Section: DVL

Original Research Article

A CLINICAL STUDY OF ADVERSE CUTANEOUS DRUG REACTIONS

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ABSTRACT

Background: To study patients with different types of clinical patterns of adverse cutaneous drug reactions.

Materials and Methods: This study population included all patients (both out-patient and in-patient) suffering from adverse cutaneous drug reactions of both sexes and all ages who attended to Bhaskar General Hospital. The study was conducted over a period of one and a half year (January 2016 to July 2017) in the Department of DVL, Bhaskar General Hospital.

Results: In this study a total of 50 adverse cutaneous drug reaction (ACDR) cases of which 66% (33) were male and 34% (17) were female were evaluated. Sex ratio of male to female is 1.94:1. The age group with most patients belonged to 41-50 years and the range was 1 year-70 years. The patients who did not avail prescription from a doctor or dentist accounted to 38%. Doctor or dentist prescription was seen in 62% cases. Most of them were on combination or multiple drugs. 22% cases were using unknown medications. The most common route of administration was oral (92%). The most common period of onset of symptoms after drug intake was 1-10 days. Most common type of ACDR was exanthematous type accounting to 20% of cases and the most common suspected drugs were antimicrobials (23 cases). Assessment using Naranjo scale and WHO-UMC causality scale showed ―possible‖ as the major group with cases. All the cases were observed in the recovered or improved categories of outcome. No deaths were noted in the study.

Conclusion: The present study concluded that, different causality scales like Naranjo scale and WHO-UMC causality scale were used to assess the cases, and most patients were in the ―possible‖ criteria. Reporting of ACDRs to the pharmacovigilance cell is important for data collection and analysis. With increase in advent of new therapies (like biologics) long term studies regarding the drug reactions is necessary to prevent and manage drug reactions.

Keywords: ACDR, Naranjo Scale, UMC, exanthematous type, antimicrobials.

INTRODUCTION

An adverse drug reaction (ADR) may be defined as ‗an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product'.[1]

The incidence of adverse drug reactions ranges from 1-3% in developed countries and in developing countries such as India, it ranges from 2-5%. About 3-8% of hospital admissions are a consequence of adverse drug reactions. The rate of adverse drug reactions increases disproportionately with increase in the number of drugs. Maximum number of cases are seen in the age group30-40yrs with slight female predominance (M:F = 0.87:1).[2]

The wide spectrum of adverse cutaneous drug reactions ranges from self-limiting conditions like exanthema (maculopapular rash) to life threatening conditions like toxic epidermal necrolysis (TEN). Other common clinical patterns are fixed drug eruption, urticaria, exfoliative dermatitis, drug rash with eosinophilia and systemic symptoms (DRESS)

syndrome, acute generalized exanthematous pustulosis (AGEP), erythema multiforme and Stevens-Johnson syndrome (SJS). These are commonly caused by non-steroidal anti-inflammatory drugs (NSAIDS), antimicrobials, antihypertensives and anticonvulsants. But any drug can produce any kind of adverse drug reaction.[2]

This wide spectrum of clinical pattern which mimics various dermatological conditions causes difficulty in diagnosis and management. This leads to a significant impact on doctor – patient relationship. To address these challenges in patients one should be aware of the drugs and clinical pattern of drug reactions.

In practice, it is most challenging to identify the drug or drugs causing the adverse cutaneous reaction. Hence diagnosis in most of the cases is based on strong clinical suspicion and the doctor‘s judgement. With the increasing trend of using and misusing of multiple drugs like antimicrobials, NSAIDS, etc. which are easily available to the patients, there is an increased probability of having an adverse drug reaction. This is making it furthermore difficult for the doctor to diagnose.

Although cutaneous adverse drug reactions (CADR) are common, their mechanism is poorly understood. Reporting of cases with cutaneous adverse drug reactions to the pharmacovigilance is not feasible to many clinical practioners due to the lack of information regarding pharmacovigilance unit in their respective places.

