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ORIGINAL ARTICLE

Evaluation of cutaneous adverse drug reactions

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ABSTRACT:

Background: Cutaneous adverse drug reactions are adverse skin reactions caused by medications. The present study was conducted to assess cutaneous adverse drug reactions. **Materials & Methods:** 94 cases of suspected CADRs presented with the use of FDCs were recorded. The causality assessment was carried out using the WHO UMC scale. The severity of these CADRs was assessed by Hartwig scale. The ADRs were also analyzed by modified Schumock and Thornton Criteria. **Results:** Cutaneous adverse drug reactions found to be MPDR in 15%, FDE in 42%, SJS- TENS in 13%, erythroderma in 8% and rash in 22%. The difference was significant (P< 0.05).Cutaneous adverse drug reactions were due to prescribed by practitioners in 32% and self-medication in 68% cases. The difference was significant (P< 0.05). **Conclusion:** Most of the adverse drug reactions were due to self-medication. A sound knowledge of the adverse drugs reactions, a careful history taking and a cautious approach during the prescription of new drugs can prevent most of these adverse drug reactions.

Key words: Cutaneous adverse drug reactions, Fixed drug, Self- medications

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INTRODUCTION

Cutaneous adverse drug reactions (CADRs) are adverse skin reactions caused by medications. These reactions can range from mild, such as a rash, to severe, such as blistering and skin peeling. CADRs can occur shortly after starting a new medication or even after prolonged use of a drug.[1] They can result from various mechanisms, including hypersensitivity reactions, direct toxicity, or metabolic reactions. They are common and may cause 3% of all disability injuries during hospitalization. The spectrum ranges from fixed-drug eruption (FDE), transient maculopapular rash, to Steven Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN).[1] Fixed-dose combination (FDC) of two or more active drugs in a single dosage form is used frequently nowadays.[2] The 19th WHO essential medicine list incorporates 27 FDCs. Similarly, the National List of Essential Medicines of India 2015 had included 24 FDCs and the National Formulary of India 2011 contains 22 FDCs.[3]However, countless FDCs are now available in India and consumed by patients both on prescription and self-medication. There is a limited number of studies on risk of self-medication practice.[4] Several benefits have been linked to appropriate self-medication, i.e., increased access to medication and relief for the patient. However, potential risks of self-medication practice include infrequent but severe adverse reactions.The majority of CADRs are diagnosed clinically. Recognition of the offending drug enables early withdrawal and improved outcomes. Observational studies are tools to know the pattern of reactions and causative drugs.[5]The present study was conducted to assess cutaneous adverse drug reactions.

MATERIALS & METHODS

The present study comprised of 94cases of suspected CADRs presented with the use of FDCs. All agreed to participate in the study with written consent.

The causality assessment was carried out using the WHO UMC scale. The severity of these CADRs was assessed by Hartwig scale. The ADRs were also analyzed by modified Schumock and Thornton Criteria to evaluate the status of preventability, especially by applying the Criteria 1, i.e., history of similar drug reaction with the same suspected drug to find out definite preventability. Results thus obtained were tabulated and subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Cutaneous adverse drug reactions with fixed-dose combination

Cutaneous adverse drug reactions	Percentage	P value
MPDR	15%	0.05
FDE	42%	
SJS- TENS	13%	
Erythroderma	8%	
Rash	22%	

Table I, graph I shows that CADR found to be MPDR in 15%, FDE in 42%, SJS- TENS in 13%, erythrodermain 8%and rashin 22%. The difference was significant (P< 0.05).

Graph I Cutaneous adverse drug reactions with fixed-dose combination

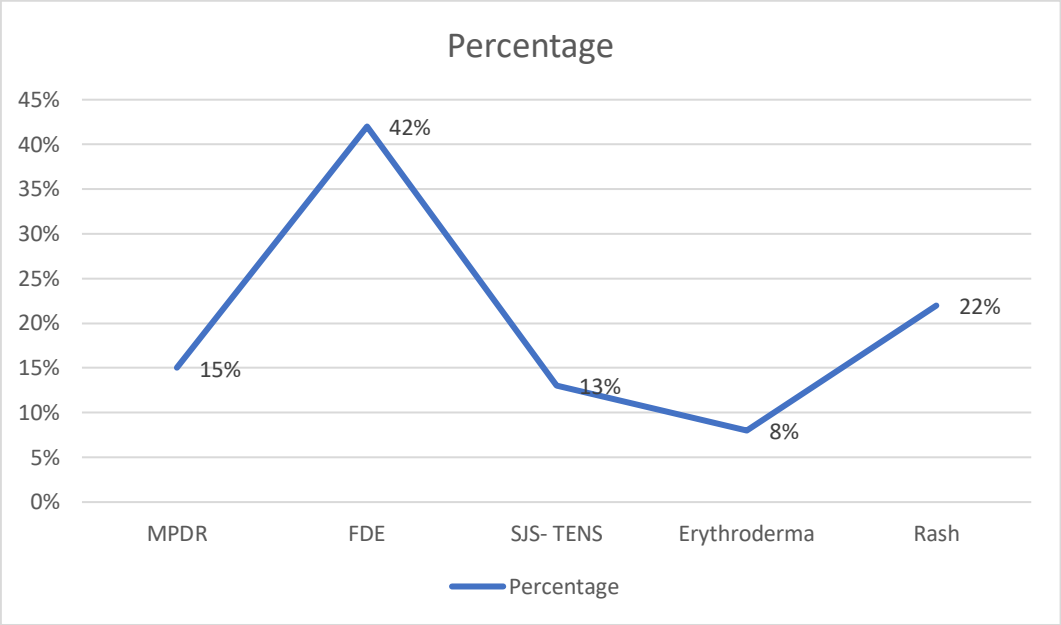

Table II CADR with prescribed or self- medication

Total	Prescribed	Self- medication	P value
CADRs	32%	68%	0.01

Table II shows that CADRs were due to prescribed by practitioners in 32% and self-medication in 68% cases. The difference was significant (P< 0.05).

