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# RETROSPECTIVE ANALYSIS OF CUTANEOUS ADVERSE DRUG REACTION AT TERTIARY CARE HOSPITAL

Saurabh Kumar Jain * and Amul Mishra

Bhupal Nobles' Institutes of Pharmaceutical Sciences, Bhupal Nobel's University, Udaipur - 313001, Rajasthan, India.

**Keywords:**

World Health Organization, Adverse drug reaction, System Organ Class, ADR Monitoring Centre

**Correspondence to Author:**
**Saurabh Kumar Jain**

Research Scholar,
Bhupal Nobles' Institutes of Pharmaceutical Sciences, Bhupal Nobel's University, Udaipur - 313001, Rajasthan, India.

**E-mail:** saurabhpharma1983@gmail.com

**ABSTRACT: Introduction:** Skin and subcutaneous tissue adverse drug reactions (ADR) are among the most common types of Cutaneous Reaction. The incidence rate of Cutaneous ADR is 1-3% for admitted patients in developed countries, whereas, in developing countries, it is 2-5% for admitted patients. **Aims & Objective:** To analyze the patient demographics, characteristics of the reaction, type of reaction, seriousness of the reaction, classification of the drugs involved, action is taken and outcome of reactions, causality assessment, severity assessment, and preventability of cutaneous ADRs. **Material and Methods:** The ADR monitoring center reported all cutaneous adverse drug reactions between September 2017 to June 2020 (34 months). All reported ADRs were clinically verified by committee members and retrospectively analyzed using various parameters such as type of reaction, causality assessment, drug preventability, and severity. **Results:** Out of 990 ADRs reported during the study period, 232 (23.43%) were cutaneous ADRs concerning 204 patients, including indoor and outdoor patients. A maximum number (48.7%) of ADRs were reported in the adult age group between 20-44 years. The majority of ADRs were considered probable (79.74%), moderate (50.0%), and Definitely preventable (70.68%) in nature. Most suspected categories included antimicrobial agents, NSAIDs, and antiretroviral drugs in our study. In this study (9.05%) serious ADRs were reported, including toxic epidermal necrolysis, Stevens-Johnson syndrome, and DRES's syndrome. The most common ADRs were reported, including fixed drug eruption (21.55%), followed by a generalized rash (19.40%). **Conclusion:** Cutaneous ADRs are common and develop in a short duration of time after the treatment starts as per prescription order. Physicians are advised patients to carry a drug allergy card and history of drug allergy information when visiting in a hospital for physician consultation.

**INTRODUCTION:** Cutaneous adverse drug reactions are classified under the system organ classification (SOC) category of skin and subcutaneous tissue disorders and are the most common adverse drug reactions reported due to different categories of medicines. Cutaneous adverse drug reactions are the most common type of allergy reaction and may be all over the body (generalized) or a localized area of the body affected, including eyelids, lips, face and genital region. A cutaneous drug reaction is an undesirable variation in the structure and function of the skin or mucous membranes. The most common cutaneous reactions include skin itching, drug eruptions, urticarial rash, *etc*.

These types of reactions are not dependent on pharmacological actions. They are a response to the single dose or only in some people, depending on qualitative factors [1]. The incidence rate of cutaneous adverse drug reactions is 1–3% for hospitalized patients in developed countries [2-3].

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Whereas in developing countries it is 2-5% for hospitalized patients [4-5]. The incidence rate in the outpatient's department was found to be 2.6% [6]. Approximately 1 in 1,000 indoor patients has a severe cutaneous adverse drug reaction [7]. The initial level of detection, assessment, understanding and prevention of cutaneous adverse drug reactions is essential for drug safety and patient safety.

## MATERIALS AND METHODS:

**Study Design:** A retrospective analysis was carried out at the Department of Pharmacology, pharmacovigilance unit of the Adverse Drug Monitoring Centre at Jawaharlal Nehru Medical College and Associated Hospital, Ajmer, Rajasthan (India).

