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Original Research Article

Analysis of spontaneously reported cutaneous adverse drug reactions in a tertiary care teaching hospital in South India

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ABSTRACT

Background: Skin is the most common organ involved in adverse reactions due to drugs. With newer drugs released into market every year, there is changing pattern of the reported cutaneous adverse drug reactions (ADRs). In order to ensure safer use of medicines in patients, there is need for continuous monitoring of ADRs. This is a retrospective study to analyse spontaneously reported cutaneous ADRs.

Methods: All the cutaneous ADRs reported between January 2017 and September 2018 were analysed for clinical patterns, suspected medications, causality, severity and preventability.

Results: Of the 1035 reports received during the study period, 232 (22.41%) included cutaneous reactions. 113 (48.7%) were male and 119 (51.29%) were female. Maculopapular rash 70 (30.17%), pruritus 31 (13.36%), palmar plantar erythrodysesthesia 30 (12.93%), acne 19 (8.19%), urticaria 16 (6.89%) and fixed drug eruptions (FDE) 13 (5.6%) were the common clinical patterns. Antimicrobial agents followed by anticancer drugs, nonsteroidal anti-inflammatory drugs (NSAIDs), hormones and related drugs, and antiepileptic drugs were the common suspected group of drugs. Causality assessment as done by WHO-UMC scale showed that 3 (1.29%) were certainly related, 174 (75%) were probably related and 55 (23.7%) were possibly related to the suspected medication.

Conclusions: Cutaneous ADRs are most frequently reported ADRs in the present study. With newer drugs released into market, there is a need for continuous monitoring of use of drugs to promote safer use of medicines in patients.

Keywords: Adverse drug reaction monitoring centre, Cutaneous adverse drug reactions, Causality, Pharmacovigilance

INTRODUCTION

According to World Health Organization (WHO), an adverse reaction to drug is one that is noxious, unintended and occurs at doses normally used in man.[1] Adverse drug reactions (ADRs) are associated with prolonged hospitalization, increased morbidity and mortality.[2,3] ADRs resulted in substantial increase in costs for the healthcare sector.[4]

Cutaneous ADR is any undesirable change in the structure or function of the skin, its appendages or mucous membranes, encompassing all adverse events related to drug eruption, regardless of the etiology.[5] Skin reactions are one of the most frequently reported ADRs and are responsible for about 3% of all disabling injuries during hospitalization.[6]

The Pharmacovigilance Programme of India (PvPI) is launched in 2010 with a broad objective to safe guard the

health of patients by ensuring safer use of medicines, with the National Coordinating Centre (NCC) at Indian Pharmacopoeia Commission (IPC), Ghaziabad. As part of this, Adverse Drug Reaction Monitoring Centres (AMCs) are established in various hospitals in all over India. AMCs play a crucial role in identifying, reporting and follow-up of suspected ADRs due to use of drugs. The Individual Case Safety Reports (ICSRs) received at NCC are periodically analysed to facilitate appropriate decisions to be taken by Central Drug Standard Control Organization (CDSCO) regarding the safer usage of drugs in Indian population.[7]

Analysis of various studies done on cutaneous ADRs in India showed variations in occurrence of different reactions. The most commonly reported reactions include maculopapular rash, fixed drug eruptions and urticaria with varied frequencies.[8] With newer drugs being approved every year, there is a change in prescribing pattern of the drugs and also the change in pattern of the reported cutaneous ADRs.[9,10] It is reported that the most common severe cutaneous ADRs are Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrosis (TEN).[8] However, early identification of these reactions helps in prompt management and further prevention of more severe adverse drug reactions.[11,12] Hence, there is need to continuously monitor various cutaneous adverse drug reactions for their clinical manifestations and the offending drugs.

The objective of the present study is to analyse the spontaneously reported cutaneous ADRs for their pattern, suspected medications, and to access causality, severity and preventability.

METHODS

This was a retrospective analytical study carried out based on the spontaneously reported cutaneous adverse drug reactions reported by healthcare professionals of all the departments to adverse drug reaction monitoring centre (AMC) of SVIMS, Sri Padmavathi Medical College for Women, Tirupati, Andhra Pradesh, India between January 2017 and September 2018. The study was started after approval by Institutional Ethics Committee.

