

## Original Research Article

# The current trend of cutaneous drug reactions at a tertiary care hospital

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## ABSTRACT

**Background:** Cutaneous adverse drug reactions (CADR) are common yet important entity in dermatological clinical practice. This study is to investigate the clinical spectrum of CADR reactions and assess its causality relationship to offending drug.

**Methods:** It was a cross-sectional observational study, conducted at a tertiary care hospital over a period of two years. Total of 200 patients with cutaneous drug rash diagnosed based on detailed history, correlation between drug intake and the onset of rash, thorough clinical examination and laboratory parameters were included and patients without details of drugs were excluded.

**Results:** Among 200 cases, mean age was 33.57 years (6 months to 87 years). The commonest age group was 19-30 years (27%) and Male: female ratio was 0.94:1. The most common morphological pattern was maculopapular rash seen in 46 cases (23%), followed by FDE- 34 (17%), urticaria- 22 (11%), acneiform eruptions- 20 (10%), drug induced hyperpigmentation- 13 (6.5%), EMF- 12 (6%), lichenoid eruptions- 12 (6%), photosensitivity- 11 (5.5%), eczematous dermatitis- 6 (3%), pruritus- 6 (3%), angioedema- 6 (3%) and SJS- 6 (3%), DRESS- 2 (1%), TEN- 2 (1%), DHS and psoriasiform dermatitis in 1 each (0.5%) respectively. The most common drug was analgesics (31.2%), followed by anti-microbials (26.25%), corticosteroids (8.75%), antiepileptics (7.5%), anti-leprosy drugs (7.5%), anti-retroviral drugs (6.87%), antitubercular drugs (3.75%) and other drugs (8.12%).

**Conclusions:** Many dermatological conditions can be induced, imitated or aggravated by drugs hence it is necessary for the health care system to promote periodic reporting to regional pharmacovigilance centres to ensure drug safety for clinician's awareness.

**Keywords:** Cutaneous adverse drug reaction, Pharmacovigilance, Morphological pattern, Drug

## INTRODUCTION

An adverse drug reaction (ADR) is defined as an undesirable clinical manifestation resulting from administration of a particular drug, this includes reactions to over dose, predictable side effects and unanticipated adverse manifestations. The incidence of ADRs varies from 6% to 30% and 3 to 8% of hospital admissions are a

due to of ADRs.<sup>1</sup> ADRs may be said to be the impending price for modern drug treatment which can ruin the doctor-patient relationship.<sup>1</sup>

Drug reaction range from simple rashes to life-threatening drug-induced diseases. The spectrum of drug reaction includes conditions those are confined only to skin such as exanthematous, urticarial, pustular and

bullous eruptions and disorders causing severe systemic reaction including drug hypersensitivity syndrome or toxic epidermal necrolysis.<sup>2</sup> Adverse cutaneous drug reactions form an important clinical entity which is often described as a great imitator in the current dermatology practice. Though CADR are common, a comprehensive information about their incidence, severity and deteriorating health effects are unavailable.<sup>3</sup> This study is intended to assess the recent trends of incidence, clinical pattern of offending drugs, and risk factors associated with the drugs.

**Objective of the study**

- To investigate the pattern of cutaneous adverse drug reactions for drugs.
- To assess the causality relationship of drug.

**METHODS**

A cross-sectional observational study, conducted in the department of dermatology in a tertiary care hospital in Southern India during January 2016 and December 2018.

**Inclusion criteria**

Patients of cutaneous drug eruptions of all age groups and either sex were included.

**Exclusion criteria**

Patients with drug reactions not having details of drug taken were excluded. A total of 200 cases of cutaneous drug reactions were involved. History regarding demography, drug history, reaction time, previous drug allergy, duration, clinical pattern were noted. Prior written consent was taken before enrolment from all the cases.

