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ORIGINAL RESEARCH

Spectrum of cutaneous adverse drug reactions reported at a tertiary health care center

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ABSTRACT

Background: Adverse drug reactions are important cause of morbidity ,hospitalization and increased expenditure .It has been observed in several studies that cases of adverse drug reactions in general population can range from 5 to 35 % in outpatient settings.(1) In developing countries like india adverse drug reactions are underreported. Cutaneous adverse drug reactions are one of the important adverse drug reactions which are underreported. Antimicrobials. anti-epileptic, anti-gout and anti-inflammatory are some of the commonest drugs implicated in causing cutaneous adverse drug reactions.(5)Since many new drugs are being approved thesedays, there is a need of constantly monitoring the cutaneous adverse drug reactions This study is basically a retrospective study to analyse spontaneously reported ADR's and the drug causing them at a tertiary health care center. **Methods:** This was a retrospective study done on spontaneously reported cutaneous adverse drug reactions reported by various department at shri shankaracharya hospital to adverse drug reaction monitoring centre at Shri Shankaracharya institute of medical sciences and hospital Bhilai, Chattisgarh, India between January 2023 to March 2024.Various information like age, name initials, weight, suspected medications, route of drug administration, indication and description of event were recorded from the suspected adverse drug reaction form. Various data obtained from ADR form included were age, weight, sex, description of the adverse event(with date of onset of reaction, date of drug administration),suspected medications (with date of administration, frequency of dosing, route of drug administration, indication) ,age at onset and concomitant drug administration were noted.Causality of the reactions were assessed using WHO-UMC (world health organization-uppasala monitoring centre) causality assessment scale. **Results:** All the 108 cutaneous adverse drug reactions analysed during the study, Maculopapular rash was the most frequent cutaneous adverse drug reaction reported adr followed by pruritus,acne urticaria, fixed drug eruption and other cutaneous adverse drug reactions. majority of the reported Adrs were due to Antimicrobial agents (60.18 % of all cases) followed by non steroidal anti-inflammatory drugs (22.22% of all cases) and Hormones and related drugs (7.40% of all cases) drugs. **Conclusions:** In the current study author found that Maculopapular rash was the most common cutaneous adverse drug reaction and antimicrobials agents were the most common drugs associated with cutaneous adverse drug reactions followed by Non steroidal anti-inflammatory drugs.

Keywords: Cutaneous adverse drug reactions, Maculo papular rash, Anti-microbials

INTRODUCTION

Adverse drug reactions are important cause of morbidity ,hospitalization and increased expenditure .It has been observed in several studies that cases of adverse drug reactions in general population can range from 5 to 35 % in outpatient settings.(1) In developing countries like india adverse drug reactions are underreported. Cutaneous adverse drug reactions are one of the important adverse drug reactions which are underreported. Cutaneous adverse drug reactions are any non desirable alteration in skin integrity, structure and function of the skin or its mucous membrane or its appendages comprising of drugs causing it.(2) Cutaneous adverse drug reactions are known by the name toxidermia (skin manifestations arising from different drug administration)(3) Cutaneous adverse drug reactions can have wide morphological and clinical presentations ranging from maculopapular rash to severe epidermal necrolysis involving multiple organs.(4) Common cutaneous ADR's oftenly reported in opd are skin rash, angioedema, fixed drug eruption, contact dermatitis etc. Serious cutaneous

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adverse drug reactions like stevens johnsons syndrome and toxic epidermal necrolysis if recognized and reported early helps in proper management. Antimicrobials. anti-epileptic, anti-gout and anti-inflammatory are some of the commonest drugs implicated in causing cutaneous adverse drug reactions.(5)Since many new drugs are being approved thesedays, there is a need of constantly monitoring the cutaneous adverse drug reactions This study is basically a retrospective study to analyse spontaneously reported ADR's and the drug causing them at a tertiary health care center.

MATERIALS AND METHODS

This was a retrospective study done on spontaneously reported cutaneous adverse drug reactions reported by various department at shri shankaracharya hospital to adverse drug reaction monitoring centre at Shri Shankaracharya institute of medical sciences and hospital Bhilai, Chattisgarh, India between January 2023 to March 2024.Various information like age, name initials, weight, suspected medications, route of drug administration, indication and description of event were recorded from the suspected adverse drug reaction form. Causality assessment of the various cutaneous adverse drug reactions were done using WHO-UMC (World health organization-Uppasala monitoring centre). Various data obtained from ADR form included were age, weight, sex, description of the adverse event(with date of onset of reaction, date of drug administration),suspected medications (with date of administration, frequency of dosing, route of drug administration, indication) ,age at onset and concomitant drug administration were noted.Incompletely filled forms were not included in the study.Causality of the reactions were assessed using WHO-UMC (world health organization-uppasala monitoring centre) causality assessment scale.