Data extracted from ADR form included patient details (age, sex, weight, initials, etc.), description of the event (date of start and recovery, other relevant history, seriousness, outcomes, relevant laboratory tests, etc.), suspected medications (dates of prescription, dosage, frequency and route of administration, duration and indication of use) and use of concomitant medications. Cutaneous ADRs in patients of all the age groups and either sex was included in the study. Cutaneous ADR forms lacking any of the mandatory fields as required by Pharmacovigilance Programme of India (PvPI) like patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information were not included in the study.

Causality assessment was done using the WHO-UMC (World Health Organization-Uppsala Monitoring Centre) causality assessment scale and the Naranjo causality assessment scale.[13,14] Seriousness of an ADR is defined as any untoward reaction to the medicinal product that may result in death, requires inpatient hospitalization or results in prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or is a medically important event or reaction.[15] Severity of the reaction was assessed using the Modified Hartwig and Siegel scale which classifies ADR into mild, moderate and severe.[16] Preventability assessment was done by using Schumock and Thornton scale which classifies the ADRs into definitely preventable, probably preventable and not preventable.[17]

Statistical analysis

A descriptive analysis of the data was done using Microsoft Excel 2013 and results were expressed as numbers and percentage.

RESULTS

Of the 1035 reports received at AMC during the study period, 232 (22.41%) reports having cutaneous ADRs were analysed. The majority of the ADRs were reported in the age group of 31 to 45 years (27.59%), followed by age group of 46 to 60 years (27.15%). Age distribution of ADRs is represented in Figure 1. Occurrence of ADRs was slightly higher in females (51.29%) compared to males (male/female = 113/119).

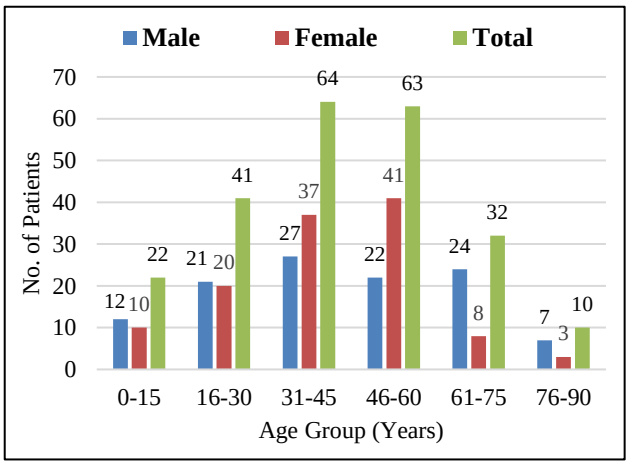

Figure 1: Age and sex distribution of ADRs.

Maculopapular rash was the most frequently reported cutaneous ADR, followed by pruritus, palmar plantar erythrodysesthesia, acne, urticaria, fixed drug eruption and other less frequent reactions. These also included serious cutaneous ADRs like Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), angioedema and DRESS syndrome. The various patterns of cutaneous drug reactions and their frequency are shown in Table 1.

Causality assessment of the reported ADRs as done by WHO-UMC causality assessment scale showed that 174 (75%) of the reported cases were probable and Naranjo's causality assessment scale showed that 149 (64.22%) of the cases were possible related to the suspected medication. Details of the causality assessment of the reported cases is presented in Table 2.

Table 1: Pattern of cutaneous ADRs (Total number = 232).

Pattern of cutaneous ADR	No of ADRs n (%)
Maculopapular rash	70 (30.17)
Pruritus	31 (13.36)
Palmar plantar erythrodysesthesia	30 (12.93)
Acne	19 (8.19)
Urticaria	16 (6.89)
Fixed Drug Eruption (FDE)	13 (5.60)
Hyperpigmentation	11 (4.74)
Dermatitis	10 (4.31)
Stevens-Johnson Syndrome (SJS)	6 (2.58)
Purpura	3 (1.29)
Morbiliform rash	3 (1.29)
Erythema Multiforme	2 (0.86)
Cutaneous Vasculitis	2 (0.86)
Acute generalized exanthematous pustulosis	2 (0.86)
Retinoid cheilitis and xerosis	2 (0.86)
Angioedema	2 (0.86)
Toxic Epidermal Necrolysis (TEN)	2 (0.86)
DRESS*	2 (0.86)
Dapsone hypersensitivity reaction	1 (0.43)
Onychomycosis with melanonychia	1 (0.43)
Tinea incognito	1 (0.43)
Steroid rosacea	1 (0.43)
Ecchymosis with cellulitis	1 (0.43)
Exacerbation of psoriasis	1 (0.43)

