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DERMATOLOGICAL ADVERSE DRUG REACTIONS IN TERTIARY CARE HOSPITAL

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ANCA (Anti Neutrophilic Cytoplasmic Antibodies), ADR (adverse drug reaction) ATT (Anti Tuberculosis Therapy).

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ABSTRACT: Adverse drug reactions are undesirable effects of drugs beyond its anticipated therapeutic uses occurring commonly in clinical practice. Although many of these ADRs are mild and disappear when the suspected drug is stopped or dose is reduced, some are more serious and last longer. Many studies have been published regarding hospital admission due to ADRs and it has been estimated that 2.9% to 5.6% of all hospital admissions are due to ADRs and 35% of the hospitalized patients experience an ADR during their hospital stay. Thus ADRs increase not only morbidity and mortality, but also add to the overall healthcare cost. In the present study a total of 1125 patients data were collected from six months study period. Out of 1125, 41 (3.64%) ADRs were identified. From among the 41patients, 22 (53.65%) were males and females were 19 (46.34%). This gender distribution percentage was compared with previous studies. The mean age of our study is 37.95±2.75 years and was compared with the previous similar studies. This study shows the high incidence of DHS 11 (26.8%), followed by drug induced acne form eruption 7 (17.2%). The study also showed that most ADRs occurred in age group of 21-30 years followed by 31-40 years. The incidence of ADRs more in male (53.65%) patients than female (46.34%) Patients. Most common ADRs were DHS (26.8%), Acne form eruption (17.2%), SJS (12.2%) and FDE (7.3%).Most common caused drugs were Antibiotics (31.7%), Antiepileptics (17%), Antituberculor drugs (12.1%) and Steroids (7.3%).

INTRODUCTION: Every occasion when a patient is exposed to a medical product, is a unique situation and we can never be certain about what might happen. A good example for this is Thalidomide tragedy in 1950s & 1960s.

Thalidomide prescribed as a safe hypnotic to many thousands of pregnant women caused severe form of limb abnormality known as Phocomelia in many of the babies born to those women. It was a seminal event that led to the development of modern drug regulations aimed to identify, conform and quantify ADRs. Adverse drug reactions are those unintended reactions caused by drugs when used at normal doses.

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The International Conference on Harmonization defines an adverse drug reaction as "a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function" [1].

In everyday clinical practice, almost all physicians come across many instances of suspected adverse cutaneous drug reactions (ACDR) in different forms. Although such cutaneous reactions are common, comprehensive information regarding their incidence, severity and ultimate health effects are often not available as many cases go unreported. It is also a fact that in the present world, almost every day a new drug enters market; therefore, a chance of a new drug reaction manifesting somewhere in some form in any corner of world is unknown or unreported. Although many a times, presentation is too trivial and benign, the early identification of the condition and identifying the culprit drug and omit it at earliest holds the

keystone in management and prevention of a more severe drug rash. Therefore, not only the dermatologists, but all practicing physicians should be familiar with these conditions to diagnose them early and to be prepared to handle them adequately. However, we all know it is most challenging and practically difficult when patient is on multiple medicines because of myriad clinical symptoms, poorly understood multiple mechanisms of drug-host interaction, relative paucity of laboratory testing that is available for any definitive and confirmatory drug-specific testing.

A common misconception is that a drug's effects can be clearly divided into two categories: desired (or therapeutic effects) and undesired (or side effects). Actually, most drugs produce several effects, but a physician usually wants a patient to experience only one (or a few) of them; the other effects are hence regarded as undesired. Although most people including healthcare practitioners use the term **'**side effect', the term 'adverse drug reaction' is more appropriate for effects that are undesired, unpleasant, noxious or potentially harmful. Although many of the ADRs are relatively mild and disappear when the drug is stopped or the dose is reduced, others are more serious and last longer. Therefore, there is little doubt that ADRs increase not only morbidity and mortality, but also add to the overall healthcare cost. Some ADRs are predictable in nature especially those where a contraindicated drug is used (in patient with a known allergy or with co-morbidities.

Contraindicating its use) or the wrong dose of a drug administered. The importance of understanding the predictability of an ADR was first reviewed in 1971, where it was estimated that 70-80% of ADRs are predictable and may be preventable [2]. It is true that some ADRs are unavoidable and will occur even with the most extraordinary precautions in place. However, a large proportion of ADRs may be preventable. Yet, in most hospitals today, too little is done to identify and understand preventable ADRs. This information is of utmost importance for guiding educational programs and systems to facilitate a reduction in the number of ADRs that occur. The preventability of ADRs is an appropriate data element which can be fed back into the system to facilitate the improvement process [3].