Aim and Objectives of Study

Aim

1. To study patients with different types of clinical patterns of adverse cutaneous drug reactions

Objectives

1. To study the clinical features of dermatoses in adverse cutaneous drug reactions.
2. To study the clinical patterns of adverse cutaneous drug reactions
3. To assess the adverse cutaneous drug reaction with different scales.

MATERIAL AND METHODS

This study population included all patients (both out-patient and in-patient) suffering from adverse cutaneous drug reactions of both sexes and all ages who attended to Bhaskar General Hospital.

The study was conducted over a period of one and a half year (January 2016 to July 2017) in the Department of DVL, Bhaskar General Hospital.

Inclusion Criteria

1. Patients of both sexes and all ages with adverse cutaneous drug reactions.

Exclusion Criteria

1. All those patients who are not willing to participate in the study.

Methodology

A structured proforma was filled and recorded after taking an informed consent. Patients were evaluated clinically based on history and thorough clinical examination (general and cutaneous).

A detailed drug history was taken which included

- name of drug (generic/trade name)
- prescribed by whom
- total number of drugs
- day of starting administration of drug/s
- duration
- dosage
- route of administration
- onset of symptoms after drug intake
- previous adverse drug reaction [ADR] (if any).

Routine investigations were also done as a part of management. Special investigations (like skin biopsy) were done in selected patients. Using Naranjo Scale and World Health Organisation-Uppsala Mo Diagnosis was made based on clinical findings, drug history, improvement after discontinuation of offending agent (dechallenge) and supportive findings from investigations

nitoring Centre (WHO-UMC) causality scale, assessment was done.

Statistical Analysis

This was a hospital based descriptive study (prospective observational study).

RESULTS

In this study, a total of 50 adverse cutaneous drug reaction (ACDR) cases have been evaluated.

Among the study sample 66% (33) were male and 34% (17) were female. Sex ratio of male to female is 1.94:1.

The commonest age group was 41-50 years (28%) followed by 21-30 years (24%). The age group range varied from as young as 1year to as old as 70 years. [Table 1]

In this study, the patients who had a previous episode of adverse cutaneous drug reaction was seen in 8 cases (16%) while others (84%) experienced their first episode. [Table 2]

Patients who didn‘t avail prescription from a doctor or dentist accounted to 38% (19 cases), of which 14% (7 cases) were self-prescribed and 24% (12 cases) took medication prescribed by non-doctors (unqualified practioners). [Table 3]

The earliest onset of symptoms after drug intake was within 1 day (<1day). The longest time period for onset of symptoms after drug intake was 30 days. But most of the reactions (54%) occurred between 1 to 10 days after drug intake. [Table 4]

Most of the patients with ACDR were due to multiple or combination drugs accounting to 48% (24) of cases. In 22% (11) of cases the number of causative agents was not known. Only 30% (15) cases were due to single suspected drug. [Table 5]

In this study ACDR mostly occurred after oral administration of the drug or drugs accounting to 92% (46) of cases. Only 3 cases (6%) received

drugs through injectables (systemic) and only 1 case (2%) had both. [Table 6]

The most common clinical pattern or type of reaction was exanthematous type (20%) followed by urticaria & angioedema (18%) and fixed drug eruption (16%). Severe cutaneous adverse reactions (SCARs) like erythema multiforme, erythroderma, AGEP, SJS/TEN and DRESS syndrome occurred in 3(6%), 2(4%) ,5(10%) ,3(6%) and 1(2%) cases respectively. [Table 7]

Antimicrobials were the commonest offending agents of ACDR in this study accounting to 23 cases. Second most common drugs implicated were NSAIDS accounting to 17 cases. Antipsychotics were used in 3 cases. Other drugs were used in 6 cases and in 11 cases the drugs causing ACDR were unknown. Some patients had used both antimicrobials as well as NSAIDS together. [Table 8]

The commonest reason for taking drugs was fever (36% of cases). Other reasons for taking medications were pain, diarrhea, burning micturition, headache, vomiting and other conditions.

