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RESEARCH ARTICLE

CLINICO-EPIDEMIOLOGICAL STUDY OF CUTANEOUS ADVERSE DRUG REACTIONS IN A TERITIARY CARE CENTRE

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Key words:-
Cutaneous Adverse Drug Reactions(CADRs), Fixed Drug Eruption(FDE), Antibiotics

Abstract

Background: Cutaneous adverse drug reactions (CADRs), sometimes referred to as toxidermia, are skin side effects of systemic medication delivery that affect 0.1-0.3% of patients who visit the DVL department. These responses might be as minor as a drug rash or as serious as life threatening reactions**.**

Aims & objectives: To evaluate the age and sex distribution, clinical types, and offending drugs causing cutaneous adverse drug reactions.

Materials and Methods: A retrospective observational study was conducted at the DVL OPD in a tertiary care hospital in Andhra Pradesh for a duration of 1 year from January 2023 to December 2023, a total of 90 patients with cutaneous drug reactions were noted.

Results: In this study, there was female dominance (46%) and most of the patients were in their 30 to 50 years of age group(62.2%) with fixed drug eruption (64.4%) being the most common clinical profile of CADRs, followed by erythema multiforme(8.88%), lichenoid drug eruption (7.77%), acneiform eruption(6.66%), maculopapular eruption (5.55%), urticarial rash (2.22%), keratolysisexfoliativa(2.22%),and SJS/TEN(2.22%). The most culpable group of drugs causing CADRs were antibiotics (40.28%), NSAIDs (28.43%), and anticonvulsants (11.6%).

Conclusion:Commonly used drugs like antibiotics and NSAIDs can cause cutaneous adverse drug reactions(CADRs). Hence judicious use of these drugs with necessary caution would be highly beneficial.

Introduction:-

As per WHO, an adverse drug reaction can be defined as “any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or the modification of physiological function”[1.] Skin is the frequently involved organ in adverse drug reactions according to the majority of previous studies[2]. Cutaneous manifestations ranging from maculopapular rashes to toxic epidermal necrolysis (TEN) can be caused by different classes of drugs[3]. Any pre-existing skin disorder can be induced or aggravated by drugs. Cutaneous adverse drug reactions constitute 0.1-0.3% of patients attending DVL OPD. CADRs can cause considerable morbidity and mortality. Hence the present study was done to assess age, sex distribution, clinical pattern, and the offending drugs. The diagnosis of cutaneous drug reactions is based on the detailed history of drug intake and the onset of rash. Discontinuation of the culprit drug is the main goal of treatment.

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Methodology:-

A retrospective observational study was done in the department of DVL, RangarayaMedical College, Kakinada, Andhra Pradesh for one year (January 2023 to December 2023). A total of 90 patients clinically diagnosed with cutaneous adverse drug reactions were recorded in this study. Age and sex distribution, offending drugs, clinical course, and treatment details were noted from the case sheets of those patients.

Ethical approval:
Institutional ethics committee approval was obtained before the commencement of study

Statistical analysis:
Results were tabulatedand percentages were calculated using Microsoft Excel.

Results:-

A total of 90 patients were reported as cutaneous drug reactions. Out of 90 patients, 44(48.89%) were males and 46 were females(51.11%). The majority of the patients belonged to the age group of 31-40 years, followed by 41-50 and 21-30 groups, with a mean age of 40.9 years [Table 1]. The youngest patient was 14 years old and the oldest was 77. The period of development of lesions after drug intake varied from 1 to 45 days.

Table 1:- Age and sex distribution.

Age group	Male	Female	Total	Percentage
11-20yrs	4	6	10	11.11%
21-30yrs	9	6	15	16.67%
31-40yrs	8	18	26	28.89%
41-50yrs	8	8	16	17.78%
51-60yrs	10	2	12	13.33%
Above 60yrs	7	4	11	12.22%

Majority of CADRs were Fixed drug eruption (64.4%), followed by erythema multiforme(8.88%), lichenoid drug eruption(7.77%), acneiform eruption(6.66%), maculopapular eruption (5.55%), urticarial rash (2.22%), keratolysisexfoliativa(2.22%), and SJS/TEN(2.22%).[Table 2]

Table 2:- Types of cutaneous adverse drug reactions(CADR) along with sex distribution:

Type of CADR	Male	Female	Frequency	Percentage
Fixed drug eruption(FDE)	36	22	58	64.5%
Erythema multiforme(EMF)	0	8	8	8.88%
Lichenoid drug eruption	3	4	7	7.77%
Acneiform eruption	2	4	6	6.66%
Maculopapular eruption	1	4	5	5.55%
Keratolysisexfoliativa	0	2	2	2.22%
urticaria	0	2	2	2.225
Steven Johnson syndrome(SJS)	1	0	1	1.11%
Toxic epidermal necrolysis(TEN)	1	0	1	1.11%

The most common culprit group of drugs causing CADRs were antibiotics (40.28%), followed by NSAIDs (28.43%),anticonvulsants(11.6%), and others(19.69%) which include both allopathic and ayurvedic medicines.