Objectives:

General Objectives:

Study and Evaluation of Dermatological Adverse Drug Reactions (ADR) in tertiary care Hospitals.

Specific Objectives:

1. To determine the causation, severity of dermatological adverse drug reactions in patients.
2. Reporting of dermatological adverse drug reactions.
3. To estimate the incidence of serious and fatal adverse drug reactions in hospital patients by Chart Review method.

Expected Outcomes:

Incorporation of pharmacist into health care team could minimize Adverse Drug Reaction.

METHODOLOGYL:

Ethical approval:

Ethical committee clearance was taken from the Institutional Ethical Committee of Owaisi Hospital and research center, for carrying out this project.

Study location:

The study will be carried out in the Krishna Institute of Medical Sciences (KIMS) hospital including both outpatient and inpatient departments.

Study design:

The study will be an observational type, Prospective and descriptive study.

Study period:

Study period will be of 6 months (March 2011 to August 2011).

Study setting:

Study will be based only on those patients who experience an dermatological adverse drug reactions in tertiary care hospitals, either during their stay in hospital (IPD) or visiting the outpatient departments (OPD).

Study criteria:

Inclusions:

- Patient's name, age, sex.
- Drug prescribed.
- Dosage of drugs prescribed & dosage form.
- Route of administration

Exclusions:

- Incomplete information regarding patient.

Data collection:

Data on the reported ADRs will be evaluated to understand the pattern of the ADRs with respect to patient demographic disease, nature of the reactions, characteristics of the drugs involved, and outcome of the reactions.

Methodology:

Dermatological ADRs in Tertiary care Hospitals.

Criteria for Identifying ADRs:

ADR identified by physicians will be considered and will be included in the study.

Analysis of ADRs:

The total number of ADRs reported:

Nature and description of ADRs reported:

Causality assessment of ADR based on Algorithm:

The degree of association of an adverse reaction with a drug is done with the help of Naranjo's algorithm.

Severity of ADRs:

After the causality assessment has been done, the severity of the ADR is analyzed using adapted Hart wig severity scale.

The scale is classified as:

1. **Mild**: A reaction that does not required treatment or hospital stay.
2. **Moderate**: A reaction that requires treatment and or prolongs hospitalization by atleast one day.
3. **Severe**: A reaction that is potentially life threatening or contributes to the death of patient is permanently disabling requires intensive medical care or results in a congenital anomaly cancer or unintentional overdose.

To study the onset of ADRs.

1. **Acute**: Acute events are those which are observed within 60 minutes after the administration of medication.
2. **Sub-Acute:** These occur within 1-24 hours from the time of administration of medication.
3. **Latent:** These reactions take 2 or more days to become apparent.

Preventability of ADRs:

Complete preventability of ADR is not possible, but some of the ADR can be preventable if that ADR can give at least one answer of Schumock and Thronton scale**.**

Predictability of ADRs:

Patients who had the drug on previous occasion(s): If the drug was previously well-tolerated at the same dose and route of administration, the ADR is Not Predictable; if there was a history of allergy or previous reactions to the drug, the ADR is Predictable. Patients who have never had the drug previously: Incidence of the ADR reported in product information or other literature determines its predictability.

Statistical Analysis:

- All the data collected during the study will be processed using SPSS software.
- All the data will be represented as average (±SEM) and percentages,
- Rates of ADR or ADR occurrence during the hospital stay will be calculated as percentage of in-patient or out-patient population treated.
- Student's t-test will be use to compare mean values.

RESULTS:

During the six months study period, total 1125 patients visited the dermatology OPD & IPD. The demographic data is as follows: Among 1125 patients, 509 were male 616 were female patients.

Out of 1125 patients, 41 patients were reported with ADR. Among them male subject patients were 22 (53.65%) and female patients were 19 (46.34%) reported. It has been showed in **Table 1**.