RESULTS

Out of all 108 cutaneous adverse drug reactions analysed majority of the adrs were reported in the age group of 30-50 years i.e 65 patients (60.18%) followed by 51-70 years i.e 33 patients (30.55%) followed by 0-15 years i.e 5 patients (4.62%) and 16-29 years i.e 5 patients (4.62%).In the current study 57 patients were females (52.77%) and 51 patients were males (47.23%) Fig no.1

Of all the 108 cutaneous adverse drug reactions analysed during the study, Maculopapular rash was the most frequent cutaneous adverse drug reaction reported adr followed by pruritus,acne urticaria, fixed drug eruption and other cutaneous adverse drug reactions. There were few serious cases of Stevens Johnson syndrome and angioedema as well. Spectrum of various cutaneous adverse reaction repoteds are given in Table no 1. Causality assessment of the cutaneous adverse drug reactions revealed that out of the all adverse reactions reported that around 85% of them were probable as depicted in Table no 2.

Analysis of all cutaneous adverse drug reactions revealed that majority of the reported Adrs were due to Antimicrobial agents (60.18 % of all cases) followed by non steroidal anti-inflammatory drugs (22.22% of all cases) and Hormones and related drugs (7.40% of all cases)drugs ,other group of drugs were responsible for rest of the adverse drug reactions as depicted in table no 3.

Figure: No 1. Age wise and sex wise distribution of cutaneous adverse drug reactions

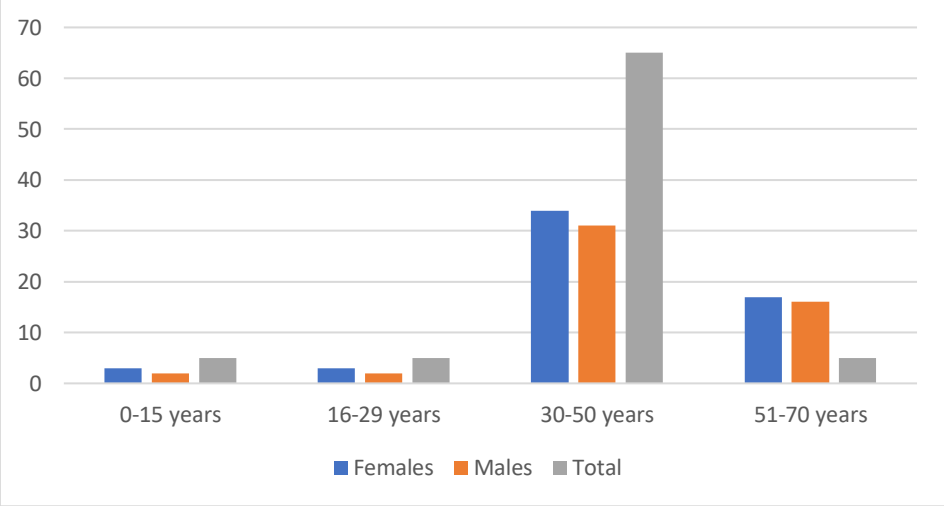

Table: no 1. Spectrum of various cutaneous adverse drug reactions (total no-108)

Spectrum of various cutaneous adverse drug reactions	Total number of various cutaneous adverse drug reactions (Total number & percentage)
Maculopapular rash	30 (27.77%)
Pruritus	25 (23.14%)

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Fixed drug eruptions	25 (23.14%)
Acne	15 (13.88%)
Hyperpigmentation	04 (3.70%)
Dermatitis	04 (3.70%)
Tinea incognito	03 (2.77%)
Angioedema	01 (0.92%)
Steven Johnsons syndrome	01 (0.92%)

Table no 2. Causality assessment through WHO UMC scale

Causality	WHO-UMC Scale
Certain	3 (2.77%)
Probable	92(85.18%)
Possible	13(12.03%)

Table no 3. Suspected class of drugs causing various cutaneous adverse drug reactions