Patients with past history of medical conditions or disease like HIV infection (4), diabetes (2), hypertension (2), epilepsy (3), atopy (1), psoriasis (1) and Hansen‘s disease (2) were seen in 15 cases.

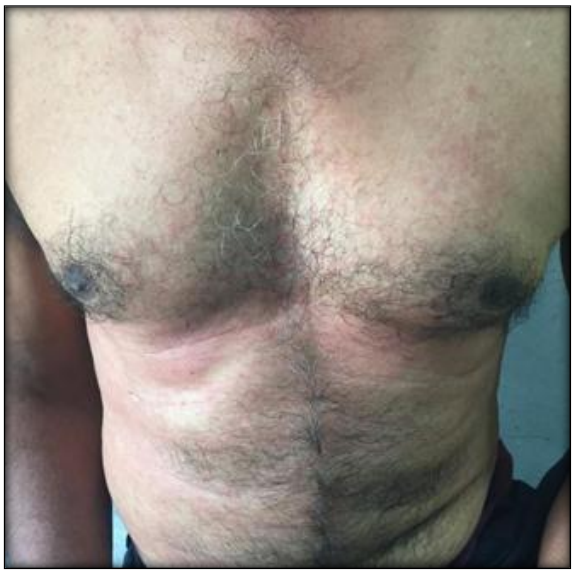
Assessment using Naranjo scale included most patients in the possible group accounting to 78% (39) of cases. 22% (11) cases were in the probable category. No cases were seen in definite and doubtful groups. [Table 9]

Assessment using World Health Organisation-Uppsala Monitoring Centre (WHO- UMC) causality scale 58% (29) cases were included in the possible category and 42% (21) in probable/likely category. No cases were seen in certain, unlikely, conditional/unclassified and unassessable/unclassifiable categories. (Rechallenge was not performed in any case due to high risk of severe adverse drug reaction). [Table 10]

Most of the patients were managed on out-patient basis. Severe reactions were advised admission.

Follow up of cases was done based on severity of the condition. The usual follow up period was for 2 weeks and in severe cases weekly follow up for 2-4 weeks was done.

The outcome of management was categorized into recovered / improved / death. All the cases were observed in the recovered or improved categories. No deaths were noted in the study. [Table 11]