TABLE 1: ASSESSMENT OF ADR ACCORDING TO GENDER

Gender	No. of non ADR patients	No. of ADR patients	Total	% 0F ADR
Male	487	22	509	53.65
Female	597	19	616	46.34
Total	1084	41	1125	

Age distribution of the patients:

All the patients were divided into seven age groups – up to 10 years, 11 to 20 years, 21 to 30 years, 31 to 40 years, 41 to 50 years, 51 to 60 years and 61 to 70 years. The ADR patients mean age group of this study was 37.95±2.75, for male patients it was 38.14 ±3.94, for female it was 37.74±3.90 years.

TABLE 2: AGE DISTRIBUTION OF THE PATIENTS

	Age distribution of Patients	
Age (yr)	Number of patients	Percentage (%)
0-10	2	4.8
11-20	5	12.1
21-30	9	21.9
31-40	7	17
41-50	6	14.6
51-60	6	14.6
61-70	6	14.6
TOTAL	41	100

Age distribution of the patients among male & female:

Among 22 male subject patients 51-60 years age group patients were highly affected, followed by 11-30 years age group. Incase of female patients 21-40 age group were highly affected, out of the 19 patients.

TABLE 3: AGE DISTRIBUTION OF THE PATIENTS AMONG MALE & FEMALE

	Age distribution in males & females	
Age (yr)	Male	Female
0-10	1	1
11-20	4	1
21-30	4	5
31-40	2	5
41-50	3	3
51-60	5	1
61-70	3	3
TOTAL	22	19

Pharmacological class Vs No. of ADRs in Patients: The most common drugs causing ADR is shown in **Table 4**. According to which Antibiotics were associated with maximum number of ADRs i.e. 13 (31.7%), followed by Antiepileptic 7 (17.07%), the other different class of drugs causing ADR were Anti tuberculosis drugs 5 (12.1%), Steroids 3 (7.3%), Antigout 3 (7.3%), NSAIDS 3 (7.3%), Immunosuppressant 1(2.4%), Anti Retroviral 1(2.4%), oral contraceptives 1(2.4%), Anticancer 1 (2.4%), Preservatives 1 (2.4%), and Bleaching agent 1(2.4%).

TABLE 4: PHARMACOLOGICAL CLASS Vs NO. OF ADRS IN PATIENTS

Pharmacologiacal class	Number of patients	% of Patients
Antibiotics	13	31.7
Anti epileptics	7	17
ATT	5	12.1
Steriods	3	7.3
Anti gout	3	7.3
NSAIDS	3	7.3
Immunosupresents	1	2.4
Antiepileptic + Antibiotics	1	2.4
Anti Retrovirals	1	2.4
Oral contrseptives	1	2.4
Anticancer	1	2.4
Preservatives	1	2.4
Bleaching Agent	1	2.4

Pharmacological class Vs No. of ADRs in male & female Patients:

Male patients were highly affected with Antibiotics [8(36.36%)] than females [5 (26.3%)], but in case of Antiepileptics [4 (21.05%)] andAnti tubercular [3 (15.7%)] female patients were highly effected than male patientsi.e.3 (13.6%); 2 (9.09%).

TABLE 5: PHARMACOLOGICAL CLASS VS NO. OF ADRS IN MALE & FEMALE PATIENTS

Pharmacological class	Male	Female
Antibiotics	8	5
Anti epileptics	3	4
ATT	2	3
Steroids	1	2
Anti gout	1	2
NSAIDS	2	1

Immune suppressants	1	0
Antiepileptic + Antibiotics	1	0
Anti Retroviral	1	0
Oral contrseptives	0	1
Anticancer	0	1
Preservatives	1	0
Bleaching Agent	1	0

Types of ADRs:

This study shows, high incidence of Drug induced Hypersensitivity Syndrome 11(26.8%), followed by Drug induced acne form eruption 7(17.2%), SJS 5(12.2%), Fixed drug eruption 3 (7.3%), Lichenoid eruption 2(4.8%), Stasis Dermatitis 2(4.8%) and Erythema multi formi 2(4.8%).

TABLE 6: TYPE OF ADRS Vs NO. & % OF PATIENTS

Type of ADR	Number of Patients	%of Patients
DHS	11	26.8
Drug induced acne form Eruption	7	17.2
SJS	5	12.2
Fixed drug eruption	3	7.3
Lichenoid eruption	2	4.8
Stasis Dermatitis	2	4.8
Erythema multi formi	2	4.8
Folliclitis & Rhinofima	1	2.4
Drug induced vasculitis ulcer	1	2.4
Nutritional Dermatitis	1	2.4
Pellagra	1	2.4
ATT induced erythroderma	1	2.4
Contact irritant dermatitis	1	2.4
Steriod induced tinea	1	2.4
SLE	1	2.4
TEN	1	2.4

Type of ADRs in Male Vs Female Patients:

Female patients were highly affected with DHS [7 (36.84%)] than males [4 (18.18%)], but in case of Drug induced acne form eruption [5 (22.72 %%)] and SJS [3 (13.63%)] male patients were highly effected than female patients i.e. 3(15.78%); 2 (10.52%).

