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A Study on Clinical Profile of Adverse Cutaneous Drug Reaction in a Tertiary Care Hospital

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Abstract: ***Background: The incidence of adverse cutaneous drug reactions are in raise as with the introduction with variety of medications. Through knowledge of ACDR helps in early identification and adequate management. Objectives: To study various clinical spectrum of ACDR and its causative agents. Methods: All patients who came to Dermatology out patient department , Father Muller medical college hospital from June 2018 to May 2019, clinically diagnosed as cases of adverse cutaneous drug reaction were included in the study. The study includes patients of all age group. Information on age, gender, occupation, comorbidities, drug/medication history prior to the onset of lesions, site, distribution and morphology of the lesions were collected. Data was collected from Dermatology out patient register, patient OPD file, IP register and IP records (admitted cases). Results: 40 patients were included in the study. The mean age of the patients were 40.5 years. Most drug reactions were observed in the age group of 30-4years.55% were females. Most common morphological type observed was maculopapular rash and SJS. Most common offending drug was levofloxacin and paracetamol. Most common offending group of drug was antibiotics. Anticonvulsants were involved with severe drug reactions. Conclusion: Most of the drug reactions were noted for the commonly used drugs. Significant number of reactions were noted due to herbal medications. Polypharmacy has increased the risk of ACDR.***

1. Introduction

Most of the doctors come across many instances of suspected adverse cutaneous drug reactions(ACDR) of different forms in everyday practice. The early identification of the condition and identifying the culprit drug and omitting it at the earliest holds the corner stone of management and prevention of a more severe drug reaction. The diagnosis of ACDR is mainly clinical as there is paucity of confirmatory laboratory test for the diagnosis of the same.

An adverse cutaneous drug reaction caused by a drug is defined as 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.[1]

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 cutaneous ADRs may result in serious morbidity and even death.[2]
Adverse cutaneous reactions to drugs are frequent, affecting 2-3% of allhospitalized patients. 2% of adverse cutaneous reactions are severe and veryfew are fatal. The incidence of ACDR in developing countries such as Indiaranges from 2-5% of the in patients. [2-5]

Studies on the epidemiology of cutaneous ADRs have rarely been reported from India. This study was therefore designed to evaluate the clinical spectrum of all cutaneous ADRs over a year in the patients attending the department of dermatology.

2. Materials and Methods

All the patients who had come to Dermatology out patient department, Father Muller medical college hospital, Mangalore, Karnataka, from June 2018 to may 2019, with clinical diagnosis of ACDR were included in the study.

- **Study design-** Retrospective observational descriptive chart based study.
- **Study location-** This was a tertiary care hospital based study done at department of dermatology, Father Muller medical college hospital, Kankanady, Mangalore, Karnataka.
- **Study duration-** June 2018 to May 2019.
- **Sample size calculation**- Time bound study

Inclusion criteria
Clinically diagnosed cases of adverse cutaneous drug reaction who came to OPD andcases that were admitted in Father Mullers medical college Hospital from June 2018 to May2019.

Exclusion criteria- None

2.1 Methodology

All patients who came to Dermatology out patient department , Father Muller medical college hospital from June 2018 to May 2019, clinically diagnosed as cases of adversecutaneous drug reaction were included in the study.

The study includes patients of all age group. Information on age, gender, occupation,comorbidities, drug/medication history prior tothe onset of lesions, site, distribution and morphology of the lesions were collected.

Data was collected from Dermatology out patient register, patient OPD file, IP register and IP records(admitted cases).

2.2 Statistical analysis

Collected data was analysed by frequency, percentage, mean and median.

3. Results

Forty patients were included in the study.

Age of the patients ranged from 5 years to 76 years and the mean age was 40.5 years.

Most of the ACDRs were seen in the age group of 31 to 40 years (27.5%) followed by age group above 50 years (25%).

Table 1: Age distribution

	Age group	Number (n)	Percentage
Age	20 and below	6	15.0%
	21 - 30	8	20.0%
	31 - 40	11	27.5%
	41 - 50	5	12.5%
	Above 50	10	25.0%
	Total	40	100.0%

Out of 40 patients 22(55%) were females and 18(45%) were males.

