse reactions and to establish the causal relationship.

Objectives
To obtain information about drug induced cutaneous adverse reactions and to establish the causal relationship.

MATERIALS AND METHODS
Observational study of cutaneous adverse drug reactions which were reported at adverse drug reaction (ADR) monitoring centre of Belgaum Institute of Medical Sciences during 1 year period was evaluated. The details of cutaneous adverse drug reactions were recorded in ADR form of Central Drugs Standard Control Organisation (CDSCO). Causality was assessed using Naranjo algorithm and also with causality assessment of scale as per World Health Organization- Uppsala monitoring centre (WHO-UMC) criteria.

Statistical Methods

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%).

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RESULTS AND DISCUSSION

Results

Out of 30 patients 26 were inpatients and 4 were outpatients, among these 18 were female and 12 were male. Most common cutaneous adverse drug reactions (CADRs) were Maculopapular rashes 14(46.6%), Stevens Johnson syndrome 8(26.66%), Fixed drug eruption were 4(13.33%), Erythema Multiforme 2(6.66%) and Urticaria/angioedema 2(6.66%). Most common drugs responsible were Nevirapine 12(40%), Antibiotics 10(30%), Non steroidal anti-inflammatory drugs (NSAIDs) were 6(20%) and Pencillins 2 (10%). Causality profile of CADR of our study population was categorized as per WHO-UMC case causality assessment. Among 30 patients, 8 cases the causality association was certain and the 20 cases were probable/likely and2 cases were possible.

Table 1: Common Cutaneous adverse drug reaction encountered

Adverse drug reaction	No. of patients	%
Maculopapular rashes	14	46.6
Stevens Johnson syndrome	8	26.6
Fixed drug eruption	4	13.3
Erythema Multiforme	2	6.66
Urticaria/angioedema	2	6.66

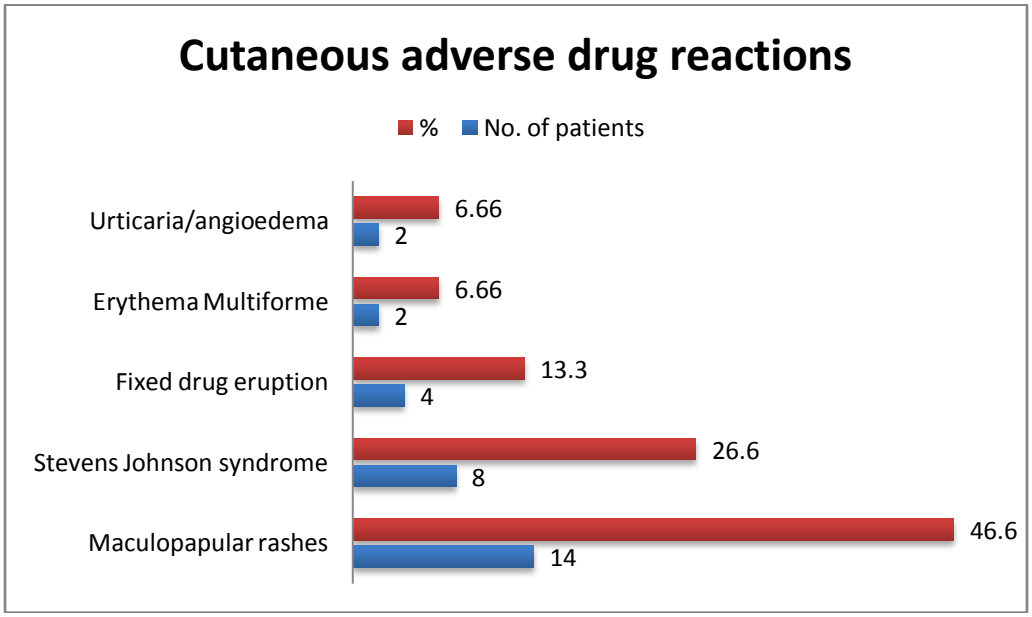

Figure 1: Common Cutaneous adverse drug reaction encountered

Table 2: Drugs responsible for cutaneous adverse drug reactions

DRUG	NO.OF.ADR	%
Nevirapine	12	40
Antibiotics	10	30
NSAIDs	6	20
Penicillin	2	10

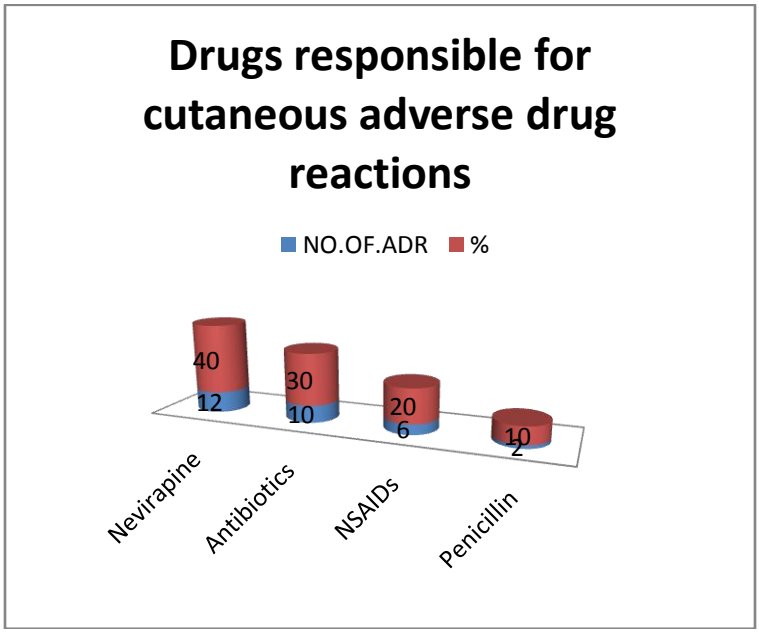

Figure 2: Drugs responsible for cutaneous adverse drug reactions

Discussion

The development of a cutaneous adverse drug reaction is frequently cited as a reason for discontinuation of treatment without completing therapeutic course. In our study, the majority patients belonged to the 20-39 years age group and predominance of female patients which is similar to study done by Pudukadan and Thappa (2004). This difference may be attributed to the fact that the females may be more conscious of any cutaneous reactions and report it

The offending drug was initiated on average three weeks before the skin reaction, similarly to previous reports, thus showing that drugs started within this timeframe should be the first to be suspected (Struck *et al.*, 2010). Adverse cutaneous drug reactions vary in their patterns of morphology and distribution. In our study most common adverse drug reactions (ADRs) were Maculopapular rashes 14(46.6%) which was similar to study done by Sushma *et al.*, (2005). The incidence of life threatening cutaneous ADRs like SJS and TEN were found to be higher compared to studies published abroad.

Commonly incriminated drugs in our study were Nevirapine 12(40%), Antibiotics 10(30%), NSAIDs 6(20%) and Pencillins 2 (10%) which differs to previous studies reports. Regarding treatment measures, withdrawal of the suspected drug occurred in virtually all cases and systemic steroids and antibiotics were frequently administered. According to previous observational studies, the early withdrawal of the causing drug is proven to improve prognosis (Chia and Leong, 2007).

Conclusion

Detection and prevention of ADRs at the earliest is very important as they can cause not only morbidity and mortality. Results of this study emphasized the need of ADR reporting in tertiary care hospital to help in assessing the benefit- risk ratio of drugs.

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