TABLE 7: TYPE OF ADRS IN MALE VS FEMALE PATIENTS

Type of ADR	Male	Female
DHS	4	7
Drug induced acne form Eruption	4	3
SJS	3	2
Fixed drug eruption	2	1
Lichenoid eruption	1	1
Stasis Dermatitis	2	0
Erythema multi formi	0	2
Folliclitis & Rhinofima	1	0
Drug induced vasculitis ulcer	0	1
Nutritional Dermatitis	0	1
Pellagra	1	0
ATT induced erythroderma	1	0
Contact irritant dermatitis	1	0
Steriod induced tinea	0	1
SLE	0	1
TEN	1	0

Causality Assessment:

According to Naranjo causality assessment scale, 29 (70.73%) of reactions assessed to be probable, 10 (24.39%) as possible and 2 (4.8%) reactions were unlikely. Female patients were highly shows probable (73.68%), possible (26.31%) than male patients (68.18%), (22.72%) but in case of unlikely male patients were higher than female.

TABLE 8: CAUSALITY ASSESSMENT

Causality	Causality Number of Patients	Male	Female
Definitive	0	0	0
Probable	29	15	14
Possible	10	5	5
Unlikely	2	2	0

Severity of ADR Distribution:

According to Hartwig severity assessment scale 21 (51.21%) of reactions were assessed to be moderate followed by 14 (34.14%) as severe and 6(14.63%) were mild. In case of mild & severe reactions, male patients (18.18%, 36.36%) shows high incidence than female (10.52%, 31.57%), but moderate (57.89%) reactions were high in female patients than male patients i.e. 45.45%.

TABLE 9: SEVERITY OF ADR DISTRIBUTION

Severity of ADR	Number of Patients	Male	Female
Mild	6	4	2
Moderate	21	10	11
Severe	14	8	6
Fatal	0	0	0

Route of Administration:

Among the different formulations, oral route was associated with maximum cases of ADR i.e. 31 (75.60%), followed by Parenteral [6 (14.63%)] and external route [4(9.75%)]. In case of oral route,

Female patients [16 (84.21%)] were highly affected than males [15 (68.18%)] but in Parenteral and external route male patients [4(18.18%); 3 (13.63%)] were highly effected than females [2 (10.52%); 1 (5.26%)].

TABLE 10: ROUTE OF DRUG ADMINISTRATION VS NUMBER OF PATIENTS

Route	Number of Patients	Male	Female
Oral	31	15	16
Parenteral	6	4	2
External	4	3	0

TABLE 11: MORPHOLOGICAL TYPES OF DERMATOLOGICAL ADRS & SUSPECTED DRUGS

S.No.	Type of ADR	Drugs implicated	No. of cases	% of Cases
1	DHS	Phenytoin(4), meropenemtrihydrate (1), allopurinol (1) leflunomide (1), cefuroxime (1), mycophenolate mofetil (1), isoniazide (1), Piperacillin + tazobactam (1)	11	26.82%
2	SJS	Oxcarbazepine (1), Meropenemtrihydrate(1), Allopurinol (2), Sulphasalazine (1)	5	12.2%
3	Acne form Eruption	Amoxicilline & clavulanicacid (1), Ofloxacin(1) Hydrocortisone(2), Eselicarbazepine (1), Rifampicine(1), ACTH iodides(1),	7	17.2%
4	Fixed drug Eruption	Ofloxacin(1), Oflaxacin & ornidazole (1), Aceclofenac & paracetamol (1)	3	7.3%
5	Lichenoid Eruption	Sodium hypochlorate (1), Sulphasalazine (1)	2	4.8%
6	Stasis dermatitis	Sulphasalazine(1), Aspirin (1)	2	4.8%
7	Erethma multi Formi	Phenytoin sodium(1), Rifampicin (1)	2	4.8
8	Drug induced vasculitis ulcer	Methotrexate (1)	1	2.4
9	Nutritional Dermatitis	Levofloxacine (1)	1	2.4
10	Pellagra	Isoniazide (1)	1	2.4
11	TEN	Nevirapine (1)	1	2.4
12	SLE	Ofloxacine (1)	1	2.4
13	ATT induced Erythroderma	Rifampicine & isoniazide (1)	1	2.4
14	Contact irritant Dermatitis	Benzalkonium (1)	1	2.4
15	Folliclitis and Rhinofima	Carbamazepine & sulphamethoxazole (1)	1	2.4
16	Steroid induced tenia	Clobetasol(1)	1	2.4