This retrospective study was conducted after approval from the Institutional Ethical Committee, Jawaharlal Nehru Medical College and Associated Hospital, Ajmer, Rajasthan (No.1533Acad-III/MCA/2020 dated 30.07.2020).

**Methodology:** We utilized the spontaneously reported voluntary ADR data of outpatients and inpatients from September 2017 to June 2020. The Suspected ADR Reporting form was recorded for adverse reactions related to drugs with all the relevant data's such as patient details including Patients initials, age at the time of event or date of birth, sex, weight, date of reaction started and recovery date, description of reaction details, suspected medications including dose, route, frequency, date of therapy started and stopped and indication, outcomes of event and reporter information [8].

**Evaluation of ADR Data:** The collected suspected ADR forms were verified by the expert committee members on a clinical basis, analyzed, and evaluated to understand the pattern of the ADRs concerning patient demographics, characteristics of the reaction, type of reaction, characteristics or classification of the drugs involved, management and outcome of reactions, causality assessment, severity assessment and Preventability were analyzed, for inpatients and outpatients in the different clinical departments in a tertiary care hospital. Patient characteristics ADRs by age and sex were included for evaluation. Patients were divided into different age groups: 0–4 years, 5–19 years, 20–44 years, 45-65 years, 66–74 years > 75 years.

We utilized the classification of drug reactions given by Rawlins and Thompson [9]. System organ Class, classified as per medical Dictionary for Regulatory Activities (MedDRA) [10]. The seriousness of ADRs was classified according to ICH E2A guideline criteria [11].

According to the Anatomical Therapeutic Chemical [ATC], drugs were classified according to WHO-ATC Index [12]. Management actions taken in response to ADRs were classified as follows: drug was withdrawn; dose reduced; dose not changed; additional treatment for ADR.

The outcome was finalized after confirmation of dechallenge and rechallenge information. Causality assessment was conducted using the WHO-UMC assessment scale [13]. The severity of ADRs was classified according to the modified Hartwig Siegel Scale [14]. Preventability of ADRs was classified using the preventability assessment criteria modified by the Schumock and Thornton Scale [15-16].

**RESULTS:** A total of 990 ADRs were reported between September 2017 to June 2020, Out of which 232(23.43%) cutaneous ADRs were reported in suspected ADR reporting forms of 204 patients, including OPD and IPD, during 34 months periods.

The majority of the reports were from admitted patients (58.82%) and(41.18%) were found from outpatients at the Adverse Drug Monitoring Centre at Jawaharlal Nehru Medical College and Associated Hospital Ajmer **Table 1.** The male to female ratio was 53.92% and 46.08%, respectively, according to the demographic analysis of the patient's **Table 2.**

**TABLE 1: HOSPITAL ADMISSION TYPE**

| Admission Type | Number of patients associated with ADRs | % of patients associated with ADRs |
|---|---|---|
| IPD | 120 | 58.82 |
| OPD | 84 | 41.18 |
| Grand Total | 204 | 100 |

**TABLE 2: GENDER WISE DISTRIBUTION OF ADRs REPORTS**

| Gender | Number of patients associated with ADRs | % of patients associated with ADRs |
|---|---|---|
| Female | 94 | 46.08 |
| Male | 110 | 53.92 |
| Grand Total | 204 | 100 |

The adult age group between 20 and 44 years had the highest number of ADRs, 113 (48.7%), followed by 22.84% in the age group 5 to 19 years, 21.98% in the age group 45-65, and only 0.86% in the age group 66 to 74 years **Table 3.**

**TABLE 3: AGE WISE DISTRIBUTION OF PATIENTS WITH ADRs (i.e. ADRs 232)**

| Age Group | Number of ADR reports | % of ADR reports |
|---|---|---|
| (0-4) | 13 | 5.6 |
| (20-44) | 113 | 48.7 |
| (45-65) | 51 | 21.98 |
| (5-19) | 53 | 22.84 |
| (66-74) | 2 | 0.86 |
| Grand Total | 232 | 100 |

In the present study, most ADRs were type B reactions 222 (95.69%), followed by type A 10 (4.31%) reactions. According to the WHO causality assessment scale, the majority of reports were classified as probable (79.74%), certain (9.92%), possible (9.05%) and unlikely (1.29%). As per the modified Hartwigsiegel scale, Reaction severity accounted for moderate 50.0%, followed by mild 43.53% and severe 6.47%.