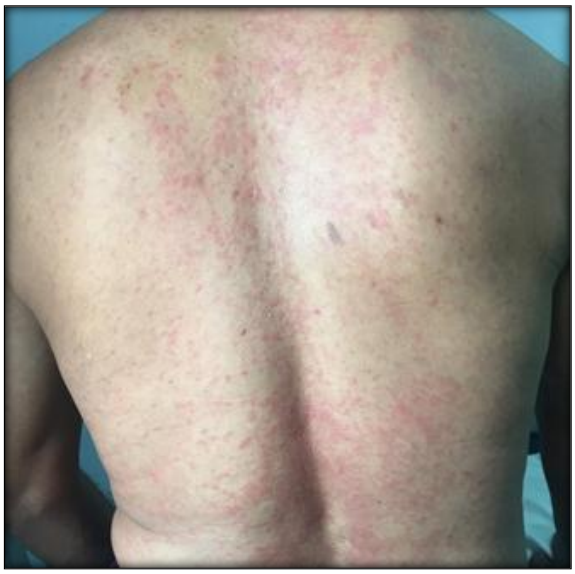


Figure 1 & 2: Exanthematous rash

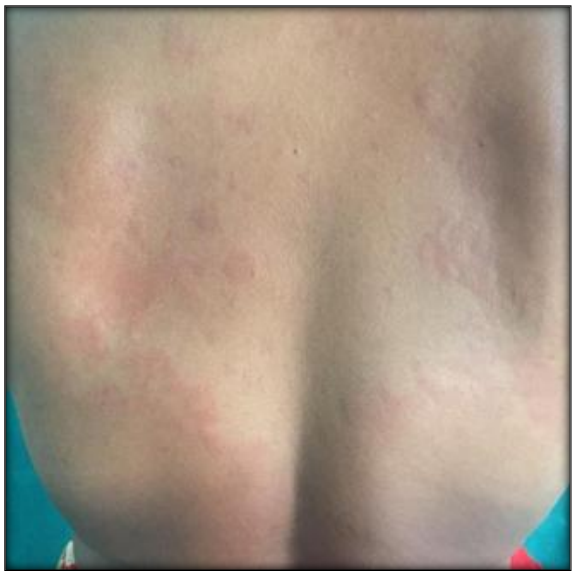
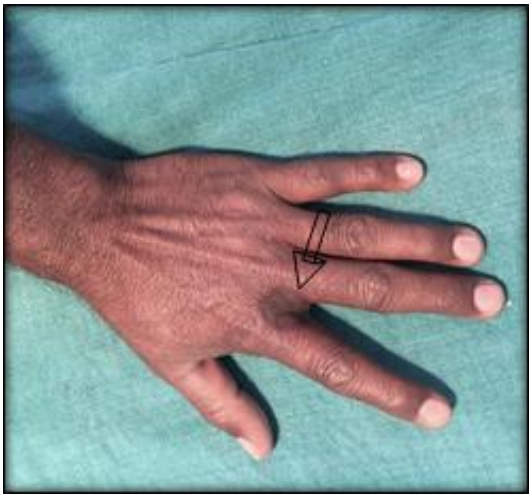


Figure 3 & 4: Angioedema and Urticaria



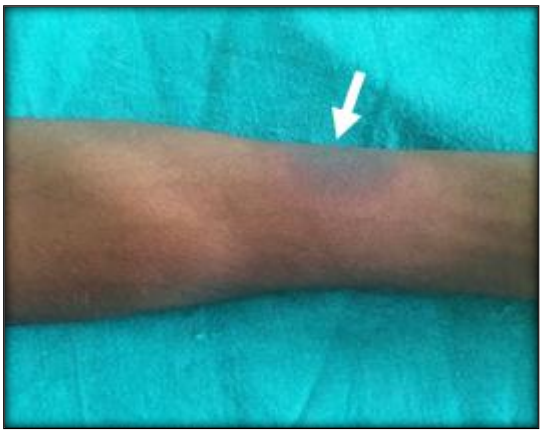


Figure 5 & 6: Fixed drug eruption on left index and middle finger interdigital space and on left forearm (cutaneous)

