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ASSESSMENT OF DIFFERENT MORPHOLOGICAL PATTERNS OF CUTANEOUS ADVERSE DRUG REACTION AND THEIR RELATIONSHIP IN INDIAN SUBJECTS

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ABSTRACT

Background: Adverse drug reactions, or ADRs, are a typical worry when it comes to medication therapy and one of the main issues surrounding it. Cutaneous adverse drug responses (CADRs), which varied depending on the medication, are the most frequent type of adverse drug reaction.

Aim: The purpose of this study was to evaluate the various morphological types of cutaneous adverse medication reactions in Indian participants and the correlation between them.

Methods: This study evaluated patients where the identification of the medicine could be determined and where cutaneous adverse drug responses were suspected. The clinical profile and medication history of each participant were evaluated. The use of the Naranjo scale for the causality evaluation came next.

Results: The most frequent cutaneous adverse drug reaction observed in 49% of research participants was drug eruption (fixed drug eruption), followed by SJS-TEN spectrum in 17% of respondents and maculopapular rash in 11% of subjects. A total of 25% (n=36) of the participants experienced severe cutaneous adverse drug reactions (SCARs), which included DRESS, AGEP, SJS-TEN overlap, and SJS. Antibiotics were the most often reported medication interaction, with NSAIDs and anticonvulsants following closely behind with 54%, 15%, and 12% of participants, respectively. The likely group included the bulk of the cutaneous adverse medication responses. The current investigation reveals that, in comparison to people from other nations, the incidence of severe cutaneous adverse responses is much greater in Indian subjects.

Keywords: Antimicrobials, adverse drug reactions, cutaneous adverse drug reactions, fixed drug eruptions, side-effects

INTRODUCTION

According to the World Health Organisation, an adverse drug reaction (ADR) is a reaction to a medication that is unwanted and occurs at dosages that are used to treat, diagnose, or prevent a disease or to alter physiological functioning. Nowadays, CADRs (cutaneous adverse drug reactions) are the most prevalent form of adverse drug response, and their reported prevalence has grown, making them common. The incidence of CADRs varies between 2 and 5% and 1% to 3% in industrialised and developing nations, respectively.1, 2

Skin eruptions that are neither life-threatening nor seriously ill comprise the majority of drug-related skin responses. Fever and systemic symptoms are linked to these illnesses, along with a number of frequently fatal consequences. These severe cutaneous adverse responses occur in around 1-2 instances per million people annually. The occurrence, however, may differ depending on the ethnicity.4

Varied medications have varied patterns of cutaneous adverse drug responses. In order to reduce the mortality associated with cutaneous adverse drug reactions, it is critical to identify the substance causing the response, obtain an

early diagnosis, and promptly remove the offending drug. All of these steps will help to better grasp the true nature of the drug reaction. Additionally, choosing safer medications might be aided by awareness about medications that may cause cutaneous adverse drug responses.5, 6

Epidemiological studies are helpful in determining the morphological pattern of different medications that associate different drug classes with cutaneous adverse drug responses reporting adverse drug responses to newly developed therapeutic pharmaceuticals as well as identifying and reporting atypical reactions to frequently used medications.7. There is a dearth of information in the literature currently available about cutaneous adverse drug reactions in India. With this context in mind, the current investigation was conducted to evaluate several morphological features of cutaneous adverse medication response and their correlation in patients from India.

MATERIALS AND METHODS

In order to evaluate several morphological types of cutaneous adverse medication reaction and their association in Indian participants, a cross-sectional observational clinical research was conducted. The study's participants were from the Institute's Department of Dermatology. Prior to their involvement in the study, all participants provided their written and verbal informed permission. There were 144 participants in the research, representing all age groups and both genders. Every research participant had a thorough medical history taken, which was followed by a physical examination that included pertinent information, a preliminary diagnosis, information on other organ involvement, areas affected, the type of rash, the length of the eruption, the offending drug, the study subject's age and gender, and other relevant details.

The appropriate history of medication use was evaluated as well, encompassing the use of allopathic, homoeopathic, and ayurvedic medicine and its temporal association with the onset of the symptom. Following the elimination of other explanations for the comparable clinical images, the study participants' final diagnosis was determined, and they underwent additional evaluation. In individuals who had taken many drugs, the medication deemed to be most likely to cause harm was identified and confirmed once the withdrawal symptoms faded.

Following the collection of a patient's medical history, standard tests were performed on each research subject, including a complete blood count, microscopic and routine urine examinations, serum electrolytes, liver function tests, blood urea, serum creatinine, and blood sugar evaluations. Additionally, ELISA tests for HIV 1 and HIV 2 as well as serum VDRL-like specific investigations were carried out if needed. The implementation of Naranjo's Algorithm scale for the causality evaluation came next. Naranjo's algorithm scale, a straightforward questionnaire capable of assigning probability ratings, was used to examine any causal association seen between an unfavourable clinical occurrence and a medicine.

