



## Incidence of Adverse Drug Reactions in a South Indian Tertiary Care Hospital

Authors

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### Abstract

*The World Health Organization defines an adverse drug reaction (ADR) as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.” The fact that drugs might have effects on humans other than the ones intended has been known for many years. During the six month study period, a total 232 patients visited the tertiary care hospital and Celestee skin and hair Clinic. Highest number of patients were from the age group of 21-30 i.e. 33.81%. Majority of the ADRs were from the drug class antibiotics 24 (25.35%). According to Naranjo’s causality assessment scale, out of 71 ADRs the dechallenge was done in all cases, out of which 45 cases (63.3%) were probable and 14 cases (19.7%) were possible where as remaining 12 cases (16.9%) were in unlikely category. We also assessed the severity by using Hartwig and Siegel severity assessment scale; it shows that highest number of cases i.e., 42 (59.15%) fall into moderate type and 10 cases (14.08%) were mild type whereas 19 cases (26.76%) fall into severe ADRs.*

**Keywords:** Adverse drug reactions, Pharmacovigilance.

### 1. Introduction

**Definition:** (WHO, 1972)

The World Health Organisation defines an adverse drug reaction (ADR) as “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.” The first remarkable adverse drug reaction (ADR) reported in Japan was anaphylactic shock caused by penicillin. The malformation of limbs, etc. caused by thalidomide was a global problem, and thalidomide was withdrawn from the market. The clinical presentation of cutaneous drug reactions is highly variable, ranging from benign reactions such as

exanthematous or maculopapular eruption to severe and potentially life-threatening reactions such as Stevens-Johnson Syndrome.

### 2. Methodology

The study has been carried out in both outpatient and inpatient departments of Bhaskar General Hospital and Celestee Skin, Laser and Hair Clinic, Hyderabad. The design used for the study is Prospective Observational Study which was carried out for 4 months from November 2017 to Jan 2018.

#### 2.1 Study setting

The study was conducted on patients those who are experiencing Adverse Drug Reactions to medicine

used during their hospital stay or visiting the outpatients department of Dermatology and General Medicine

### Study Criteria

#### Inclusion Criteria

- Study includes adults, pediatric and geriatric patients.
- Subjects who are under multi drug therapy.
- Subjects under long term treatment.
- Subjects detected with ADRs

#### Exclusion Criteria

- Expectation of surgery
- Pregnant Women's
- Lactating mothers.
- Study population

The patients who were coming to the dermatology and general medicine departments of Bhaskar General Hospital and Celestee Skin, Laser and Hair Clinic Hyderabad during November 2017 to January 2018 were enrolled in the study.

### 2.2 Data collection

The data was collected on regular basis with direct patient interaction at inpatient and outpatient wards of Dermatology and General Medicine departments. It includes patient's demographic details, medical history, medication history, social history and present medications which are the main sources to find out the possibility of adverse drug reactions.

### 2.3 Analysis of ADRs

The reported CADR<sub>s</sub> can be analyzed by considering the following methods:

Causality assessment of the ADRs based on the scores of the Naranjo's probability scale: Probability is assigned via a score termed definite, probable, possible or doubtful. Values obtained from this algorithm are sometimes used in peer reviews to verify the validity of author's conclusions regarding adverse drug reactions. Severity assessment of ADRs analyzed by using the Modified Hartwig's and Siegel Severity assessment scale this can be classified into Mild, Moderate and Severe.

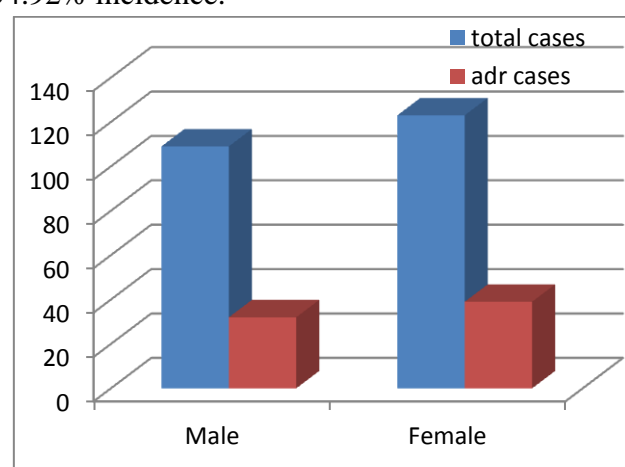
### 3. Results

The study was conducted for four months during which a total 232 patients visited the Dermatology and General Medicine departments. The demographic details are as follows:

**Table-1:** Gender wise distribution of Adrs

Gender	Male	Female
Total cases	109	123
ADR cases	32	39

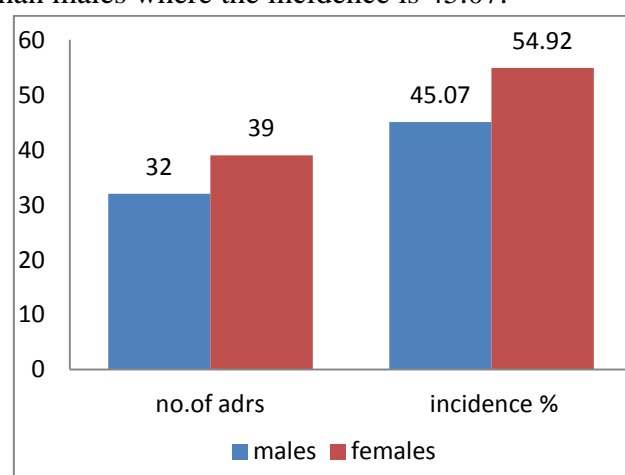
In a total of 232 patients, the ADR patients were 71. And among those reported 71 cases, 32 were male with 45.07% incidence and 39 were female with 54.92% incidence.



**Table-2:** Gender wise Incidence of ADRs

Gender	No. of ADRs	Incidence%
Males	32	45.07
Females	39	54.92

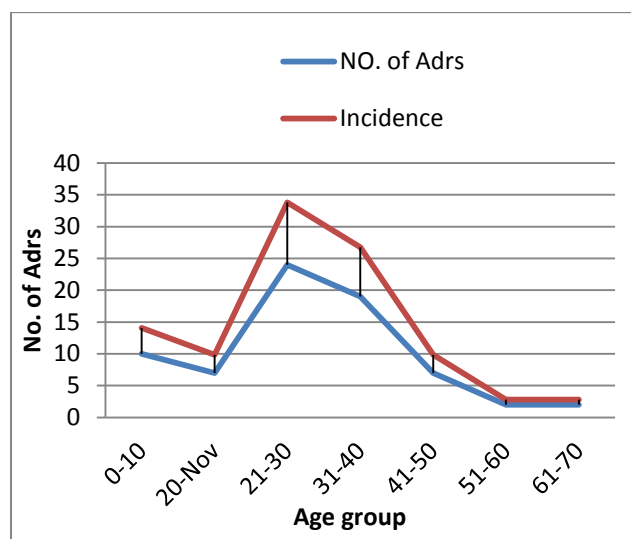
Among the reported 71 ADRs, the incidence of females is 54.92% which is relatively 9% higher than males where the incidence is 45.07.



**Table-3:** Age wise distribution of ADRs

Age	No. of ADRs	Incidence%
0-10	10	14.08
11-20	07	9.85
21-30	24	33.8
31-40	19	26.76
41-50	07	9.85
51-60	02	2.81
61-70	02	2.81

Based on age, the age-group of 21-30 had relatively highest number of ADRs i.e., 24 cases (33.8%) followed by the age group 31-40 with 19cases (26.76%). The age groups 11-20 and 41-50 had same number of ADRs with 07 cases (9.85%) each. Similarly the age groups 51-60 and 61-70 shared same number of cases that is 02(2.81%) ADRs each

**Table-4:** Age wise distribution of ADRs among gender

Age	Males	Incidence	Females	Incidence
0-10	4	12.5	6	15.3
11-20	4	12.5	3	7.6
21-30	9	28.1	15	38.4
31-40	9	28.1	10	25.6
41-50	3	9.3	4	10.2
51-60	1	3.1	1	2.5
61-70	2	6.2	0	0

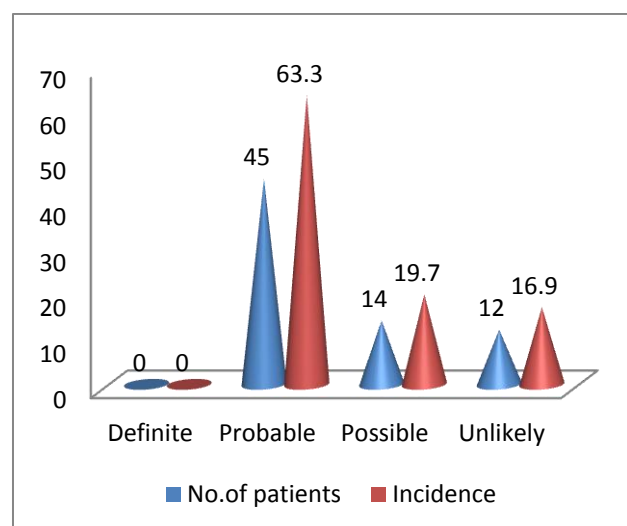
Distribution of cases based on Gender among different age groups is seen in the table. There were 04 male cases each in the age groups 0-10 and 11-20 with 12.5% incidence whereas there were 06(15.3%) and 03(7.6%) female cases respectively.