Suspected class of drugs	Total Number of total cutaneous adverse drug reactions reported
Antimicrobials	65 (60.18%)
Non steroidal anti-inflammatory drugs(NSAIDS)	24 (22.22%)
Hormones and related drugs	08 (7.40%)
Radio contrast agents	05 (4.62%)
Antiepileptic and sedative drugs	04 (3.70%)
Iron supplements	01 (0.92)
Herbal drugs	01 (0.92)

DISCUSSION

The current study is a retrospective study on spontaneously reported cutaneous adverse drug reactions at a tertiary health care center between January 2023 and March 2024. . In this study majority of the reported cutaneous adverse drug reactions were reported in the age group of 30-50 years which was similar to study done by Konda et al. (2) However in a study done by Gangaiah et al, the maximum number of adverse drug reactions were reported in the age group of 20-39 years (6),In this study the prevalence of cutaneous adr's in females (52.77%) was slightly greater than males which was also similar to study by Konda et al.(2) Similar preponderance of cutaneous adr in female population was also seen in study done by Chindhalore et al (7),however in a study done Modi et al more no of cutaneous adverse drug reactions were seen in male population. Amongst all the cutaneous adrs reported in the study maculopapular rash was the most common adr (27.77 %)reported followed by pruritus (23.14%) fixed drug erution (23.14%)and acne (13.88%)this was in line with study done by Konda et al and Wen yi Ding.(2,7,9) with some differences , like in study done by Konda et al there were many cases of palmar erythrodysesthesia(most of them were caused by antineoplastic drugs) however at our center antineoplastic treatment wasn't available which might suggest that there were zero reporting of palmar erythrodysesthesia as an adr .Systematic review done by Patel et al also suggested that maculopapular rash was the most common cutaneous adr reported.(5)However in a study done by ashifha et al pruritus was the most common cutaneous adrs reported.(10) In our study majority of the cutaneous adverse drug reaction were attributed to the antimicrobial group of drugs (60.18%) followed by Non steroidal anti inflammatory drugs (22.22%) hormones and related drugs (7.40%) and radiocontrast agents (4.62%),all the adrs caused by contrast agents in our studies were pruritus. Antimicrobial agents especially fluroquinolones, beta lactam antibiotics and sulfonamides and trimethoprim were responsible for most of the cutaneous adverse drug reactions like pruritus, fixed drug reaction, in a study by Konda et al antimicrobial agents were responsible for majority of the pruritus cases reported.(2)In a study by Linden et al ,antibacterial agents were responsible for 13.3% of pruritus cases reported in that study.(11)

Most of maculopapular eruptions in our study were caused by antimicrobial agents followed by NSAIDS and antiepileptic and sedative drugs, study by Konda et al was similar to our study.(2) However in few studies by Noel et al & Chatterjee et al antiepileptic agents were responsible for majority of maculopapular eruptions reported. (12,13)There were 15(13.88%) cases of acne reported in our current study ,most of the cases were attributed to corticosteroids followed by antitubercular drugs and antimicrobials (especially tetracyclines),Antipsychotic drugs, antitubercular drugs and corticosteroids are responsible for acneiform eruptions in majority of reported adverse drug reactions.(14) In our study three cases of tinea incognito were reported (2.77%) due to the use of topical corticosteroids combination with other antimicrobial agents. In a study by Macwana et al tinea incognito were reported due to use of topical steroid combination with antimicrobials.

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In this study one case of stevens Johnson syndrome due to herbal medicine consumption was reported. However in a study by Konda et al six cases of Stevens Johnson syndrome were reported which were attributed to antimicrobial agents and anticonvulsant agents.(2) The current study is a retrospective study ,we were able to identify adverse drug reactions and their suspected medications however the information pertaining to concomitant medications were missing in some adr reporting forms. Study design of the current study prevents us from obtaining information regarding time required for recovery from the adverse drug reaction. A prospective study would be able to obtain more information and will overcome such limitations

CONCLUSION

Amongst all the adverse drug reactions reported at a hospital, cutaneousadrs have a significant percentage, Antimicrobials were the most common group of drugs causing cutaneous adverse drug reactions followed by non steroidal anti inflammatory drugs followed by hormones and related drugs. Prescription patterns vary greatly between different hospitals and with the advent of new drugs it has become quite necessary for frequent studies on adverse drug reactions.

Conflict of interest -NIL

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