Concerning the scoring system, possible, probable, and definitive relationships between drug and clinical event were seen for scores of 1 to 4, 5 to 8, and more than or equal to 9 respectively. The chi-square test and SPSS software version 21.0 (IBM Corp., Armonk, NY, USA) were used for the statistical analysis of the collected data. The statistics were presented as percentage, frequency, mean, and standard deviation. An acceptable p-value for statistical significance was <0.05. Repeated measures and ANOVA (analysis of variance) were employed to assess the change in parameters of any group before and after surgery.

RESULTS

In order to evaluate several morphological types of cutaneous adverse medication reaction and their association in Indian participants, a cross-sectional observational clinical research was conducted. There were 144 participants in the research, representing all age groups and both genders. Two men and two girls, or 2.77% (n=4) of the research volunteers, were under the age of eleven.

There were 12 girls and 10 men in the 11–20 age group, making up 15.27% (n=22) of the total participants. There were 16 girls and 32 men aged 21–30, making up 33.3% (n=48) of the participants. There were 22 men and 18 women in the age range of 31 to 40, making up a total of 27.7% (n=40) of the participants. There were 8 females and 6 men in the 41–50 age group, or 9.72% (n=14) of the participants. There were two females and eight men aged 51 to 60, making up 6.94% (n=10) of the total participants. There were 2.77% (n=4) participants in the 61–70 age range, and they were all male. Table 1 indicates that of the individuals aged 71-80, 1.38% (n = 2) were male.

The majority of the research individuals' cutaneous adverse medication responses were found to be fixed when the distribution of these reactions was examined. As stated in Table 2, drug eruptions were observed in 48.61% (n=70) of the subjects, followed by maculopapular rash in 11.1% (n=16) of the subjects, SJS and TEN in 6.94% (n=10) of the subjects, acute generalised exanthematous pustulosis and erythema multiforme in 5.55% (n=8) of the subjects, SJS-

TEN, DRESS, erythroderma, and urticaria in 2.77% (n=4) of the subjects, and exfoliative dermatitis, drug-induced lichen planus, and angioedema in 1.38% (n=2) of the subjects. When it came to the most prevalent medications that induced cutaneous adverse drug reactions in the research participants, antimicrobials were the most common, accounting for 54.16% (n=78) of the patients' offending drugs, followed by NSAIDs in 15.27% (n=22) subjects, According to Table 3, anticonvulsants made up 12.5% (n=18) of the study subjects, antifungals, 6.94% (n=10), homoeopathy, 2.77% (n=40), and dapsone, sulfasalazine, antitubercular medications, and antimalarials, each made up 1.38% (n=2) of the study subjects.

DISCUSSION

144 participants of all ages and genders participated in the current investigation. Two men and two girls, or 2.77% (n=4) of the research volunteers, were under the age of eleven. There were 12 girls and 10 men in the 11–20 age group, making up 15.27% (n=22) of the total participants. There were 16 girls and 32 men aged 21–30, making up 33.3% (n=48) of the participants. There were 22 men and 18 women in the age range of 31 to 40, making up a total of 27.7% (n=40) of the participants.

These statistics matched those from studies by Posadzski P et al. (2012) and Suthar JV et al. (2011), in which the authors evaluated participants using demographic information comparable to those of the current investigation. There were 8 females and 6 men in the 41–50 age group, or 9.72% (n=14) of the participants. There were two females and eight men aged 51 to 60, making up 6.94% (n=10) of the total participants. There were 2.77% (n=4) participants in the 61–70 age range, and they were all male. There were 1.38% (n=2) participants aged 71–80 years, and they were all male. The results were similar to those of Noel MV et al. 10 in 2004 and Sudharani C et al. 11 in 2016, whose age and gender distributions mirrored those of the current investigation was reported by the authors in their respective studies in subjects with cutaneous adverse drug reactions.

According to the study's findings, the most common cutaneous adverse drug reaction among the subjects under investigation was fixed drug eruptions, which affected 48.61% (n=70). Maculopapular rash was observed in 11.1% (n=16) of the subjects, while SJS and TEN were observed in 6.94% (n=10) of the subjects. Acute generalised exanthematous pustulosis and erythema multiforme were observed in 5.55% (n=8) of the subjects, while SJS-TEN, DRESS, erythroderma, and urticaria were observed in 2.77% (n=4) of the subjects, and exfoliative dermatitis, drug-induced lichen planus, and angioedema were observed in 1.38% (n=2) of the subjects. These findings aligned with research by Spillers NJ et al. (12) in 2023 and Patel T et al. (13) in 2014, whose authors documented comparable cutaneous adverse medication responses to those seen in the current investigation.

Antimicrobials were found to be the most common drug offending in 54.16% (n=78) of the study subjects that experienced cutaneous adverse drug reactions. NSAIDs came in second with 15.27% (n=22), followed by anticonvulsants with 12.5% (n=18), antifungals with 6.94% (n=10), homoeopathy with 2.77% (n=40), and antimalarials, dapsone, sulfasalazine, and antitubercular medications with 1.38% (n=2) study subjects each. These results corroborated those of Pudukadan D et al.(2004) and Al-Raaie F et al.(2008), who found that NSAIDs and antibiotics were the most often prescribed medications that resulted in cutaneous adverse drug responses.