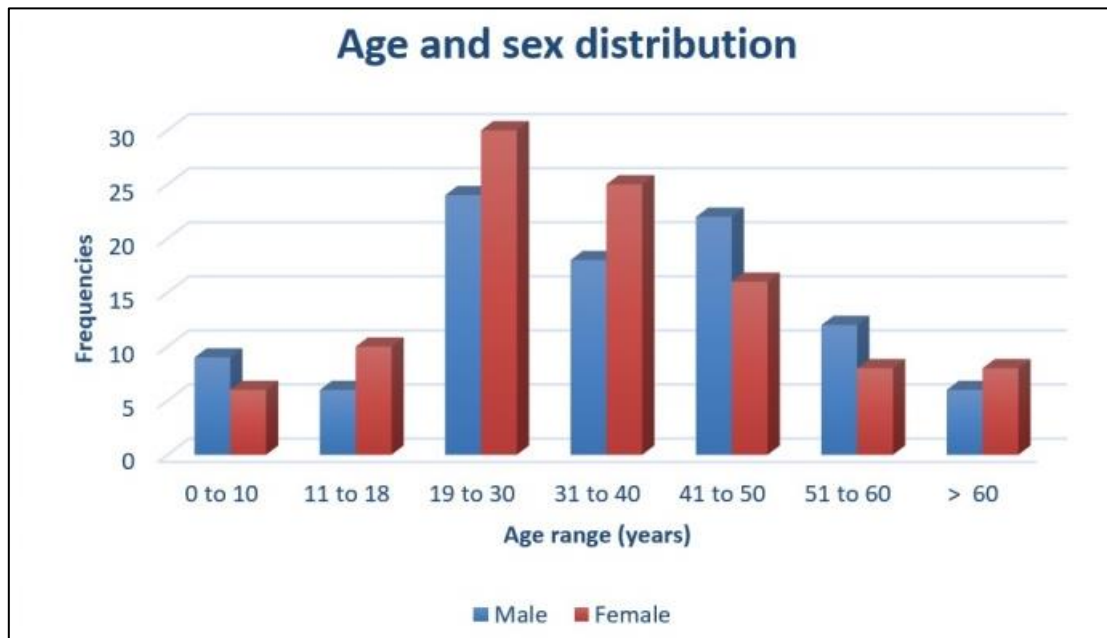
A detailed cutaneous examination and mucosal examination was done. Mean, Standard, deviation and Proportion was calculated using SPSS software version 20.

**Investigations**

Complete blood count, absolute eosinophil count, serum electrolytes, random blood sugar, liver function tests, renal function tests, VDRL and ELISA for HIV were done. Drug rechallenge test was done in selected cases.

**RESULTS**

Out of the 200 cases with cutaneous adverse drug reactions, 97 were male and 103 were female with Male to female ratio of 0.94:1, the age group ranged from 6 months to 87 years with a mean age of 33.57 years. The most common age group was 19-30 years (27%) and least common age group was >60 years (7%) (Figure 1).



**Figure 1: Age and sex distribution.**

The most common CADR was maculopapular rash seen in 46 cases (23%), followed by FDE in 34 cases (17%), urticaria in 22 cases (11%), acneiform eruptions in 20 (10%), drug induced hyperpigmentation in 13 cases (6.5%), EMF in 12 cases (6%), lichenoid eruptions in 12

(6%), photosensitivity in 11 (5.5%), eczematous dermatitis in 6 (3%), pruritus in 6 (3%), angioedema in 6 (3%) and Stevens Johnson syndrome (SJS) in 6 (3%), Drug reaction, eosinophilia and systemic symptoms (DRESS) in 2 cases (1%), Toxic epidermal necrolysis

(TEN) in 2 (1%), Dapsone hypersensitivity syndrome and psoriasiform dermatitis in 1 each (0.5%) respectively (Table 1).