On the evaluation of the preventability of ADRs it was evident that most of them were definitely preventable (70.68%), followed by non-preventable (24.15%) and probably preventable (5.17%) **Table 4.**

**TABLE 4: ANALYSIS OF ADRs (REACTION TYPE, CAUSALITY ASSESSMENT, SEVERITY AND PREVENTABILITY)**

| Reaction type | Number of ADRs | (%) of ADRs |
|---|---|---|
| Type-A (Augmented) | 10 | 4.31 |
| Type-B(Bizarre) | 222 | 95.69 |
| Grand Total | 232 | 100 |
| **Causality Assessment** | | |
| Certain | 23 | 9.92 |
| Possible | 21 | 9.05 |
| Probable | 185 | 79.74 |
| Unlikely | 3 | 1.29 |
| Grand Total | 232 | 100 |
| **Severity** | | |
| Mild | 101 | 43.53 |
| Moderate | 116 | 50.00 |
| Severe | 15 | 6.47 |
| Grand Total | 232 | 100 |
| **Preventability** | | |
| Definitely preventable | 164 | 70.68 |
| Probably preventable | 12 | 5.17 |
| Non-preventable | 56 | 24.15 |
| Grand Total | 232 | 100 |

The majority of the reports of ADRs were reported from the department of medicine (25.98%), followed by the department of skin (23.04), paediatric (15.69%), ART center (10.29%), and respiratory medicine (9.31%) **Table 5.**

**TABLE 5: DISTRIBUTION OF ADRs ACCORDING TO DEPARTMENT WISE ADRs Reports**

| Department | Number of ADRs Reports | Number of ADRs Reports (%) |
|---|---|---|
| ART centre | 21 | 10.29 |
| Blood bank | 11 | 5.39 |
| Gastroenterology | 10 | 4.90 |
| Medicine | 53 | 25.98 |
| Oncology | 1 | 0.49 |
| Pediatric | 32 | 15.69 |
| Psychiatry | 4 | 1.96 |
| Skin | 47 | 23.04 |
| Surgery | 6 | 2.94 |
| Respiratory Medicine | 19 | 9.31 |
| Grand Total | 204 | 100 |

In the present study, 32 types of adverse events with different frequencies were reported due to 79 types of drugs and a combination of drugs. The majority of ADRs were reported due to the category of an antimicrobial class of drugs, including ceftriaxone sodium (8.62%), followed by antiretroviral drug combinations including Efavirenz + Lamivudine + Tenofovir disoproxil

fumarate (6.90%), nonsteroidal anti-inflammatory drug combinations including Diclofenac sodium + Paracetamol (5.60%), glycopeptide antibiotics including Vancomycin (5.60%) and (Ofloxacin + Ornidazole) (4.74%) **Table 6.** The majority of ADRs were reported, including fixed drug eruption (21.55%), followed by a generalized rash (19.40%), generalized itching (11.64%), generalized urticarial rash (9.48%), itching generalized (6.03%), itchy rash (3.88%), erythematous skin rash (2.59%), Stevens-Johnson syndrome (2.59%) and toxic epidermal necrolysis (2.59%) **Table 6.**