Figure 7: Mucosal Fixed drug eruption

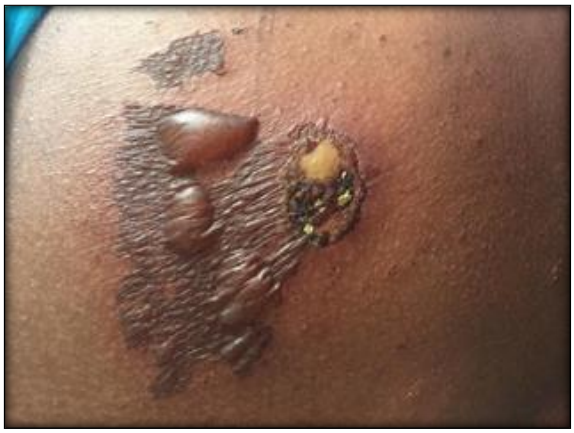


Figure 8: bullous fixed drug eruption on back

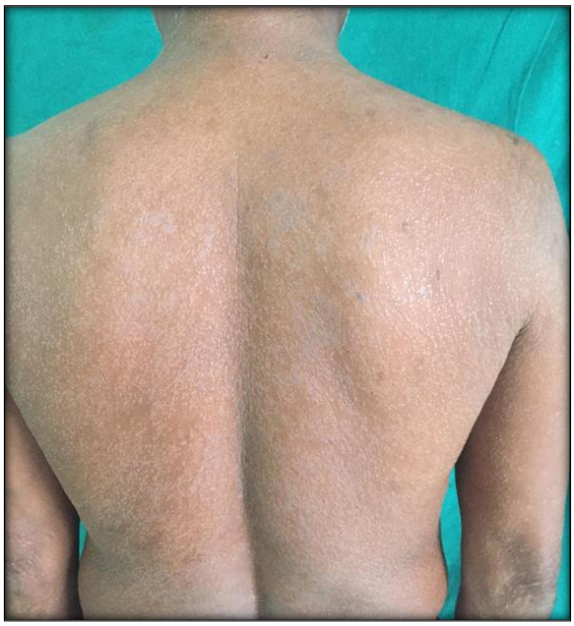


Figure 9: Lichenoid drug eruption

Table 1: Sex Distribution

Sex Distribution		
Gender	No. of. Patients	Percentage
Male	33	66%
Female	17	34%
Total	**50**	**100%**

Table 2: Age Distribution

Age Distribution		
Age in years	**No of Patients**	**Percentage**
< 10	3	6%
10 to 20	5	10%
21 to 30	12	24%
31 to 40	9	18%
41 to 50	14	28%
> 50	7	14%
Total	50	100%

Table 3: ADR History

History of Previous ADR		
Y/N	**No Of Patients**	**Percentage**
Yes	8	16%
No	42	84%

Table 4: Prescribed Medication

Prescribed Medication		
Categories	**No of Patients**	**Percentage**
Self	7	14%
Non-doctor	12	24%
Doctor/ Dentist	31	62%

Table 5: Onset of Symptoms after Drug intake

Onset of Symptoms after Drug intake		
Time ofOnset	**No of Patients**	**Percentage**
<1 Day	21	42%
1 to 10 days	27	54%
11 to 20 days	1	2%
21 to 30 days	1	2%
> 30 days	0	0%

Table 6: No of Causative Agents

No of Causative Agents		
No Of Drugs	**No of Patients**	**Percentage**
Single Drug	15	30%
Multiple / Combination Drugs	24	48%
Unknown	11	22%

Table 7: Route of Administration

Route of Administration		
Types	**No of Patients**	**Percentage**
Oral	46	92%
Systemic(Injections)	3	6%
Both	1	2%

Table 8: Type of reaction / Clinical pattern

Type of reaction / Clinical pattern		
Types	**No of Patients**	
Exanthematous	10	20%
urticaria & angioedema	9	18%
Fixed drug eruption	8	16%
Lichenoid eruption	4	8%
Stevens-Johnson syndrome (SJS)/Toxic epidermal necrolysis(TEN)	3	6%
Drug rash with eosinophilia andsystemic symptoms (DRESS) syndrome	1	2%
Acute generalized Exanthematous pustulosis (AGEP)	5	10%
Bullous Eruption	3	6%
Erythroderma	2	4%
Erythema multiforme	3	6%
Others	2	4%

Table 9: Suspected Agents Causing Drug Reactions

Suspected Agents Causing Drug Reactions		
Types	**No of Patients**	
Antimicrobials	23	
NSAIDS	17	
Antipsychotics	3	

Others	6	
Unknown	11	

Table 10: Naranjo Scale categories

Naranjo Scale categories			
Category	**Score**	**No of Patients**	**Percentages**
Definite	>9	0	0%
Probable	5 to 8	11	22%
Possible	1 to 4	39	78%
Doubtful	Zero	0	0%

Table 11: WHO - UMC Causality Categories

WHO - UMC Causality Categories		
Category	**No Of Patients**	**Percentages**
Certain	0	0%
Probable/ Likely	21	42%
Possible	29	58%
Unlikely	0	0%
Conditional / Unclassified	0	0%
Unassessable / Unclassifiable	0	0%

DISCUSSION

The study was conducted at a rural area (Moinabad) in a tertiary care center (Bhaskar General Hospital) during the period of January 2016 to July 2017 (one and half year).