**Table 1: Clinical pattern of cutaneous drug reaction.**

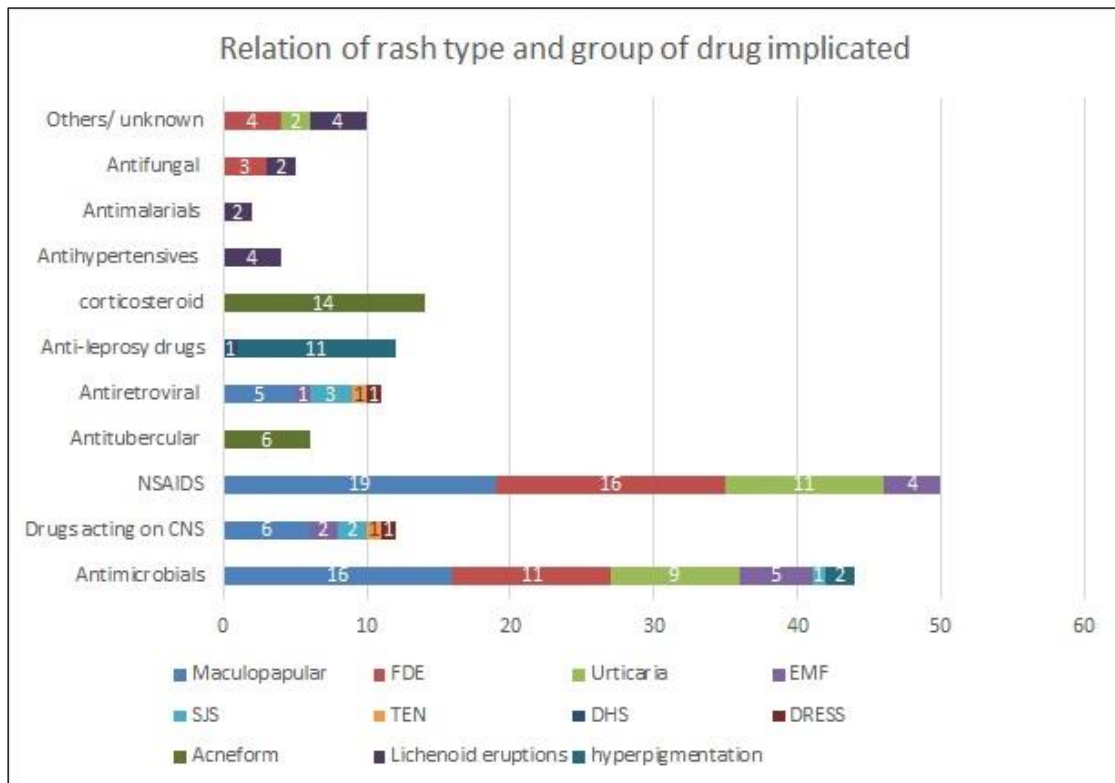
Clinical pattern	Present study	Percentage (%)
Maculopapular	46	23
Fixed drug eruptions	34	17
Urticaria	22	11
Acneiform eruptions	20	10
Steven Johnson syndrome	6	3
DRESS	2	1
Dapsone hypersensitivity syndrome	1	0.5
Erythema multiforme	12	6
Toxic epidermal necrolysis	2	1
Angioedema	6	3
Pruritus	6	3
Photosensitivity	11	5.5
Hyperpigmentation	13	6.5
Psoriasiform dermatitis	1	0.5
Lichenoid eruptions	12	6
Eczematous	6	3
Total	200	100

Among the paediatric age group, the most common type of rash was maculopapular rash in 6 cases followed by 4 cases of FDE, 4 cases of urticaria and 2 cases of SJS. The trend of occurrence of cutaneous adverse drug reaction was almost similar compared to adults.

In 200 cases of adverse drug reactions, 160 drugs were implicated in causing reactions. The most common group of drugs implicated were nonsteroidal anti-inflammatory drugs (NSAIDs) in 50/160 (31.2%), followed by antimicrobials 42/160 (26.25%), corticosteroids 14/160 (8.75%), drugs acting on CNS 12/160 (7.5%), anti-leprosy drugs 12/160 (7.5%), anti-retroviral drugs 11/160 (6.87%) antitubercular drugs 6/160 (3.75%) and other drugs 13/160 (8.12%) (Figure 2).