**TABLE 6: DESCRIPTION OF SUSPECTED DRUGS, INDIVIDUAL REACTION WITH FREQUENCY, AND TOTAL NUMBER IF ADRs ASSOCIATED WITH DRUGS**

| Suspected drug/Active ingredients | ADR (Frequency of Occurrence) | Number of ADRs |
|---|---|---|
| Dextrose and electrolyte | Erythematous Skin rash | 1 |
| Ethionamide | Pruritus | 1 |
| Ibuprofen + Paracetamol | Fixed drug eruption | 1 |
| Itraconazole | Generalized rash | 1 |
| Levocetirizine | Generalized rash | 1 |
| Levofloxacin | Pruritus | 1 |
| Abacavir sulfate+ Lamivudine | Rash on leg | 1 |
| Aceclofenac + Paracetamol | Generalized urticarial rash Skin peeling Stevens Johnson syndrome Toxic epidermal necrolysis | 4 |
| Acetylsalicylic acid | Drug-induced hypersensitivity syndrome | 1 |
| Amikacin sulfate | Erythematous Skin rash Generalized urticarial rash | 2 |
| Amitriptyline hydrochloride | DRESS syndrome | 1 |
| Amoxicillin trihydrate +Clavulanate potassium | Fixed drug eruption(2) Itching – generalized Stevens-Johnson syndrome Vesiculobullous rash | 5 |
| Atropine sulfate | Allergic rash | 1 |
| Azithromycin | Generalized rash Stevens-Johnson syndrome | 2 |
| Blood, whole | Generalized rash(4) Generalized urticarial rash(4) Itching – generalized(3) Itchy rash(2) | 13 |
| Calcium chloride dehydrate + Potassium chloride+ Sodium chloride+ Sodium lactate | Skin peeling | 1 |
| Carbamazepine | DRESS syndrome Generalized rash(2) Toxic epidermal necrolysis | 4 |
| Cefalexin | Stevens Johnson syndrome | 1 |
| Cefixime | Fixed drug eruption Maculopapular rash | 2 |
| Cefixime trihydrate + Ofloxacin | Skin peeling | 1 |
| Cefotaxime sodium | Generalized itching(3) Generalized rash Generalized urticarial rash Urticaria localized | 6 |
| Ceftriaxone sodium | Erythematous skin rash Generalized itching(7) Generalized rash(5) Generalized urticarial rash(4) Itching – generalized Itchy rash Localized itching | 20 |
| Ceftriaxone sodium + Sulbactam sodium | Generalized urticarial rash | 1 |
| Cefuroxime | Localized itching | 1 |
| Chlorphenamine maleate | Generalized rash | 1 |
| Chlorphenamine maleate+ Dextromethorphan hydrobromide | Toxic epidermal necrolysis | 1 |
| Ciprofloxacin | Erythema Fixed drug eruption Generalized itching Hand rash Itching – generalized Localized itching | 6 |
| Ciprofloxacin hydrochloride + Tinidazole | Fixed drug eruption | 1 |
| Clofazimine | Skin discoloration | 1 |
| Cyanocobalamin+ Ferrous fumarate+ Folic acid | Itchy rash | 1 |
| Cycloserine | Pruritus | 1 |
| Diclofenac sodium | Fixed drug eruption(4) Generalized rash Rash on leg Stevens-Johnson syndrome | 7 |
| Diclofenac sodium+ Paracetamol | Fixed drug eruption(8) Generalized rash Generalized urticarial rash (2) Itching – generalized Toxic epidermal necrolysis | 13 |
| Dicycloverine hydrochloride | Generalized urticarial rash (2) Itching – generalized | 3 |