DISCUSSION: Drugs can be remarkably beneficial, lengthen life and improve its quality by reducing symptoms and improving well-being. However, all drugs have adverse effects and carry the potential for causing injury, even if used properly. Proper data about the adverse effects of drugs helps physicians to use drugs balancing the benefits and hazards. Adverse drug reactions are undesirable effects of drugs beyond its anticipated therapeutic uses occurring commonly in clinical practice. Although many of these ADRs are mild and disappear when the suspected drug is stopped or dose is reduced, some are more serious and last longer. Many studies have been published regarding hospital admission due to ADRs and it has been estimated that 2.9% to 5.6%of all hospital admissions are due to ADRs and 35% of the hospitalized patients experience an ADR during their hospital stay. Thus ADRs increase not only morbidity and mortality, but also add to the overall healthcare cost [4].

In the present study a total of 1125 patients' data were collected from six months study period. Out of 1125, 41 (3.64%) ADRs were identified. From among the41patients, 22 (53.65%) were males and

females were 19 (46.34%). This gender distribution percentage was similar to previous study in south India (52% & 48%), but lesser when compared with study in Chandigarh (59.6% & 40.4%).The mean age of our study is 37.95±2.75 years, in Nepal [5] it was 34.65 years and 37.06 years in Pondicherry. Among the all age groups, 21-30 (21.9%) years patients were highly affected with ADRs, followed by 31-40 years and 41-70 years, but in Pondicherry [6] 21-39 (52.2%) years and in South India [7] 21-40 years age group patients were highly affected than other age groups.

This study shows the high incidence of DHS 11 (26.8%), followed by drug induced acne form eruption 7 (17.2%), SJS 5 (12.2%), fixed drug eruption 3(7.3%), lichenoid eruption 2 (4.8%), erythematic multi formi 2 (4.8%) and Stasis dermatitis 2 (4.8%). But this result is different from the other studies in Chandigarh, Thailand [39], Bangalore [8], Pondicherry [9] and Nepal [10] , which all these studies showsthe high incidence of maculopapular rashes, fixed drug eruptions, urticaria, SJS and erythema multi formi. Among the 11 cases of DHS, 7 (36.84%) ADRs were observed infemale patients, but in case of Drug induced acne form eruption [5 (22.72 %%)] and SJS [3 (13.63%)] male patients were highly effected than female patients i.e.3 (15.78%); 2(10.52%). The therapeutic drug classes most commonly implicated in the reported ADRs were analyzed. They were Antibiotics13 (31.7%), followed by Anti epileptics 7(17%) ATT 5 (12.1%), Steroids 3 (7.3%), Anti gout 3 (7.3%), NSAIDS 3(7.3%) and others include Immunosuppressant's, Anti cancer drugs and oral contraceptives.

In antibiotic category, flouroquinolones (5 cases) were most common followed by sulphasalazine (3 cases). In case of Anti epileptics, Phenytoin sodium (5 cases) was common drug and steroids include hydrocortisone (2 cases). This order was similar to previous studies in Thailand [11], South India [12] and Nepal [10], but percentages was different i.e. 45% of Antibiotics, 19% of Antiepileptics in South India & 45% of Antibiotics , 30% of Antiepileptics in Nepal. But some previous studies (Chandigarh, Bangalore [13], Pondicherry [14]) shows high incidence of ADRs produced by Anticonvulsants (41.6%) followed by sulfonamides (43.3%) and NSAIDS (24.3%) at Chandigarh.