The most common drug causing maculopapular rashes (46, 23%) were NSAIDs (19 out of 46 - 41.3%) followed by anti-bacterial drugs (16 out of 46 - 34.7%) and antiepileptic drugs (6 out of 46- 13%).

Major drugs causing FDE (34, 17%) were NSAIDs (16 out of 34 - 47%), fluoroquinolones (6 out of 34 - 17.6%), Tetracyclines (5 out of 34 - 14.7%) and other miscellaneous drugs in 7 cases. The common site of FDE was trunk (18 cases) and limbs (12 cases). Lip involvement was noticed in all 4 cases of Diclofenac sodium induced FDE. FDE accounted for only 2% of all the drugs in children in contrast to adults.



**Figure 2: Morphology of rash and drug implicated.**

Out of 22 (11%) cases of urticaria, common drugs implicated were analgesics (11 out of 22), amoxicillin (5 out of 22) and cephalosporins (4 out of 22). Among 6 (3%) cases of angioedema, 5 (83.3%) were following intravenous injection of analgesics and one case following cephalosporin injection.

Among the cases of acneiform eruptions (20, 10%), most of them were caused by topical and systemic corticosteroids (14 out of 20) followed by antitubercular medications (6 out of 20). Among cases of drug induced hyperpigmentation (13, 6.5%) majority were secondary to clofazimine (11) followed by minocycline (2). Lichenoid eruptions (12, 6%) was seen commonly in individuals on antihypertensives (4 out of 12) followed by antimalarials (2 out of 12), antifungal (2 out of 12) and other medications (4 out of 12). Photosensitivity (11, 5.5%) was most commonly seen in individuals on oral and topical retinoids (6 out of 11), followed by antifungal (3 out of 11) and miscellaneous drug (2 out of 11). Cases with eczematous dermatitis - 6 (3%), pruritus in 6 (3%) and psoriasiform dermatitis 1(0.5%) were on multiple drugs.

Most common drugs causing EMF (12.6%) were fluoroquinolones (5 out of 12), analgesics (4 out of 12), antiepileptics (2 out of 12) and antiretroviral drugs in one case.

Severe drug reactions include SJS, TEN, DHS and DRESS seen in 11(6.5%) cases. Commonest was SJS was seen in 6 (3%) cases caused by antiretroviral drugs in 3 cases, antiepileptic drug in 2 and 1 case by ciprofloxacin. TEN was seen in 2 cases, one who was on carbamazepine and other on antiretroviral medication. Two cases DRESS were observed following carbamazepine and antiretroviral drugs respectively. Dapsone hypersensitivity syndrome following dapsone seen in one case.

Among HIV/AIDS patients on antiretroviral medications (11 cases), the most common rash was maculopapular (5 out of 11), followed by SJS (3 out of 11) and TEN, DRESS and EMF one each respectively and all of them recovered completely.

Among cases on antiepileptic drugs (12 cases), majority (6 out of 12) of them had maculopapular rash, 2 had EMF, rest of them (4 out of 12) had severe reactions- 2 had SJS, one each case had TEN and DRESS respectively. Most common implicated drugs were carbamazepine (7 out of 12) and phenytoin (5 out of 12)

Among 50 cases of drug reaction caused by analgesics, the most common drug observed was diclofenac sodium (in 28 out of 50) followed by nimesulide (10 out of 50), Aceclofenac (9 out of 50) and paracetamol (3 out of 50) (Table 2). Most common rash caused by analgesics was maculopapular rash in 19 (out of 46) cases followed by

FDE in 16 (out of 34) cases, urticaria in 4 (out of 22) cases and EMF in 3 (out of 12) cases.