| | | |
|---|---|---|
| Domperidone+ Naproxen sodium | Fixed drug eruption | 1 |
| Domperidone+ Pantoprazole | Pruritus | 1 |
| Doxorubicin hydrochloride | Alopecia | 1 |
| Doxycycline | Generalized urticarial rash | 1 |
| Efavirenz+ Lamivudine+ Tenofovirdisoproxil fumarate | Drug rash Erythematous Skin rash Generalized rash (14) | 16 |
| Ethambutol | Generalized itching Hair loss Vitiligo | 3 |
| Ethambutol + Isoniazid+ Pyrazinamide+ Rifampicin | Itchy rash Maculopapular rash | 2 |
| Etoricoxib | Erythema multiforme | 1 |
| Fluconazole | Fixed drug eruption | 3 |
| Folic acid + Iron | Generalized urticarial rash | 1 |
| Folic acid+ Nicotinamide + Vitamin B12 | Erythema Generalized itching Localized itching | 3 |
| Gentamicin | Generalized itching | 1 |
| Glucose + Sodium chloride | Itching – generalized | 1 |
| Haloperidol | Generalized itching | 1 |
| Ibuprofen | Fixed drug eruption Generalized rash Itching – generalized | 3 |
| Ibuprofen+ Paracetamol | Fixed drug eruption (4) Generalized rash (2) Generalized urticarial rash | 7 |
| Immunoglobulin anti-corynebacteri. dipht. | Erythematous Skin rash | 2 |
| Isoniazid | Generalized pruritus Generalized rash | 2 |
| Isoniazid+ Pyrazinamide+ Rifampicin | Generalized itching | 1 |
| Ketoconazole | Generalized rash | 1 |
| Lamivudine+ Nevirapine+ Zidovudine | Generalized rash | 1 |
| Mecobalamin | Localized itching | 1 |
| Metronidazole | Fixed drug eruption(2) Generalized itching(3) Itching – generalized Rash trunk Small papule | 8 |
| Nevirapine | Generalized rash | 1 |
| | Rash on leg | 1 |
| Nimesulide | Fixed drug eruption | 1 |
| Nimesulide + Paracetamol | Fixed drug eruption | 1 |
| Norfloxacin+ Tinidazole | Fixed drug eruption | 1 |
| Ofloxacin | Fixed drug eruption(2) Toxic epidermal necrolysis | 3 |
| Ofloxacin + Ornidazole | Fixed drug eruption(9) Generalized rash Stevens Johnson syndrome | 11 |
| Ondansetron | Generalized urticarial rash | 1 |
| Ornithine aspartate | Generalized itching | 1 |
| Paracetamol | Fixed drug eruption(6) Generalized itching Maculopapular rash | 8 |
| Phenytoin | Allergic rash Generalized rash Toxic epidermal necrolysis | 3 |
| Platelets | Itchy rash | 1 |
| Propofol | Erythema | 1 |
| Pyrazinamide | Generalized pruritus Generalized itching(4) | 5 |
| Pyridoxine | Itchy rash | 1 |
| Rabies antiserum | Generalized rash | 1 |
| Ranitidine hydrochloride +Domperidone | Fixed drug eruption | 1 |
| Rifampicin | Generalized itching | 1 |
| Snake venom antiserum | Generalized urticarial rash(2) Itching – generalized | 3 |
| Sulfamethoxazole +Trimethoprim | Generalized rash | 1 |
| Tramadol | Allergic rash | 1 |
| Vancomycin | Erythema Generalized itching Generalized rash Itching – generalized(2) Itchy rash(2) Rash on face(3) Red man syndrome(3) | 13 |
| Vitamin B complex | Generalized rash | 1 |
| Grand Total | | 232 |

ADRs were described in **Tables 7 (A) & 7(B)** based on seriousness criteria. A total of 211 (90.95%) ADRs were nonserious and 21(9.05%) ADRs were found to be serious. Out of these serious ADRs, prolonged hospitalization was reported in 20 (95.24%) cases, only one life-threatening case was reported and no case was

found to have died, disabling and congenital anomaly due to serious ADRs in the present study.

**TABLE 7(A): DISTRIBUTION OF ADRs ACCORDING TO SERIOUSNESS**

| Seriousness of Reaction | Number of ADRs | % of ADRs |
|---|---|---|
| Non Serious | 211 | 90.95 |
| Serious | 21 | 9.05 |
| Grand Total | 232 | 100 |

**TABLE 7(B): DISTRIBUTION OF ADRs BASED ON SERIOUSNESS CRITERIA AS PER ICH GUIDELINE**

| Seriousness Criteria | Number of ADRs | % of ADRs |
|---|---|---|
| Caused / Prolonged hospitalisation | 20 | 95.24 |
| Life-threatening | 1 | 4.76 |
| Disabling / incapacitating | 0 | 0 |
| Other medically important condition | 0 | 0 |
| Death | 0 | 0 |
| Congenital anomaly | 0 | 0 |
| Grand Total | 21 | 100 |

