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Original Research

Assessment of Cutaneous adverse drug reactions in health centre

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ABSTRACT:
Background: Cutaneous adverse drug reactions (CADRs) are common and may cause 3% of all disability injuries during hospitalization. The present study was conducted to assess the CADRs with various FDCs. **Materials & Methods:** 150 cases of suspected CADRs presented with the use of FDCs were included. The severity of these CADRs was assessed by Hartwig scale. **Results:** CADR found to be SJS- TENS in 15.5%, Erythroderma in 6%, MPDR in 12.5%, FDE in 45% and rash in 21%. The difference was significant (P< 0.05). CADRs were due to self medication in 65% and prescribed by practitioners in 35%. The difference was significant (P< 0.05). **Conclusion:** Most of the adverse drug reactions were due to self medications.
Key words: Self medications, Cutaneous adverse drug reactions, Fixed drug.

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INTRODUCTION

Cutaneous adverse drug reactions (CADRs) 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. As per the studies by Bangalore et al., FDCs decrease the risk of medications noncompliance and should be considered in patients with chronic conditions such as hypertension and diabetes.[2] However, FDCs are twice as riskier as a single drug having many disadvantages. 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 limited number of studies on risk of self-medication practice. 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.[4]

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. Most Indian studies are of limited duration and have small sample sizes.[5] The present study was conducted to assess the CADRs with various FDCs.

MATERIALS & METHODS

The present study was conducted among 150 cases of suspected CADRs presented with the use of FDCs. The detailed information of the patients were collected in the suspected ADR.

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 Different cutaneous adverse drug reactions with fixed-dose combination

CADR	Percentage	P value
SJS- TENS	15.5%	0.02
Erythroderma	6%	
MPDR	12.5%	
FDE	45%	
Rash	21%	

Table I shows that CADR found to be SJS- TENS in 15.5%, Erythroderma in 6%, MPDR in 12.5%, FDE in 45% and rash in 21%. The difference was significant (P< 0.05).

Graph I Different cutaneous adverse drug reactions with fixed-dose combination

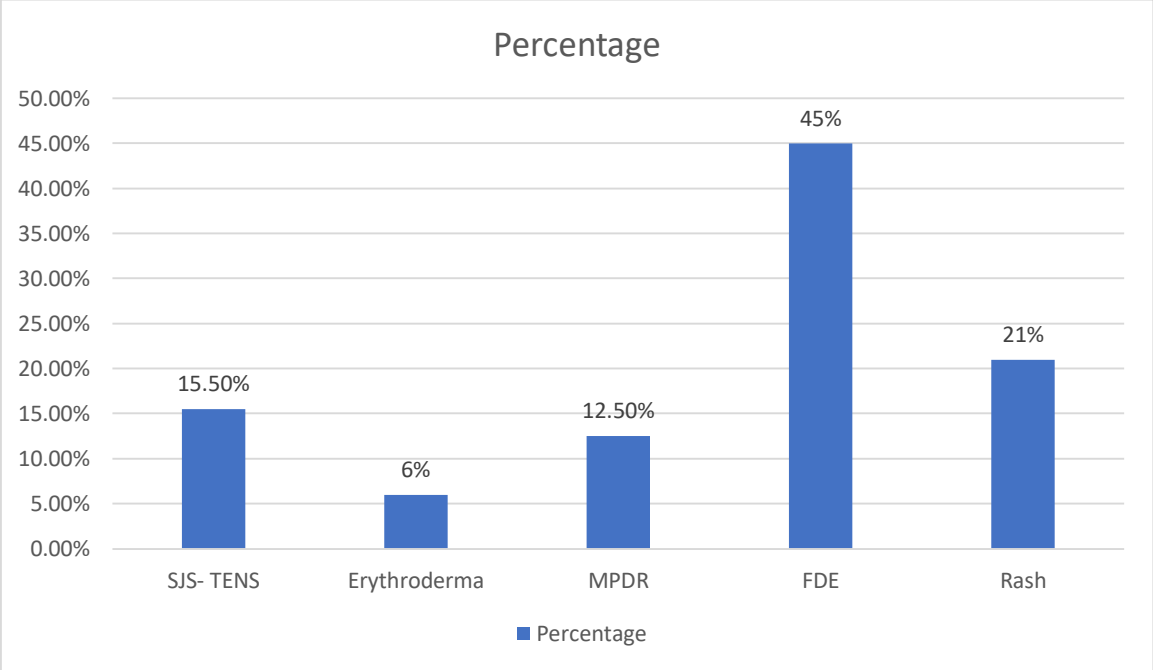

Table II CADR with prescribed or self- medication

Total	Prescribed	Self- medication	P value
CADRs	35%	65%	0.021

Table II shows that CADRs were due to self medication in 65% and prescribed by practitioners in 35%. The difference was significant (P< 0.05).

DISCUSSION

Cutaneous adverse drugs reactions (CADRs) are common among ADRs. They account for patients' suffering, hospitalization and economic burden, and may sometimes be fatal. The common CADRs are skin rash, urticaria, fixed drug eruption (FDE), angioedema, and contact dermatitis.[6] Serious CADRs endangering patient's life are Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP). The common offending drugs are antimicrobials, nonsteroidal anti-inflammatory drugs (NSAIDs), anti-epileptic drugs and anti-gout agents. The cutaneous reaction pattern and causative drugs may vary with prescribing habits and level of health care.[7] The present study was conducted to assess the CADRs with various FDCs.

In present study, CADR found to be SJS- TENS in 15.5%, Erythroderma in 6%, MPDR in 12.5%, FDE in 45% and rash in 21%. Patel et al[8] found that of 8337 retrieved references, 18 prospective studies were selected for analysis. The pooled incidence was 9.22/1000 total among outpatient and inpatient cases. 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%), non-steroidal 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.

Tripathy et al[9] included suspected CADRs with the use of FDCs. A total of 74 CADRs were detected; 68.91% were detected with antimicrobial and 31.09% with nonsteroidal anti-inflammatory drug-based FDCs. Fluoroquinolones + nitroimidazole was the most commonly suspected medications. Majority of CADRs (44.59%) were fixed-drug eruptions, which was significantly higher than others. Analysis of preventability showed that there was a significantly higher occurrence of definitely preventable CADRs in self-medication group (40%) in comparison to prescribed group (6.81%).

Radhika et al[10] have shown FDE as the most common CADR and antimicrobial-based FDCs as the highest numbers. Study has also focused on subgroup of antimicrobials and showed the clinical significance of fluoroquinolones + nitroimidazole FDCs as the highest suspected FDCs in CADRs. In contrast to study by Shah et al[11] on overall CADRs, they have shown co-trimoxazole as the most common FDC followed by fluoroquinolones among the antimicrobials, which was again the most commonly suspected drug in their study.

We found that CADRs were due to self medication in 65% and prescribed by practitioners in 35%. A systematic review of SJS/TEN in the Indian population reports fluoroquinolones and sulfa drugs as common causative antimicrobials. One out of nine fluoroquinolone-related CADRs are severe. Clinicians should be cautious about cross-reactivity among fluoroquinolones keeping in mind their high frequency of severe reactions. Slow acetylator phenotype or genotype predispose to sulfonamide-induced CADRs. Indian population has a high frequency of the slow acetylator genotype.[12]

CONCLUSION

It has been concluded that most of the adverse drug reactions were due to self medications.

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