**Table 2: Rash type and common drugs implicated.**

Rash type	Drug implicated	Total
<b>Maculopapular</b>	Antimicrobials	16
	Drugs acting on CNS	6
	NSAIDs/Analgesics/ Antipyretics	19
	Antiretroviral	5
	Total	46
<b>FDE</b>	Antimicrobials	11
	NSAIDs/Analgesics/ Antipyretics	16
	Others	7
	Total	34
<b>Urticaria</b>	Antimicrobials	9
	NSAIDs/Analgesics/ Antipyretics	11
	Others	2
	Total	22
<b>SJS</b>	Antimicrobials	1
	Drugs acting on CNS	2
	Antiretroviral	3
	Total	6
<b>TEN</b>	Antiretroviral	1
	Drugs acting on CNS	1
	Total	2
<b>Dapsone hypersensitivity syndrome</b>	Dapsone	1
<b>DRESS</b>	Antiretroviral	1
	Drugs acting on CNS	1
<b>Acneiform eruptions</b>	Steroids	16
	Antitubercular	4
	Total	20
<b>Lichenoid eruptions</b>	Antihypertensive	8
	Antimalarials	2
	Others	2
	Total	12
<b>EMF</b>	NSAIDs/Analgesics/ Antipyretics	4
	Antimicrobials	5
	Antiretroviral	1
	Drugs acting on CNS	2
	Total	12
<b>Drug induced hyperpigmentation</b>	Antileprosy (clofazimine)	11
	Minocycline	2
	Total	13

The mean incubation period for the onset of drug rash highest (23 days) for Drug hypersensitivity reaction, followed by SJS and TEN (7 days), maculopapular rash (4 days), urticaria (3 days) and lowest value for FDE (2.5 days) (Table 3).

**Table 3: Relation of rash type with incubation period.**

Rash	Total number of cases	Mean incubation period (days)	Range
Maculopapular	46	4	6 hours to 14 days
Fixed drug eruption	34	2.3	1 to 5 days
Urticaria	20	3	2 hours to 4 days
SJS	18	7	5 days to 2 weeks
TEN	08	7	5 days to 2 weeks
DHS	16	23	3 to 6 weeks

Out of the 200 patients with cutaneous adverse reaction 98 were on multiple drugs. Hence to confirm the offending drug oral re-challenge was done, but only 30 patients gave consent and causative drug was confirmed in only 20 patients.

According to WHO causality assessment algorithm, definite diagnosis was done in 28 cases (14%), possible in 56 cases (28%) and probable in 116 cases (58%).

## DISCUSSION

WHO defines an adverse drug reaction “as a response to a drug that is noxious and unintended and occurs at doses for the prophylaxis, diagnosis or therapy of disease or for modification of physiological function.”<sup>4</sup>

According to WHO-UMC causality assessment system, the causality assessment of suspected adverse drug reactions is classified as:

- **Certain:** A clinical event, including a laboratory test abnormality, that occurs in a plausible time relation to drug administration, and which cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the drug (dechallenge) should be clinically plausible. The event must be definitive pharmacologically or phenomenologically, using a satisfactory rechallenge procedure if necessary.
- **Probable/likely:** A clinical event, including a laboratory test abnormality, with a reasonable time relation to administration of the drug, unlikely to be attributed to concurrent disease or other drugs or chemicals, and which follows a clinically reasonable response on withdrawal (dechallenge). Rechallenge information is not required to fulfil this definition.
- **Possible:** A clinical event, including a laboratory test abnormality, with a reasonable time relation to administration of the drug, but which could also be

explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal may be lacking.

- **Unlikely:** A clinical event, including a laboratory test abnormality, with a reasonable time relation to administration of the drug, which makes a causal relation improbable, and in which other drugs, chemicals, or underlying disease provide plausible explanation.
- **Conditional/Unclassified:** A clinical event, including a laboratory test abnormality, reported as an adverse reaction, about which more data are essential for a proper assessment or the additional data are being examined
- **Unassessable/Unclassifiable:** A report suggesting an adverse reaction that cannot be judged, because information is insufficient or contradictory and cannot be supplemented or verified.<sup>5</sup>

A cutaneous adverse drug reaction should always be considered in three specific situations.