DISCUSSION

Among ADRs, cutaneous adverse drug reactions (CADRs) are frequent. They take into consideration the pain, expense, and hospitalization of patients, and they can occasionally be lethal.[6,7] Skin rash, urticaria, angioedema, fixed drug eruption (FDE), and contact dermatitis are the most prevalent CADRs.Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) are the six serious CADRs that put patients' lives at jeopardy.[8] Antimicrobials, nonsteroidal anti-inflammatory drugs (NSAIDs), anti-epileptic medications, and anti-gout medications are among the commonly offending pharmaceuticals. The degree of healthcare and prescribing practices can affect the cutaneous reaction pattern and medicines that cause it.[9,10]The present study was conducted to assess cutaneous adverse drug reactions.

We found that cutaneous adverse drug reactions found to be MPDR in 15%, FDE in 42%, SJS- TENS in 13%, erythroderma in 8% and rash in 22%. Chattopadhyay et al[11] found that out of 2000 patients observed in each college 75 patients in dental College and 200 patients in Medical College were documented to have different kinds of cutaneous drug reactions. A total of 30 were male and 45 female in dental college whereas 90 male and 110 female patients were enrolled in Medical College. The age group of the patients in both colleges ranged from 18 to 75 years. Common culprits observed in this study were antibiotics and NSAIDs. They had contributed 53% and 40% of the total skin reactions respectively in dental college and 47.5% and 45% in Medical College. They encountered 6 patients of systemic lupus erythematosus (SLE), 20 patients with allergic rhinitis and 12 patients with bronchial asthma in the whole proceedings. The duration of drug intake varied from 15 minutes to 2 weeks. The most common reaction noted was maculopapular rash 37 (50.5%), urticaria 15 (20%), fixed drug eruption (FDR) 15 (20%), angioedema 6 (8%) in dental College whereas a little different trend was observed in the medical college. Hospitalization was required in two cases of Steven--Johnson syndrome caused by NSAIDS in the dental College whereas 11 patients were hospitalized for the same indication in the medical College. Except for maculopapular rash, all other skin reactions were observed more frequently with NSAIDS in dental College whereas Steven--Johnson syndrome is predominantly observed in Medical College with anticonvulsants. In all the cases causative drugs were withdrawn.

We observed that cutaneous adverse drug reactions were due to prescribed by practitioners in 32% and self-medication in 68% cases.Patel et al[12] found that commonly observed reactions were maculopapular rash (32.39%), fixed drug eruptions (FDEs) (20.13%), urticaria (17.49%) and Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) (6.84%). The major causative drug groups were antimicrobials (45.46%), nonsteroidal anti-inflammatory drugs (NSAIDs) (20.87%) and anti-

epileptic drugs (14.57%). Commonly implicated drugs were sulfa (13.32%), β-lactams (8.96%) and carbamazepine (6.65%). High frequency of CADRs is observed with anti-epileptic drugs in DPC studies only. Carbamazepine, phenytoin and fluoroquinolones had higher severe to nonsevere cutaneous reaction ratio than other drugs. Antimicrobials were the main causative drugs for maculopapular rash, FDEs and SJS/TEN, and NSAIDs for the urticaria. The mortality for overall CADRs, SJS/TEN, and exfoliative dermatitis were 1.71%, 16.39%, and 3.57%, respectively. "Definitely preventable", "probably preventable" and "not preventable" categories CADRs were 15.64%, 63.14%, and 34.64%, respectively.

Inbaraj et al[13] in their study one hundred eighty-one patients with suspected drug allergy were screened and 59 patients with Cutaneous Drug Reactions (CDRs) were recruited. The mean age of the patients with the cutaneous drug reactions was 30.5 years. Most of them were in the age group of 26-37 years, with 52.5% females and 47.5% males. The most common reactions observed were urticaria (32.2%), fixed drug eruptions (25.4%), acneform eruptions (13.6%), morbilliform eruptions (6.8%), maculopapular rashes (5.1%), and angio-oedema (3.4%). The most common drugs which caused the reactions were non- steroidal anti-inflammatory drugs (NSAIDs) (39.1%), Quinolones (22.1%), Amoxicillin (8.5%) and Corticosteroids (8.5%). Most of the reactions were mild to moderate in severity and all of them were preventable.

CONCLUSION

Authors found thatmost of the adverse drug reactions were due to self-medication. A sound knowledge of the adverse drugs reactions, a careful history taking and a cautious approach during the prescription of new drugs can prevent most of these adverse drug reactions.

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