*DRESS - Drug Rash with Eosinophilia and Systemic Symptoms

Table 2: Causality assessment by WHO-UMC scale and Naranjo's scale.

Causality term	WHO scale n (%)	Naranjo scale n (%)
Certain/Definite	3 (1.29)	0
Probable	174 (75)	83 (35.78)
Possible	55 (23.70)	149 (64.22)

It was observed that maximum number of cutaneous ADRs were due to antimicrobial agents (29.74%), followed by anticancer drugs (25.86%), non-steroidal anti-inflammatory drugs (NSAIDs) (12.06%), hormones and related drugs (11.2%), antiepileptic drugs (6.46%) and less frequently by other group of drugs. Frequencies of suspected class of medications that caused the reported cutaneous ADRs are mentioned in Table 3. When the antimicrobial agents were further analysed, it was observed that fluoroquinolones were the major group followed by cephalosporins and penicillins. The frequency of various antimicrobial agents responsible for cutaneous ADRs is depicted in Table 4.

Table 3: Suspected class of medication and frequency of cutaneous ADRs.

Suspected class of medication	No of ADRs n (%)
Antimicrobial agents	69 (29.74)
Anticancer Drugs	60 (25.86)
NSAIDs*	28 (12.06)
Hormones and related drugs	26 (11.20)
Antiepileptics	15 (6.46)
Radio-contrast agents	7 (3.01)
Antiulcer agents	4 (1.72)
Antihypertensive agents	4 (1.72)
Vitamin supplementations	3 (1.29)
Anticoagulants	2 (0.86)
Bronchodilators	2 (0.86)
Local anaesthetic agent	2 (0.86)
DMARDs**	2 (0.86)
Antipsychotic agent	1 (0.43)
MR Vaccine***	1 (0.43)
Herbal extract	1 (0.43)
Skeletal muscle relaxants	1 (0.43)
Immunoglobulin	1 (0.43)
Antidiabetic drugs	1 (0.43)
Thyroid related drugs	1 (0.43)
Antiseptics	1 (0.43)

*NSAIDs - Nonsteroidal Anti-inflammatory Drugs
**DMARDs - Disease Modifying Anti Rheumatoid Drugs
***MR vaccine - Measeles-Rubella Vaccine

A total of 46 (19.83%) out of 232 were serious. The reasons for considering cutaneous ADR to be serious is requirement of hospitalization/prolongation of hospitalization (15.08%) and occurrence of life threatening ADRs (4.74%). When serious cutaneous ADRs were further analysed, it was observed that antimicrobial agents were responsible for 16 (34.78%) reports. The seven levels of severity as assessed by modified Hartwig and Siegel scale is categorised into mild (Level 1 and 2), moderate (Level 3 and 4) and severe (Level 5, 6 and 7) and the details are presented in Table 5. It was observed that majority of the cases (49.57%) were moderate in severity. Preventability assessment of the reported cutaneous ADRs using Schumock and Thornton scale revealed that 20 (8.62%) cases were probably preventable whereas the remaining 212 (91.38%) cases were not preventable.

DISCUSSION

This is a retrospectively analysis of spontaneously reported cutaneous ADRs between January 2017 and September 2018. Of the total reports received at AMC

during the study period, 232 (22.41%) reports were due to cutaneous ADRs. It was observed that the percentage of cutaneous ADRs among the total number of ADRs received at AMCs varied among different studies.[18-20]

Table 4: Distribution of suspected cutaneous ADRs due to various categories of antimicrobial drugs.