Discussion:-

The incidence of CADR was 0.186% out of a total 48327 OPD attending the DVL department in the year 2023 from January to December.There has been a rise in the incidence of adverse cutaneous drug reactions in recent times. In our study, we intended to identify common patterns of cutaneous adverse drug reactions and the offending drugs. The frequency of CADR in a particular population is influenced by the drug utilization habit, the reaction rates of commonly used drugs, and the pharmacogenetic traits of the population studied.

In our study Fixed drug eruption (64.4%) was most commonly observed clinical pattern followed by Erythema multiforme (8.88%) and lichenoid drug eruption(7.77%). Pudukadan et al, reported similar results in that the most common pattern in their study was FDE (31.1%) followed by a maculopapular rash (12.2%)[4]. In contrast to our study, Malhotra et al reported morbilliform rash in 29.63%, SJ/TEN in 22.22% and urticaria in 9.26% of cases as the common patterns of eruption[5]. Jhaj et al. reported 50% cases of morbilliform rash, 21% cases of urticaria, 13.9% cases of SJ syndrome, and 4.9% cases of TEN[6].

Female preponderance was noted in our study which was similar to other studies[7]. similar results were observed in the data from the Italian spontaneous reporting system[8].

In our study the most common culprit group of drugs for cutaneous reactions were antibiotics (40.28%), NSAIDs (28.43%),anticonvulsants(11.6%),and others(19.69%). T K Patel et al in their review of CADR in the Indian population observed similar findings[9]. In a 9-year South Indian study of 404 patients, the drug classes implicated were antibiotics (45%) followed by antiepileptics (19%) and NSAIDs (19%)[10]. Sharma VK et al in their study found the causative as antimicrobials in 42.6%, anticonvulsants in 22.2%, and NSAIDs in 18%[11]. Other important classes of drugs were corticosteroids either topical or systemic causing mainly acneiform eruptions. In our study, steroids were the causative drugs in 6 patients. In the study done by R Sharma et al corticosteroids were found to be the third most common drug class implicated in CADR accounting for 14.6% of patients[12]. S Ghosh et al in their study reported 4% of cutaneous drug reactions to be due to steroids[13].

The ultimate goal of management is always to discontinue the offending medication if possible. The treatment is mainly supportive and depends on the type of reaction. In our study, most of the patients were managed on an outpatient basis 75 (83.33%) whereas 15 cases (16.66%) were treated as inpatients of which two cases were in the Intensive Care Unit.

Conclusion:-

This study highlights the need for proper drug history, to warn the patient to avoid multiple drugs and to avoid the use of similar drugs in the future, and to maintain records informing pharmacovigilance to formulate better preventive measures. Knowledge of adverse drug reactions is essential for early recognition of minor to major reactions and treatment should be given accordingly at the earliest.

Figure 1:- Fixed drug eruption.

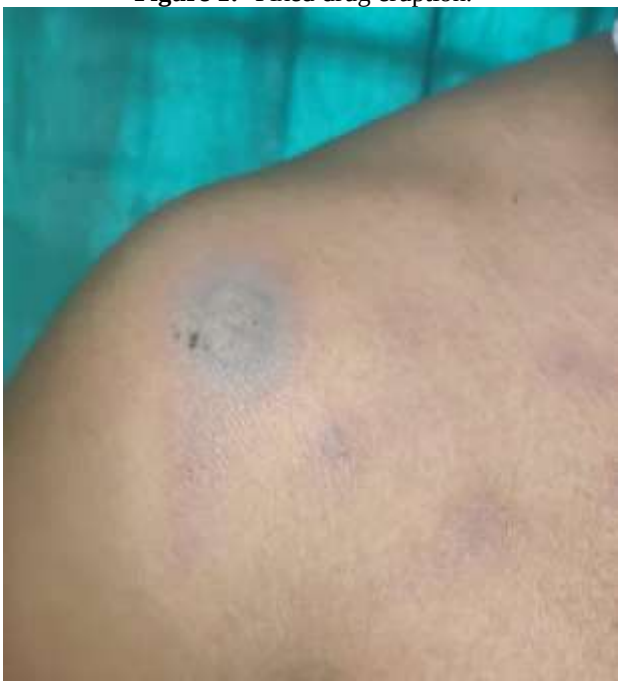

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Figure 2:- Lichenoid drug eruption.