In the majority of 190 (93.14%) of the reports, the suspected drug was withdrawn for the management of ADR, followed by does not change 11 (5.39%), and not applicable 3(1.47%) **Table 8.**

**TABLE 8: MANAGEMENT OF ADRs REPORTS**

| Action taken | Number of ADRs | (%) of ADRs |
|---|---|---|
| Drug Withdrawn | 190 | 93.14 |
| Dose not Changed | 11 | 5.39 |
| Not Applicable | 3 | 1.47 |
| Grand Total | 204 | 100 |

A total of 107(46.12%) ADRs were recovered, 92(39.66%) ADRs were recovering, followed by not recovered 29 (12.5%) and 3 (1.29%) recovered with sequelae **Table 9.**

**TABLE 9: FINAL OUTCOME OF ADRs**

| Final Outcome | Number of ADRs | % of ADRs |
|---|---|---|
| Recovered | 107 | 46.12 |
| Recovering | 92 | 39.66 |
| Not Recovered | 29 | 12.5 |
| Recovered with Sequelae | 3 | 1.29 |
| Unknown | 1 | 0.43 |
| Fatal /Death | 0 | 0 |
| Grand Total | 232 | 100 |

In the present study, the majority of ADRs were reported by physicians 185(90.69%) as compared with nursing professionals 14(6.86%) and pharmacists 4(1.96%) and consumers 1(0.49%) **Table 10.**

**TABLE 10: DISTRIBUTION OF ADRs REPORTS ACCORDING TO REPORTER TYPE**

| Reporter type | Number of ADRs | % of ADRs |
|---|---|---|
| Physician | 185 | 90.69 |
| Nursing Professional | 14 | 6.86 |
| Pharmacist | 4 | 1.96 |
| Consumer | 1 | 0.49 |
| Grand Total | 204 | 100 |

In the present study, 129 (55.60%), of ADRs were reported due to the oral route of administration, followed by 84 (36.21%) intravenous route, 13 (5.60%) intradermal route, 3 (1.29%) intramuscular and 3 (1.29%) topical route **Table 11.**

**TABLE 11: DISTRIBUTION OF ADRsS ACCORDING TO ROUTE OF ADMINISTRATION**

| Route of administration type | Number of ADRs | % of ADRs |
|---|---|---|
| Oral | 129 | 55.60 |
| Intravenous | 84 | 36.21 |
| Intradermal | 13 | 5.60 |
| Intramuscular | 3 | 1.29 |
| Topical | 3 | 1.29 |
| Grand Total | 232 | 100 |

**DISCUSSION:** This study examined the pattern of cutaneous adverse drug reactions at a tertiary care hospital. Adverse drug reactions were analyzed on the basis of baseline parameters, including past history of patients, initial clinical impression including morphology of the cutaneous reaction and extracutaneous signs, analysis of drug exposure, literature survey, evaluation laboratory results and diagnostic tests. All parameters were monitored by a healthcare professional before the final diagnosis. The reporting rate of cutaneous ADRs was 23.43% in the present study, similar to the study conducted by Ghosh *et al*. (25.8%) [17].

In our study, a greater number of ADRs were reported from indoor patients (IPD) than the outpatients (OPD) because IPD patients were monitored closely by physicians compared to the outpatients. Another reason was the busy schedule of physicians during OPD, so ADR cases were missed during OPD due to the high patient load. Another factor contributing to the increased number of ADRs during IPD is polypharmacy; because more medicines are prescribed in IPD patients than in OPD patients, the probability of ADR occurring in IPD patients due to drug-drug interaction is higher. In our study males were more affected due to adverse drug reactions compared to

females, which was similar to the other study by Sharma *et al* [18]. Out of 232 ADRs reported, 48.7% and 22.84% belonged to age groups (20 to 44 years) and (5 to 19 years) in the current study. Our results were akin to the study done by Sharma V. K. *et al.*[18]. In our study, most ADRs were type B reactions. Similar to the study done by Ghosh S *et al.* [17]. Most of the cutaneous ADRs are type B reactions, immunological abnormalities, and not related to pharmacological actions. In this study, the most common causality assessment was probably followed by certain and possible in nature according to WHO-UMC criteria, similar to the study done by Padmavathi S *et al.* [19] and Krishna J *et al.* [20].