Most of the ACDR were noted within 5 days of usage of a particular drug(67.5%) , in the remaining cases ACDR was seen after 5 days of usage.

28(70%) patients were on single drug and 12(30%) patients were on multiple drugs.

Most of the patients presented with involvement of trunk (82.5%). Mucosal involvement was seen in 18(45%) patients.

Table 2: Areas of body involved

	Number (N)	Percentage
Face	25	62.5%
Trunk	33	82.5%
Extremities	23	57.5%
Eyes	15	37.5%
Oral cavity	18	45.0%
Genitals	8	20.0%

Most common morphological pattern seen in the study was maculopapular rash and Steven's- Johnson syndrome (25%), followed by fixed drug eruption (12%).

Table 3: Frequency of morphological pattern of ACDR

	Type	Number (N)	Percentage
Morphological type	AGEP	2	5.0%
	DRESS syndrome	5	12.5%
	Enanthem	1	2.5%
	FDE	6	15.0%
	Maculopapular rash	10	25.0%
	SJS	10	25.0%
	TEN	3	7.5%
	Urticarial rash	3	7.5%
	Total	40	100.0%

Most common offending drug found in the study was levofloxacin (12.5%) and paracetamol (12.5%) patients, followed by herbal medications.

Table 4: Frequency of offending drugs involved in ACDR

	Drug	Number (n)	Percentage
Offending drug	Allopurinol	2	5.0%
	Amoxycillin	3	7.5%
	Aspirin	1	2.5%
	Ayurvedic med	4	10.0%
	Cefpodoxime	1	2.5%
	Ciprofloxacin	2	5.0%
	cotrimoxazole	2	5.0%
	Dapsone	2	5.0%
	Diclofenac	3	7.5%
	Fluconazole	2	5.0%
	Ibuprofen+PCT	1	2.5%
	Levofloxacin	5	12.5%
	Linezolid	1	2.5%
	Norfloxacin	1	2.5%
	Paracetamol	5	12.5%
	Phenytoin	3	7.5%
	Sorafinib	1	2.5%
	Valproate	1	2.5%
Total		40	100%

Most common group of drug involved was antibiotics (37.5%), followed by non-steroidal anti-inflammatory drugs(25%).

Table 5: Frequency of group of drugs involved in ACDR

	Group	Number (n)	Percentage %
Offending group of drugs	Antibiotics	15	32.5
	NSAIDS	10	25
	Herbal medications	4	10
	Anticonvulsants	4	10
	Antifungals	2	0.5
	others	5	12.5
Total		40	100

Most common group of drugs presented with systemic involvement was antibiotics (12.5%), followed by anticonvulsants (10%).

Constitutional symptoms were present in 20(50%) patients.

Systemic involvement was present in 13(32.5%) patients.

Table 6: Offending drugs with systemic involvement

	Group of drug	Number (n)	Percentage %
Systemic involvement	Antibiotics	5	38.5
	Anticonvulsants	4	30.5
	Dapsone	2	15
	Allopurinol	1	7.5
	Herbal medication	1	7.5
Total		13	100

DRESS, SJS, TEN and dapsone syndrome were associated with systemic involvement

Table 7: Morphological type of ACDR with systemic involvement

		Number	Percentage
Morphological type versus systemic involvement	AGEP	0	.0%
	DRESS syndrome	3	23%
	Dapsone syndrome	2	15.38
	Enanthem	0	.0%
	FDE	0	.0%
	Maculopapular rash	0	.0%
	SJS	6	46.2%
	TEN	2	15.4%
	Urticarial rash	0	.0%
	Total	13	100.0%

4. Discussion

Adverse cutaneous drug reactions are commonly encountered in everyday practice. Doctors should be mindful to have high suspicion of the condition to efficiently identify and treat the drug reactions.