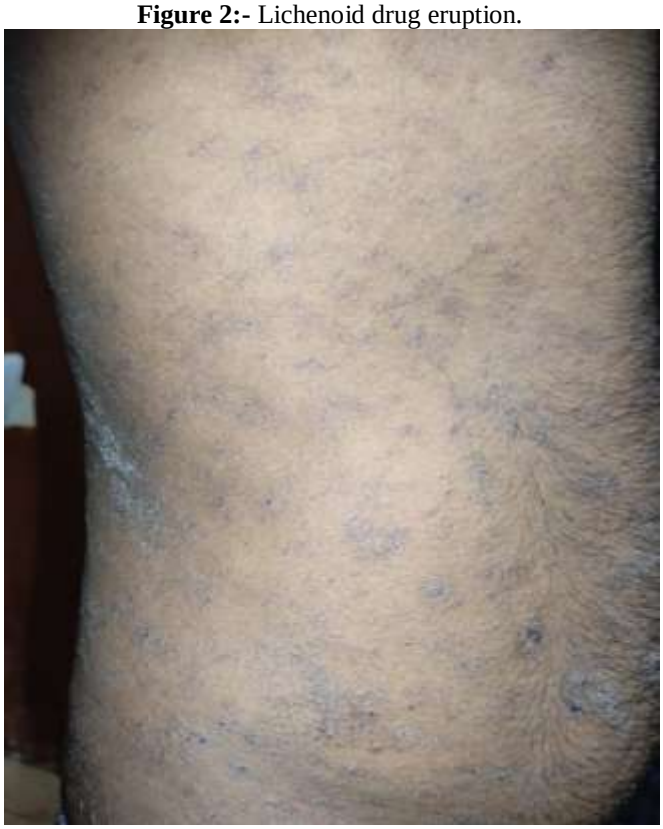

Figure 3:- Stevens Johnson syndrome.

Figure 4:- Toxic Epidermal Necrolysis.

References:-

1. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, 2000;356(9237):1255-9.
2. French LE(ed): Adverse Cutaneous Drug Eruptions. ChemImmunol Allergy. Basel, Karger. 2012;97:ppI-XIV.
3. Svensson CK, Cowen EW, Gaspari AA. Cutaneous drug reactions. Pharmacol Rev 2001;53:357-379.
4. Pudukadan D, Thappa DM. Adverse cutaneous drug reactions: Clinical pattern and causative agents in a tertiary care center in South India. Indian J DermatolVenereolLeprol2004;70:20-4.
5. Malhotra S, Chopra SC, Dogra A, Gupta C. Cutaneous adverse drug reactions- one-year pharmacovigilance study in a tertiary care hospital. Indian J Pharmacol 2004; 36:S41-42.
6. Jhaj R, Uppal R, Malhotra S, Bhargava VK. Cutaneous adverse reactions in in-patients in a tertiary care hospital. Indian J DermatolVenereolLeprol1999;65:14-7.
7. Nayak S, Acharya B. Adverse cutaneous drug reaction. Indian J Dermatol2008;53:2-8.
8. Naldi L, Conforti A, Venegoni M, et al. Cutaneous reactions to drugs. An analysis of spontaneous reports in four Italian regions. Br J Clinical Pharmacol1999;48:839-846.
9. Patel TK, Thakkar S, Sharma DC. Cutaneous adverse drug reactions in Indian population: A systematic review. Indian Dermatol Online J 2014; 5(Suppl 2):S76-S86.
10. Sushma M, Noel MV, Ritika MC, James J, Guido S. Cutaneous adverse drug reactions. A 9-year study from a South Indian Hospital. Pharmacoepidemiol Drug Saf2005;14:567 570.
11. Sharma VK, Sethuraman G, Kumar B. Cutaneous adverse drug reactions:clinical pattern and causative agents- a 6-year series from Chandigarh, India. J Postgrad Med 2001;47(2):95-99.
12. Sharma R, Dogra D, Dogra N. A study of cutaneous adverse drug reactions at a tertiary center in Jammu, India. Indian Dermatol Online J 2015;6,3:168-217.
13. Ghosh S, Leelavathi D, Padma GM. Study on evaluation of various cutaneous drug reactions in Kasturba HospitalManipal. Indian J Pharm Sci 2006; 68(2):212-215.