Similarly the age groups 21-30 and 31-40 shared same number of male cases that is 09 with 28.1% incidence while female cases were 15(38.4%) and 10(25.6%) respectively. The age group 41-50 had 03 male cases with 9.3% incidence and 04 female cases with 10.2% incidence. The age group 61-70 had 02 male cases with 6.2% incidence with no female case. Finally the age group 51-60 had least number that is a single (1) male case with 3.1% incidence and a single female case with 2.5% incidence

**Table-5:** Distribution of Naronjo Causality Assessment Scale

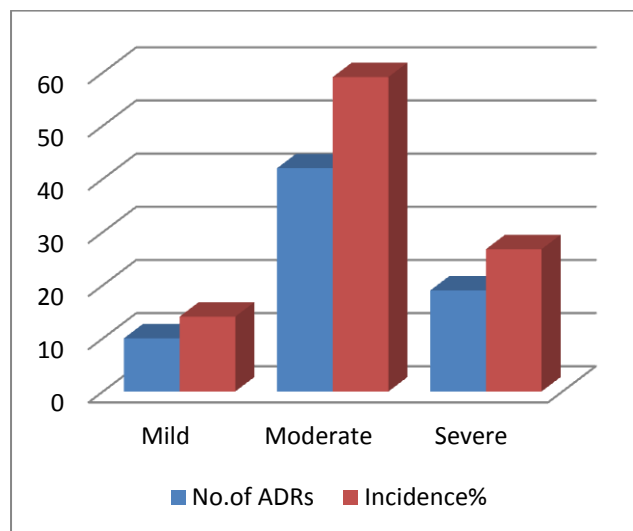
Causality	No.of ADRs	Incidence%
Definite	0	0
Probable	45	63.3
Possible	14	19.7
Unlikely	12	16.9

In the causality assessment using the scale, there were 45 cases with 63.3% incidence that were found to be probable type, 14 cases with 19.7% incidence that were possible type and 12 cases with 16.9% incidence that were unlikely type. There were zero (0) cases that came under definite category

**Table-6:** Distribution of Hertwig and seigel severity assessment scale

Severity	No.of ADRs	Incidence%
Mild	10	14.08
Moderate	42	59.15
Severe	19	26.76

On categorizing the drug based on their severity most of them fell under Moderate category with 42 cases and 59.15% incidence followed by the category Severe with 19 cases and 26.76% incidence and the least were under Mild category with 10 cases and 14.08% incidence



#### 4. Discussion

The study was aimed at assessing the incidence of ADRs in the population of age group from 1- 70 years. Out of 232 patients 71 cases were suspected with the ADRs in the Dermatology and General medicine departments. Of the total cases 32 ADRs were males and 39 ADRs were females. Highest number of patients were from the age group of 21-30 i.e. 24ADRs with 33.8% incidence followed by 31-40 i.e. 19 ADRs with 26.76% incidence, which is in accordance with the Sharma *et al.* study that also reported similar observations. (Sharma *et al.*, 2001). According to Naranjo's causality assessment scale, of the total ADRs the dechallenge was done in all cases, and was found out that most of them were Probable cases with 45 ADRs at 63.3% incidence, whereas Possible cases were 14 ADRs at 19.7% incidence followed by Unlikely cases with 12 ADRs at 16.9% incidence. The severity assessment of cases was also done using Hartwig and Siegel severity assessment scale; which shows that highest number of cases i.e., 42(59.15%) fall into moderate type, 19 cases(26.76%) were Severe type and 10 (14.08%) cases were mild type.

#### 5. Conclusion

In our study we screened a number of subjects attending Dermatology and General Medicine departments. The findings of which were as follows A total of 232 patients were screened of which 71 patients were found with ADRs, among which females were reported with more ADRs than males. The number of ADRs reported in the age group of 21-30 were more prominent than other age groups. Causality assessment was performed using Naranjo's Causality Assessment scale through which it is concluded that more number of ADRs reported were of probable type followed by Possible and Unlikely types. The Severity Assessment was performed using Hertwig & Seigel Severity Assessment scale where most of them were of Moderate category followed by Severe and Mild types.

#### 5.1 Drug Therapies that could be used in case of ADRs

Corticosteroids (applied topically, taken orally, or given intravenously), such as Prednisone, hydrocortisone.

Antihistamines, Antipruritic treatments (to relieve itching)

Surgical removal of dead tissue debris may be necessary in cases of severe reactions.

#### Nutrition

Vitamin C helps skin heal. Some studies suggest that vitamin C can lower histamine levels (which cause hives). Lower dose if diarrhea develops.

B-complex with extra B12 aids in skin health. Vitamin B12 injections help reduce the severity of hives, but it is not clear whether taking B12 orally has the same effect. Vitamin B5 or Pantothenic acid helps heal wounds.

Vitamin E and zinc help skin heal. Both are also sometimes applied topically.

Bromelain, an enzyme derived from pineapple, reduces inflammation.

Omega-3 fatty acids, such as those found in fish oil, help maintain skin health and may have anti-inflammatory properties. If you take blood-thinning

medication, talk to your doctor before taking omega-3 fatty acids.

Rutin or quercetin may improve skin health.

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