TABLE 12: COMPARISON STUDY

Place	Duration	No. of ADRs	Mean Age	M/F %	ADRs	Drugs
Current study (Hyderabad)	6 months	**41**	37.9	53.6/46.4	DHS (26.8%), Acne form eruption (17.2%), SJS (12.2%)	Antibiotics (31.7%), Antiepileptics (17%), ATT (12%), Steroids (7.3%)
Chandigarh	6 years	**500**	-----	59/41	Maculopapular rash (34.6%), FDE (30%), Urticaria (14%)	Anticonvulsants (41.6%),Sulfonamides (43.3%),NSAIDS (31%),Pencillins(20%)
Thailand [39]	1 year	**132**	-----	------	Maculopapular rash ,FDE, Urticaria	Antibiotics Antifungals
Bangalore **[40]**	11 months	**56**	-----	-----	Maculopapular rash (35%), TEN (20%), SJS (15%)	Antiepileptics (56%)
Pondicherry **[38]**	2 years	**90**	37.06	------	FDE(31.1%),Maculopapular rash (12.2%)	Cotrimoxazole (22%), Dapsone (17.7%)
South India **[28]**	9 years	**404**	-----	52/48	Maculopapular rash (42.7%), SJS (19.5%), FDE (11.4%)	Antibiotics (45%), Antiepileptics (19%), NSAIDS (19%)
Nepal	4 years	**33**	34.5	-----	EM , SJS, TEN	Antibiotics, Anticonsulvants, NSAIDS

In this study, the DHS (11 cases) was most caused by Phenytoinsodium (4 cases, 36.36%) followed by Meropenamtrihydrate (1case), Allopurinol (1case), Leflunomide (1case), Cefuroxime (1case), Mycophenolatemofetil (1case), Isoniazid (1case) and Piperacillin with Tazobactum (1case) combination. In case of Acne form eruption (7 cases) mostely occurred by Hydrocortisone (2

cases, 28.57%) followed by amoxicillin with clavulanic acid, Eselicarbazapine, Rifampicin and Ofloxacin. SJS (5 cases) mainly occurred by Allopurinol (2 cases, 40%) followed byoxcarbazepine, Meropenamtrihydrate, Sulfasalazine.

In case of fixed drug eruption (3cases) caused by ofloxacin (2 cases, 66.6%).According to Naranjo causality assessment scale, probable cases were 29(70.73%), possible were 10 (24.39%) and 2 (4.8%) reactions were unlikely. Female patients were highly shows probable (73.68%), possible (26.31%) than male patients (68.18%), (22.72%) but in case of unlikely male patients were higher than female. According to Hartwig severity assessment scale, moderate reactions were 21 (51.21%) and followed by 14 (34.14%) as severe and 6 (14.63%) were mild.

In case of mild & severe reactions, male patients (18.18%, 36.36%) shows high incidence than female (10.52%, 31.57%), but moderate (57.89%) reactions were high in female patients than male patients i.e. 45.45%. In this study, maximum ADRs occurred by oral route i.e. 31 (75.60%), followed by Parenteral [6 (14.63%)] and external route [4 (9.75%)]. In case of oral route, female patients [16 (84.21%)] were highly affected than males [15 (68.18%)]. Butin Parenteral and external route, male patients [4 (18.18%); 3 (13.63%)] were highly effected than females [2 (10.52%); 1 (5.26%)].

CONCLUSION: Adverse drug reactions are unwanted or unintended effects of drugs, which occurs during its proper usage. The burden of these ADRs on the health care system account for considerable morbidity, mortality and extra costs. The present study shows that,

- Total number of ADRs observed was 41. The incidence of ADR was 3.64%.
- The mean age of this study was 37.95± 2.75 years.
- Most ADRs occurred in age group of 21-30 years followed by 31-40 years.
- The incidence of ADRs more in male (53.65%) patients than female (46.34%) patients.
- Most common ADRs were DHS (26.8%), Acne form eruption (17.2%), SJS (12.2%) and FDE (7.3%).
- Most common caused drugs were Antibiotics (31.7%), Antiepileptics (17%), Antituberculor drugs (12.1%) and Steroids (7.3%).
- According to Naranjo Causality assessment scale, 70.7% of probable ADRs, 24.39% of possible and 4.8% ADR reactions were unlikely.
- According to Hartwig severity assessment scale, 51.21% of moderate ADRs, 34.14% of severe and 14.6% ADR reactions were mild.
- Most of the ADRs were occurred by oral route (75.6%) followed by parenteral (14.63%) and external route (9.75%).
- There is statistical significant was found between the gender and incidence of ADRs i.e. p value is 0.0096.

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