In this study, a total of 50 cases of ACDR of which 66% were male and 34% were female with sex ratio with male predominance of 1.94:1.

In study conducted by David P et al, the male to female sex ratio was 0.87:1 showing a slight female predominance, unlike in the present study.2

Similar to our study, J Das et al, Sharma VK et al and Sehgal S et al studies showed a male predominance with 7:3, 1.47:1 and 1.35:1 respectively.[3,4,5]

The age group with most number of cases was in 41-50 years (28%) group followed by 21-30 years (24%). The age group range varied from as young as 1year to as old as 70 years.

Similar study by Raksha MP et al showed maximum patients belonging to 41-50 years followed by 21-30 and 31-40 years. The youngest was 1 year and the oldest was 80 years.[6]

In this study, the patients who had a previous episode of adverse cutaneous drug reaction was seen in 8 cases (16%) while others (84%) experienced their first episode. In other studies, the information regarding the cases with history of previous adverse drug reactions is lacking.

As observed in the present study, patients who didn't avail prescription from a doctor or dentist accounted to 38% (19 cases), of which 14% (7 cases) were self-prescribed and 24% (12 cases) took medication prescribed by non-doctors (unqualified practioners). Patients who took medication from doctor or dentist were 62% (31 cases). This observation reveals that a significant number of patients use medications without proper doctor or dentist prescription.

The information regarding the prescribers of medications i.e, either doctor or dentist, non-doctor and self were lacking in the studies used for comparison.

The onset of symptoms after drug intake (reaction time) is very varied in this study. The earliest onset of symptoms after drug intake was within 1 day (<1day). The longest time period for onset of symptoms after drug intake was 30 days. But most of the reactions (54%) occurred between 1 to 10 days after drug intake.

In the study by Sharma R et al, the interval between drug intake by all routes and cutaneous adverse drug reaction (CADR) ranged from a few minutes to 30 days.[7] This was in concordance with the present study.

In the study by Noel MV et al, reaction time (RT) i.e. the time taken for the reaction to appear since the last exposure to the suspected drug was observed to be 2-7 days for maculopapular rash, 2-3 weeks for TEN, 1-3 weeks for SJS, 1-3 days for urticaria, 1-2 weeks for erythema multiforme, 1-4 weeks for DHS, 3-4 weeks for photodermatitis, 6 weeks for exfoliative dermatitis and 1 day for FDE.[8]

In this study, most of the patients with ACDR were due to multiple or combination drugs accounting to 48% (24) of cases. In 22% (11) of cases the number of causative agents was not known. Only 30% (15) cases were due to single suspected drug. This shows that patients are using more than one agent for their condition which may lead to ACDR. This makes it furthermore difficult for the examining clinician to identify the causative agent for the ACDR.

In this study it was observed that, ACDR mostly occurred after oral administration of the drug or drugs accounting to 92% (46) of cases. Only 3 cases (6%) received drugs through injectables (systemic) and only 1 case (2%) had both.

In the study by Riedl MA et al, it was mentioned that the factor affecting the frequency of hypersensitivity drug reactions is the route of drug administration; topical, intramuscular, and intravenous administrations are more likely to cause hypersensitivity reactions. These effects are caused

by the efficiency of antigen presentation in the skin, the adjuvant effects of repository drug preparations, and the high concentrations of circulating drug antigen rapidly achieved with intravenous therapy. Oral medications are less likely to result in drug hypersensitivity.[9]

As observed in this study, a wide variety of clinical patterns ranging from exanthematous type to severe adverse drug reaction like SJS/TEN, AGEP and erythroderma were seen. Hence it is extremely difficult to ascertain a particular type of clinical pattern for ACDR.