CONCLUSIONS

Taking into account its limitations, the current study comes to the conclusion that participants from India had a much greater rate of severe cutaneous adverse responses than those from other nations. The study's drawbacks, including its shorter monitoring period and small sample size, call for more longitudinal research with bigger sample numbers and longer evaluation times.

REFERENCES

1. Kaniwa N, Saito Y. Pharmacogenomics of severe cutaneous adverse reactions and drug-induced liver injury. J Hum Genet 2013;58:317-26.
2. Patel S, Jain N, Badkur M, Mehar M. Study of a pattern of antibiotic-induced adverse cutaneous drug reactions in a tertiary care hospital. J Evol Med Dent Sci 2016;5:2892-4.
3. 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.
4. Gupta L, Martin A, Agarwal N, D'Souza P, Das S, Kumar R, *et al*. Guidelines for the management of Stevens–Johnson syndrome/toxic epidermal necrolysis: An Indian perspective. Indian J Dermatol Venereol Leprol 2016;82:603.

5. Raksha M, Marfatia YS. Clinical study of cutaneous drug eruptions in 200 patients. Indian J Dermatol Venereol Leprol 2008;74:80.

6. Edwards IR, Aronson JK. Adverse drug reactions: Definitions, diagnosis, and management. Lancet 2000;356:1255-9.

7. 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;6:168-71.

8. P Posadzki 1, A Alotaibi, E Ernst Adverse effects of homeopathy: A systematic review of published case reports and case series. Int J Clin Pract 2012;66:1178-88.

9. Suthar JV, Desai SV. A study of adverse cutaneous drug reactions in outdoor patients attending to Skin and V.D. Department of Shree Krishna Hospital, Karamsad. Int J Res Pharm Biomed Sci 2011;2:2229-3701.

10. Noel MV, Sushma M, Guido S. Cutaneous adverse drug reactions in hospitalized patients in a tertiary care center. Indian J Pharmacol 2004;36:292-5.

11. Sudharani C, Udayakumar B, Geetakiran A. Adverse cutaneous drug reactions to Anticonvulsants – A study at a tertiary care center in Telangana. IOSR J Dent Med Sci 2016;15:11-5.

12. Spillers NJ, Luther PM, Talbot NC, Ly GH, Downs EM, Lavespere G, *et al*. Association of acetaminophen with Stevens-Johnson syndrome and toxic epidermal necrolysis: Pharmacologic considerations and treatment options. Cureus 2023;15:e41116

13. Patel T, Thakkar S, Sharma DC. Cutaneous adverse drug reactions in Indian population: A systematic review. Indian Dermatol Online J 2014;5:76-86.

14. 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.

15. Al-Raaie F, Banodkar DD. Epidemiological study of cutaneous adverse drug reactions: In Oman. Oman Med J 2008;23:21-7.

TABLES

S. No	Age range (years)	Females	Males	Total (n)	Percentage (%)
1.	**<11**	2	2	4	2.77
2.	**11-20**	12	10	22	15.27
3.	**21-30**	16	32	48	33.3
4.	**31-40**	18	22	40	27.7
5.	**41-50**	8	6	14	9.72
6.	**51-60**	2	8	10	6.94
7.	**61-70**	0	4	4	2.77
8.	**71-80**	0	2	2	1.38
9.	**Total**	58	86	144	100

Table 1: Gender and age distribution in the study subjects

S. No	Reaction pattern	Number (n)	Percentage (%)
1.	**Exfoliative dermatitis**	2	1.38
2.	**Drug-induced lichen planus**	2	1.38
3.	**Angioedema**	2	1.38
4.	**Urticaria**	4	2.77
5.	**Erythroderma**	4	2.77
6.	**Erythema multiforme**	8	5.55
7.	**DRESS**	4	2.77
8.	**Acute generalized exanthematous pustulosis**	8	5.55
9.	**SJS-TEN**	4	2.77
10	**TEN**	10	6.94
11	**SJS**	10	6.94
12	**Maculopapular rash**	16	11.1
13	**FDE**	70	48.61
14	**Total**	144	100

Table 2: Distribution of morphological pattern of CADRs in the study subjects

S. No	Offending drug	Number (n)	Percentage (%)
1.	**Antimicrobials**	78	54.16
2.	**NSAIDs**	22	15.27
3.	**Anticonvulsants**	18	12.5
4.	**Antifungals**	10	6.94
5.	**Antimalarials**	2	1.38
6.	**Antitubercular drugs**	2	1.38
7.	**Sulfasalazine**	2	1.38
8.	**Homeopathy**	4	2.77
9.	**Dapsone**	2	1.38

Table 3: Common offending drugs causing CADRs in study subjects