According to the modified Hartwig and Seigel scale in the present study, most of the cutaneous ADRs were moderate in nature, followed by mild and severe. Similar results were also reported by Padmavathi S *et al*.[19] and Krishna J *et al.* [20]. In most cases, suspected drugs were withdrawn to prevent harm and overall patient safety. According to the modified Schumock and Thorton scale, most of the cutaneous ADRs were definitely preventable, followed by non-preventable, and probably preventable. But in another study, most of the ADRs were not preventable as per Ghosh S *et al.* [17] & Modi *et al*.[21]. Most of the ADRs were clinical diagnoses in the present study and patients were medically treated. Finally, most of the adverse drug reactions are prevented.

In the present study, most ADRs were reported from the department of medicine because, in our study duration, the maximum number of patients were visited in the medicine department in both the OPD & IPD sections. In our study majority of ADRs were reported due to suspected category of drugs and combination of drugs including antimicrobials class of drug including ceftriaxone sodium, vancomycin, ciprofloxacin & cefotaxime sodium, followed by NSAIDs including (Diclofenac sodium + Paracetamol), (Ibuprofen + paracetamol) & (Acelofenac + Paracetamol), antiretroviral and antitubercular drugs, Similar results were found by Ghosh S *et al*.[17]. The physicians most Commonly prescribe these classes of drugs for most common indications including fever, cold, different types of pain & infections. In the present study, the most common cutaneous ADR was fixed drug eruption (21.55%), followed by a generalized rash (19.40%) and generalized urticarial rash (9.48%). But in other studies maculopapular rash (34.6%) and fixed drug eruption (30%) followed by urticaria (14%) were common cutaneous ADRs as per Sharma V.K. *et al*.[18]. In total, 21 (9.05%) serious ADRs were reported in this study, including toxic epidermal necrolysis (28.57%), Stevens-Johnson syndrome (23.81%), DRESS syndrome (9.52%), fixed drug eruption (9.52% ), generalized urticarial rash (9.52%)and skin peeling (9.52%) cases. This study was similar to the study done by Saha A *et al.* [22] but another study's results were dissimilar from the present study. Ghosh S *et al.*[17].

In the present study, most of the suspected drugs were withdrawn, similar to a study done by Ghosh S *et al.*[17]. In our study, the majority of patients recovered from the cutaneous reaction, which is similar to a study done by Ghosh S *et al.*[17] and no death case was reported in our study, but in another study one death case was reported due to Stevens-Johnson syndrome done by Modi A *et al.*[21]. The reporting frequency of ADRs with respect to the healthcare professional's majority of reports through physicians was 90.69%, as compared with nursing staffs' 6.86% and pharmacists' 1.96%. Under-reporting through nursing and pharmacist staff because of lack of awareness, but physicians are more aware of the ADR reporting system because more than a thousand physicians attended training programmes about ADR monitoring and reporting system in India during our study period. In the present study, the maximum number of ADRs were reported from the oral route of drug administration. Most physicians prescribed oral medicine for the treatment of patients because oral medicines were easy to take by patients, including children.

**CONCLUSION:** The clinical pattern of cutaneous ADRs is remarkably similar to those observed in other studies, except for a few variations. In this study, most ADRs were nonserious in nature and recovered after medical treatment. Only a small number of serious ADRs were reported, including toxic epidermal necrolysis (28.57%), Stevens-Johnson syndrome (23.81%), DRESS syndrome (9.52%) with prolonged hospitalization and under

recovering at the time of reporting of the adverse event.

Most cutaneous adverse drug reactions were reported due to antimicrobial agents & NSAIDs class of suspected drug. Physicians reported the highest number of ADRs, and they closely monitored patients during treatment to detect and prevent cutaneous ADRs.

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