- No alternate explanation for the reaction.
- The time interval between introduction of the drug and onset of a reaction should be within a specific time described in the literature for. The reaction was not considered as drug induced if the drug was administered after the onset of cutaneous reaction.
- Improvements in the condition of the patient after dechallenge/ withdrawal of the suspected drug.<sup>6</sup>

The current classification of adverse drug reactions (Table 4) which is most accepted is: a) Non-immunological, b) Immunological (unpredictable) and c) miscellaneous.<sup>6</sup> Immunologic reactions require host immunological pathway, activation of host whereas non-immunologic mechanisms occur due to side effects, overdose, exacerbation of pre-existing conditions, etc.<sup>7</sup>. Almost 75-80% of adverse drug reactions are caused by predictable, non-immunologic effects, remaining 20-25% are caused by unpredictable effect suggesting that majority was predictable.<sup>8,9</sup>

Evaluation of CADR is important in confirming a diagnosis which would centre on two foci, either In vitro or In vivo. In vitro tests include absolute eosinophil count, Basophil degranulation test, Radio-allergosorbent test (RAST) for specific Ig E antibody, lymphocyte transformation test, haemagglutination test. In vivo tests include discontinuation of the drug and rechallenges. Rechallenge is done either by skin testing (patch test, prick test, photo patch test, and intradermal tests) or oral provocation, these provocation tests attempted only in mild to moderately severe drug rashes but not in severe drug reactions as they can precipitate life threatening reactions. Diagnosis of CADR by provocation or rechallenge lies in the fact that many drugs that are suspected to cause a particular cutaneous adverse reaction due to a temporal relationship may be required by the patient in future, and hence helps in confirming the causative agent.<sup>6</sup>

**Table 4: Immunological classification of cutaneous adverse drug reaction.**

<b>A. Non-immunological</b>	Predictable	Over dosage, Side effect, Cumulation, Delayed toxicity, Facultative effects, Drug interactions, Metabolic alterations, Teratogenicity
	Unpredictable	Idiosyncrasy and Intolerance
<b>B. Immunological (unpredictable)</b>	1. Type I:	IgE-dependent drug reactions (Example: Urticaria, Angioedema)
	2. Type II:	Cytotoxic drug-induced reactions (Example: Hemolytic anemia, purpura)
	3. Type III:	Immune complex-dependent drug reactions (Example: Vasculitis, Stevens-Johnson syndrome, TEN)
	4. Type IV:	Cell-mediated immune reaction-delayed type (Example: Morbilliform (exanthematous), Photoallergic reactions, Bullous eruptions, Lichenoid, Fixed Drug eruption is produced by an unknown mechanism of hypersensitivity)
<b>C. Miscellaneous</b>	1. Jarisch-Herxheimer reactions 2. Infectious mononucleosis-ampicillin reaction.	

**Table 5: Comparison of rash morphology between other studies.**

Clinical pattern	Present study	Padukadan et al <sup>10</sup>	Qayoom et al <sup>12</sup>	Sharma et al <sup>11</sup>	Malhotra et al <sup>13</sup>	Jatana et al <sup>15</sup>	Patel et al <sup>16</sup>	Chatterjee et al <sup>3</sup>	Chattopadhyay et al <sup>7</sup>
<b>Maculopapular</b>	23	12.2	17.3	13.3	29.63	28.64	18	25.43	50.5
<b>Fixed drug eruptions</b>	17	31.1	45.3	33.3	-	15.11	30.55	25.16	20
<b>Urticaria/angioedema</b>	11			7.3	9.26	18.13	18.5	25.19	20/8
<b>SJS/TEN</b>	13		5.33		22.22				
<b>Drug hypersensitivity syndrome</b>	8								
<b>Erythema multiforme</b>	6		6.66						

In the present study of the 200 cases, the commonest age group was 19 to 30 years, this was similar to other studies by Padukadan et al (20 to 39 years) and Sharma et al (21 to 30 years) the mean age of patients was 33.5 years and with female preponderance of male to female ratio (0.94:1), it was comparable to that of Padukadan et al (37.06 and 0.87:1) Sharma R et al (33.26 and 1.7:1.2) and Qayoom et al (39.36±16.77 and 0.97:1) respectively.<sup>10-12</sup> Most of the studies have shown slight female preponderance which may be attributed to gender related differences in pharmacokinetic, immunological and hormonal factors in women compared to men.