S .no	Category	Suspected medication	Reaction
1	Fluoroquinolones (16)	Ciprofloxacin (13) Levofloxacin (2) Norfloxacin (1)	Pruritus (9) Maculopapular rash (3) Urticaria (2) DRESS* (1) Fixed Drug Eruption (1)
2	Cephalosporins (12)	Ceftriaxone (5) Cefpodoxime+Clavulinic acid (3) Cefixime (2) Cefperazone+Sulbactam (1) Cefotaxim (1)	Maculopapular Rash (4) Pruritus (3) Angioedema (2) Fixed Drug Eruption (1) Dermatitis (1) Toxic Epidermal Necrolysis (1)
3	Penicillins (10)	Amoxicillin+Clavulinic acid (6) Piperacillin+Tazobactam (3) Benzathine penicillin (1)	Pruritus (3) Urticaria (2) Erythema Multiforme (1) Fixed Drug Eruption (1) Steven Johnson Syndrome (1) Maculopapular Rash (1) Cutaneous Vasculitis (1)
4	Glycopeptide antibiotic (10)	Vancomycin (10)	Maculopapular Rash (6) Pruritus (3) Morbilliform Rash (1)
5	Antitubercular agents (9)	Isoniazid + Rifampicin + Ethambutol + Pyrazinamide (4) Isoniazid (2) Rifampicin (2) Pyrazinamide (1)	Urticaria (2) Pruritus (2) Acne (1) Purpura (1) Steven Johnson Syndrome (1) Dermatitis (1) Hyperpigmentation (1)
6	Macrolides (4)	Azithromycin (4)	Maculopapular Rash (1) Steven Johnson Syndrome (1) Hyperpigmentation (1) Acute Generalized Exanthematous Pustulosis (1)
7	Tetracyclines (2)	Doxycycline (2)	Steven Johnson Syndrome (2)
8	Aminoglycosides (1)	Amikacin (1)	Maculopapular Rash (1)
9	Antimalarial agents (1)	Chloroquine (1)	Maculopapular Rash (1)
10	Antifungal agents (1)	Fluconazole (1)	Morbilliform Rash (1)
11	Lincosamide antibiotic (1)	Clindamycin (1)	Pruritus (1)
12	Antiamoebic agent (1)	Metronidazole (1)	Pruritus (1)
13	Oxazolidinones (1)	Linezolid (1)	Urticaria (1)

Table 5: Severity of cutaneous ADRs as assessed by modified Hartwig and Siegel scale.

Severity		No. of ADRs n (%)
Category	**Level**	
Mild	1 2	95 (40.94)
Moderate	3 4	115 (49.57)
Severe	5 6 7	22 (9.49)

The majority of the cutaneous ADRs (54.74%) were in the age group of 31 to 60 years. This findings were in consistent with studies that reported that the overall occurrence of ADRs in any system organ class were higher in this age group.[19,21] With regard to gender preponderance of occurrence of cutaneous ADRs, the available literature suggests that there is mixed response. The present study showed ADRs to be slightly higher prevalent in female (51.29%) and this association was also observed in other studies.[6,22,23]

Of the various cutaneous ADRs reported in this study, maculopapular rash (30.17%) was the commonest

followed by pruritus (13.36%), palmar plantar erythrodysesthesia (12.93%), acne (8.19%), urticaria (6.89%) and fixed drug eruption (5.6%). With the exception of palmar plantar erythrodysesthesia and acne, the occurrence of other cutaneous ADRs were in conformity with other studies.[10,22,24,25] The higher occurrence of palmar plantar erythrodysesthesias in the present study compared to other studies is due to cancer chemotherapy drugs used in medical oncology department of this institute. These variations observed among various studies could be due to different patterns of drug usage as per the scope and services of the respective hospitals. In addition, the role of difference in ethnicity among different parts of the country should also be considered for this variation in pattern of cutaneous ADRs.[26]

Antimicrobial agents were responsible for maximum number (29.74%) of cutaneous ADRs, followed by anticancer drugs (25.86%), NSAIDs (12.06%), hormones and related drugs (11.2%) and antiepileptic drugs (6.46%). With the exception of anticancer drugs, the occurrence of cutaneous ADRs with other group of drugs were similar to previous studies done by Manjhi and Sharma. [25,27] When cutaneous ADRs due to antimicrobials were analysed further, it was observed that fluoroquinolones, cephalosporins, penicillins and glycopeptide antibiotics were responsible for majority of cutaneous ADRs reported and this findings were consistent with the study done by Jung et al.[28]