In this study, the most common clinical pattern or type of reaction was exanthematous type (20%) followed by urticaria & angioedema (18%) and fixed drug eruption (16%). Severe cutaneous adverse reactions like erythema multiforme, erythroderma, AGEP, SJS/TEN and DRESS syndrome occurred in 3(6%), 2(4%) ,5(10%) ,3(6%) and 1(2%) cases respectively. Though exanthematous and urticarial type of eruptions can occur due to different causes, hence in this study other causes were ruled out before diagnosing as a drug reaction.

In studies by Ding WY et al exanthematous type of clinical pattern was common which is comparable to the present study.[11]

This study shows that, antimicrobials were the commonest offending agents of ACDR accounting to 23 cases. Second most common drugs implicated were NSAIDS accounting to 17 cases. Antipsychotics were used in 3 cases. Other drugs were used in 6 cases and in 11 cases the drugs causing ACDR were unknown. Some patients had used both antimicrobials as well as NSAIDS together.

In the studies by Hunziker T et al, Ghosh S et al, Sharma R et al, David P et al, J Das et al, Akpinar F et al, Farshchian M et al and Sharma VK et al, antimicrobials were the commonest, similar to the present study.[2,3,4,7,12,13,14,15]

In this study, the commonest reason for taking drugs was fever (36% of cases). Other reasons for taking medications were pain, diarrhea, burning micturition, headache, vomiting and other conditions. In study by Patel RM et al, most of the patients had taken medication for pain, fever and infection.[45]

As observed in this study, patients with past history of medical conditions or disease like HIV infection (4), diabetes(2), hypertension(2), epilepsy(3), atopy(1), psoriasis(1) and Hansen‘s disease(2) were seen in 15 cases.

In the study by Fiszenson-Albala F et al, The most frequent associated disorders were: human immunodeficiency virus (HIV) infection (19%), connective tissue disease (10%) and viral or autoimmune hepatitis (12%).[16]

A score more than 9 was considered definite, score between 5-8 was considered probable, score between 1-4 was considered possible and 0 score was doubtful.

Naranjo scale was also used by the studies Sharma R et al, Inbaraj SD et al, Ghosh S et al and by Patel TK et al.[7,17,15,18]

In Sharma R et al study, Naranjo scale indicated probable association of 77.3%, highly probable association of 12.6%, and 1% possible association with the implicated drugs.[7]

In Inbaraj SD study, Naranjo scale showed 98.3% of the reactions were probable and 1.7% were possible reactions.[18]

In this study, World Health Organisation-Uppsala Monitoring Centre (WHO-UMC) causality scale was also used to assess the cases. 58% (29) cases were included in the possible category and 42% (21) in probable/likely category. No cases were seen in certain, unlikely, conditional/unclassified and unassessable/unclassifiable categories.

WHO-UMC causality scale was used in the studies, Saha A et al and Noel MV et al. In the study by Saha A et al, among 53 subjects, in only 10 (18.9%) cases the causality association was certain and the majority were either probable/likely (n=22, 41.5%) or possible (n=21, 39.6%).[19]

In the study by Noel MV et al, one patient was classified under the category of certain, as rechallenge data was available (this patient was a case of Fixed drug eruption to metronidazole who was administered the drug for the second time unknowingly), 45 as probably associated as only dechallenge data was available and

10 as having possible association with the drug, as dechallenge data was not available.[8]

In the present study both, Naranjo scale and WHO-UMC causality scale were done and in both the scales ―possible‖ criteria had most number of patients unlike in other studies where ―probable‖ criteria had most number of patients.[20]

Relevant investigations like complete blood picture, complete urine examination, liver function tests and renal function tests were done in the cases.

Nayak S et al study mentions the diagnostic tests and laboratory investigations like blood workups that are useful in order to aid the clinical diagnosis. These include complete blood count (atypical lymphocytosis, neutrophilia, eosinophilia, etc.) and liver and renal function tests. An elevated peripheral eosinophil counts is an uncommon finding in cutaneous drug eruptions, and, therefore, in contrast to the popular belief, its presence or absence is of little importance in excluding or confirming the diagnosis. Guidelines of the American Academy of Dermatology state that eosinophil counts more than 1000 cells/mm 3 indicate a serious drug-induced cutaneous eruption.