The most common morphological pattern seen was maculopapular rash seen in 46 cases (23%), followed by FDE in 34 cases (17%), urticaria in 22 cases (11%), acneiform eruptions in 20 (10%), Drug induced hyperpigmentation in 13 cases (6.5%), EMF in 12 cases (6%), SJS in 6 (3%), DRESS in 2 cases (1%), TEN in 2 (1%), DHS in 1 (0.5%). This was comparable with

Malhotra et al, who reported morbilliform rash in 29.63%, SJS/TEN in 22.22% and urticaria in 9.26% cases as the common morphological pattern and Jhaj et al who reported 50% cases of morbilliform rash, 21% cases of urticaria, 13.9% cases of SJS and 4.9% cases of TEN, and also in study by Jatana et al exanthem was most common drug eruption (28.63%) followed by acute urticaria (18.13%).<sup>13-15</sup> In contrast to other studies of Padukadan et al, Sharma R et al and other studies where FDE was the commonest type.<sup>10-12,16</sup> This majority of the analgesics and anti-bacterial agents prescribed in our study caused maculopapular rash (Table 5).

In the present study the most common group of drugs implicated were analgesics 31.2%, followed by antimicrobials 26.25%, which was similar to Patel RM et al study where NSAIDs were commonest followed by sulfa drugs.<sup>16</sup> These results were in contrast to other studies by Sharma et al, Qayoom et al and Jatana et al where antimicrobial agents were most common in 40%, 57.33%

and 37.2% respectively.<sup>11,12,15</sup> This may be due to different prescription pattern by physicians or self-medication in various setting for pain and fever.

NSAIDs (16, 47%), fluoroquinolones (6, 17.6%), Tetracyclines (5, 14.7%) were major drugs causing FDE in our study. Jatana et al showed similar results with most common drug causing FDE was NSAIDs in 44.76% patients, followed by antimicrobials in 25.70%, and antifungals in 4.76% cases, but studies by Patel et al, Singh et al and Shrivastava et al found cotrimoxazole as common cause, quinolones were commonest in Qayoom et al, tinidazole and metronidazole in Sharma et al and Acharya et al studies respectively.

The most common drug causing maculopapular rashes were analgesics (19, 41.3%), followed by anti-bacterial drugs (16, 34.7%) this was in contrast to studies by Sharma et al and Ghosh et al where amoxicillin is commonest.<sup>11,12,15-17,19,20</sup>

Anti-retroviral drugs and anti-convulsants are the common drugs causing severe drug reactions (11, 6.5%) as SJS, TEN and DHS, amongst which SJS (6, 3%) was the commonest and these results were comparable to studies by Chatterjee et al and Chattopadhyay et al.<sup>3,7</sup>

The definite diagnosis was done in 28 cases (14%), possible in 56 cases (28%) and probable in 116 cases (58%) almost similar to study done by Puavilai et al and was in contrast to Thong et al study but the drawback of this assessment is the possibility of personal bias can be present because of disagreement in the causality assessment.<sup>21,22</sup>

Limitations of our study were the definite association of drug reaction was not done in all patients as consent was not given in few cases and it was not done in severe drug reactions.

## CONCLUSION

Adverse drug reactions are a definite challenge for the treating physician, practising proper guideline of specific drug for rational use is very much necessary. The pattern of drug reaction is changing every year mainly due to emergence of resistance for existing drug changing prescription pattern due to physician and patient preference or due to emergence of new drugs in the market. One should be vigilant of adverse events concerned with particular prescribed drugs which emphasises adequate knowledge regarding the pharmacokinetics and regional immunological pattern for the prescribed drug. This could be achieved by health care professional by responsible reporting of drug reactions, documentation and regular reporting to pharmacovigilance centres. Clinical decision support systems and its data base can provide recent trends in adverse drug reaction and serves as source of information. Cutaneous drug reaction is the great imitator

in the current dermatological practice hence adequate knowledge of clinical presentation and timely intervention is required in saving lives in severe CADRs.

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