Most cases of maculopapular rash in the present study was caused by antimicrobial drugs (25.71%), followed by NSAIDs (14.28%), anticancer drugs (11.42%) and antiepileptics (10%). Our study differ from others, where antiepileptic drugs were responsible for more than 50% cases of maculopapular eruptions.[10,24,29] Pruritus was reported in 13.36% of the cases in the present study and this was observed to be in consistent with the study done by Raksha and Marfatia that reported pruritus in 12.5% of their cases.[30] Antimicrobial agents were the most common cause for pruritus in this study constituting about 9.48% of the reported cases. A study on skin reactions to antibacterial agents in general practice done by van der Linden et al reported pruritus to be responsible for 13.3% of the reported cases.[31]

There were 19 reports (8.19%) of acne in the present study, among which 13 reports (5.6%) were due to corticosteroids and 4 reports (1.72%) were due to anticancer drugs. Corticosteroids, neuropsychotherapeutic drugs, antitubercular drugs, and immune-modulators molecules are the most common drugs associated with drug induced acne.[32] Presently, the list of drugs that causes acne is increasing with the newer drugs, especially chemotherapeutic agents that are being added every year.[33]

Urticaria was observed in 6.89% and FDE in 5.6% of the reported cases in the present study. As observed for maculopapular rash, antimicrobial agents were the commonest cause for both urticaria and FDE followed by NSAIDs. A systematic review done by Patel et al. reported that frequency of urticaria in various studies was in the range of 4.7% to 48.1% and that of FDE in the range of 3.77% to 15.34%.[8]

In the present study, among the six reports of Stevens-Johnson Syndrome, azithromycin, sulfasalazine, piperacillin and tazobactam, carbamazepine was responsible for one each and two reports were due to phenytoin. Ceftriaxone and combination of aceclofenac, paracetamol and serratiopeptidase were responsible for each reported case of toxic epidermal necrolysis. There is much variability in reporting of SJS and TEN across various studies. Studies done in Malaysia reported higher rates of SJS and TEN compared to Indian studies.[9,34] This difference could be due to variation in patterns of drug usage and ethnic characteristics. Other more severe form of cutaneous ADRs in the present study was DRESS syndrome. There were two reports (0.86%) of DRESS in the present study caused one each by phenytoin and norfloxacin. The reported frequency of DRESS was higher in few studies compared to the present study.[35,36]

Mild and moderately severe cases in the present study were 40.94% and 49.57% cases. They were managed by withdrawal of suspected medication and supportive treatment. 9.49% (22 cases) were severe cases that required immediate stopping of the suspect medication, hospitalization/prolonged hospitalization and intensive medical care. Variability observed in the severity of the reported cases across various studies could be due to difference in the clinical settings and the difference in speciality healthcare services provided by different hospitals.[25,37,38] It was observed that 8.62% of the reported cutaneous ADRs were probable preventable and the remaining 91.38% were not preventable and this is in accordance with a previous study.[37]

As this is a retrospective analytical study, we could analyse the reactions and suspected medications as notified in the reporting form. Information on all the concomitant medications used by patients for other conditions is lacking in few reports. The study design also limits us from getting more details like time taken for recovery from adverse reactions, information on all the drugs used to treat the reported adverse reactions. Few reports lacked relevant laboratory data related to the reported cutaneous ADRs. A study designed in a prospective way will overcome such limitations.

CONCLUSION

Cutaneous ADRs are the most frequently reported adverse reactions to drugs. Analysis of these reports reveals that antimicrobial agents were the most common cause followed by anticancer drugs, NSAIDs, hormones and related drugs, and antiepileptic drugs. Early identification of the suspected medication causing ADRs will help in effective management of patient and reduction in cost of treatment. The difference in the occurrence of the reported

cutaneous ADRs and their pattern across various studies is due to different clinical settings and the scope of healthcare services provided by the respective institute. In addition, with new drugs coming into market every year and the change in prescribing patterns, there is also change in the trends of reported ADRs. Hence, there is need for continuous monitoring of ADRs.

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