In our study we came across 40 patients of ACDR in a period of 1 year. 22 were females (55%) and 18 were males(45%). The sex distribution is comparable with other studies line Neupane S et al.[6]

Most of the ACDRs were seen in the age group of 31 to 40 years (27.5%) followed by age group above 50 years (25%). The higher incidence in age group above 50 can be attributed to prevalence of co-morbidities in that age group with usage of multitude of drugs. Also due to impaired renal and hepatic functions predispose them to the risk of drug reactions.

Most of the drug reactions were noted within first 5 days of usage of drugs (67.5%).

The most common morphological pattern seen in the study was maculopapular rash and Steven's- Johnson syndrome(25%), followed by fixed drug eruption(12%), which is similar to study done by Neupane et al where they found maculopapular rash to be the commonest morphological type followed by fixed drug eruption.[6] In a study done by Chatterjee et al[7] they noted urticaria to be the most common type followed by FDE and Stern RS et al[8] noted maculopapular rash followed by urticarial rash.

Most common group of drug involved was antibiotics (37.5%), followed by non-steroidal anti-inflammatory drugs (25%). This findings were comparable to other studies.[6]

Most common offending drug found in the study was levofloxacin (12.5%) and paracetamol (12.5%) patients, followed by herbal medications. Paracetamol and levofloxacin are used frequently for various conditions. The cautious use of these drugs is warranted. This is similar to a study Verma R et al where they noted fluroquinolones to be the most common offending drugs.[9]

Most common group of drugs presented with systemic involvement was antibiotics (12.5%), followed by anticonvulsants (10%). Anticonvulsants and dapsone were associated with severe adverse cutaneous drug reactions which was also noticed in other studies.[6]

5. Conclusion

In our study the most common morphological pattern observed was maculopapular rash and SJS. More cases pf SJS cases reported in the study could be attributed to ours being a tertiary care referral centre. Herbal medications were implicated in a significant number of cases. So it should be kept in mind that any drug can cause ACDR. Significant number of patients were on multiple drugs. Suggesting the increased risk of drug reactions with the practice of polypharmacy. From this study its imperative that drug reactions are common phenomenon that we come across and judicious usage is warranted to prevent catastrophic events.

References

[1] Nayak S, Acharjya B. Adverse cutaneous drug reaction. Indian J Dermatol. 2008;53:2–8.
[2] Noel MV, Sushma M, Guido S. Cutaneous adverse drug reactions in hospitalized patients in a tertiary care centre. Indian J Pharmacol. 2004;36:292–5.
[3] Uppal R, Jhaj R, Malhotra S. Adverse drug reactions among in patients in a north Indian referral hospital. Natl Med J India. 2000;13:16–8.
[4] Jhaj R, Uppal R, Malhotra S, Bhargava VK. Cutaneous adverse reactions in in-patients in a tertiary care hospital. Indian J Dermatol VenereolLeprol. 1999;65:14–7.
[5] Pudukadan D, Thappa DM. Adverse cutaneous drug reactions: Clinical pattern and causative agents in a tertiary care center in South India. Indian J Dermatol Venereal Leprol. 2004;70:20–4.
[6] Neupane S, Basnet B. Cutaneous Adverse Drug reactions: A Four-Year Study from Western Nepal. Journal of Gandaki Medical College-Nepal. 2017;10(2):21-6.
[7] Chatterjee S, Ghosh AP, Barbhuiya J, Dey SK. Adverse cutaneous drug reactions: A one year survey at a dermatology outpatient clinic of a tertiary care hospital. Indian J Pharmacol. 2006;38:429–31.
[8] Stern RS, Wintroub BU. Cutaneous reactions to drugs. In: Freedberg IM, Eisen AZ, Wolff K, Austen KF, Goldsmith LA, Katz SI, editors. Fitzpatrick's Dermatology in genera medicine. 5th ed. McGraw-Hill: New York; 1999. pp. 1634–42.
[9] Verma R, Vasudevan B, Pragasam V. Severe cutaneous adverse drug reactions. medical journal armed forces India. 2013 Oct 1; 69(4):375-83..