All other blood tests (enzymes, electrolytes, biochemistry, ESR, ANA, bacterial and viral serology, etc.) can be requested depending on the suspected diagnosis. Culture (skin, blood, tissue, etc.) and medical imaging can also be carried out if appropriate, which may aid in confirming or ruling out potential diagnoses.

Drug levels are of value when eruption is associated with over dosage or other nonallergic type of reaction or in a comatose or noncommunicative patient to establish the presence of drug. It can also be useful to confirm the presence of the drug at the time of the rash as well as the overdose of this drug.
In the present study 11 cases (22%) were taking unknown medication there by making it difficult to know the causative agent. Management of these cases is utmost challenging to the treating physician.
Furthermore, studies regarding the pathogenesis of the cutaneous drug reactions is insufficient. This leads to trouble in understanding the disease outcome.
Due to increased polypharmacy by both the patient (self) and the prescriber (doctor and non-doctor) the exact cause of drug reaction cannot be ascertained. There is an increased trend in using combination or multiple drugs in the present study.
Hospitalization of patients with adverse cutaneous drug reaction was done in cases as a part of management. This leads to decreased morbididty and mortality in the cases. But areas with lack of tertiary care centers, management is difficult especially in severe adverse drug reactions.
All the cases in the present study were enrolled in the pharmacovigilance cell that was present in the hospital where the study was conducted. This helps in improving the data collection regarding the causative agents and trends in the clinical patterns.

In Naranjo scale, a series of 10 questions are given and each question is scored as shown below

Table 12: Naranjo scale

Question	Yes	No	Don't know
Are there previous conclusion reports on this reaction?	1	0	0
Did the adverse event appear after the suspect drug was administered?	2	–1	0
Did the adverse reaction (AR) improve when the drug was discontinued or a specific antagonist was administered?	1	0	0
Did the AR reappear when drug was re-administered?	2	–1	0
Are there alternate causes [other than the drug] that could solely have caused the reaction?	–1	2	0
Did the reaction reappear when a placebo was given?	–1	1	0
Was the drug detected in the blood [or other fluids] in a concentration known to be toxic?	1	0	0
Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	1	0	0
Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	1	0	0
Was the adverse event confirmed by objective evidence?	1	0	0

In the WHO-UMC causality scale the patients are grouped in to categories as follows

Table 13: WHO-UMC causality scale

Causality term	Assessment criteria (all points should be reasonablycomplied)
Certain	• Event or laboratory test abnormality, with plausible timerelationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically,pathologically) • Event definitive pharmacologically or phenomenologically (ie, an objective and specificmedical disorder or a recognized pharmacologic phenomenon) • Rechallenge satisfactory, if necessary
Probable/likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs
Causality term	Assessment criteria (all points should be reasonably complied)
	• Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanation
Conditional / unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable / unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or contradictory • Data cannot be supplemented or verified

CONCLUSION

In the current trend, adverse cutaneous drug reactions can mimic a wide range of dermatoses. ACDRs may range from mild exanthems to severe conditions like toxic epidermal necrolysis(TEN). Hence the clinician should possess the knowledge regarding drug reactions. The present study aimed to analyze various clinical patterns of adverse cutaneous drug reaction in patients attending a

tertiary care center in rural area over a period of one and half year. There was a male predominance(M:F=1.94:1) with the commonest age group being 41-50 years. Exanthematous type of clinical pattern was the commonest in the present study and antimicrobials were the commonest drugs causing the ACDR. Different causality scales like Naranjo scale and WHO-UMC causality scale were used to assess the cases, and most patients were in the ―possible‖ criteria. Reporting of ACDRs to the pharmacovigilance cell is important for data collection and analysis. With increase in advent of new therapies (like biologics) long term studies regarding the drug reactions is necessary to prevent and manage drug reactions.

Conflict of Interest: None

Finding Support: Nil

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