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Inclination of Pharmacological Drugs in Incidence of ADRs

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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. Antibiotics was highest in affecting patients whereas most cases were of Drug Induced Urticaria and Oral Route being the most common.***

Keywords: Adeverse Drug Reaction, Pharmacology

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 caused by thalidomide was a global problem, and thalidomide was withdrawn from the market.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 (SJS).Some drug eruptions, although trivial, may cause cosmetic embarrassment and Fixed Drug Eruption is one of them. Several anti-tuberculosis agents have been implicated as being Hepatotoxic. Isoniazid and Pyrazinamide cause Hepatic Dysfunction more frequently than ethambutol and streptomycin, which cause hepatitis problems rarely

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. About the study design this is a Prospective Observational Study which was carried out for four 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

2.2 Study Criteria:

a) Inclusion Criteria:
- Study includes adults, pediatric and geriatric patients.
- Subjects who are under multidrug therapy.
- Subjects under long term treatment.
- Subjects detected with ADrs

b) Exclusion criteria
- Expectation of surgery
- Pregnant Women's
- Lactating mothers.

2.3 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.

2.4 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.

2.5 Analysis of ADRs

The reported ADRs can be analyzed by considering the following methods:

Distribution of ADRs by pharmacological drug category for example Antitubercular drugs, NSAIDs,etc and Genderwise distribution of ADRs by pharmacological drug category, Distribution of types of ADRs for example Steven Johnson Syndrome, Drug Induced Urticaria,etc and Genderwise Distribution of types of ADRs, Distribution of ADRs based on Route of Administration.

3. Results

Table 1 and Figure 1: Distribution of adrs by pharmacological drug category

Pharmacological Class	No.of ADRs	Incidence%
Antitubercular drugs	6	8.45
NSAIDs	10	14.08
Antibiotics	18	25.35
Anti convulsants	4	5.63
Corticosteroids	6	8.45
Ayurvedic medicines	9	12.67
Anti-fungals	1	1.4
Anti-diabetics	2	2.81
Others	15	21.12

The different drug categories that were responsible for different ADRs are shown with their respective incidence rates. The highest incidence was seen with Antibiotics i.e.,25.35% with 18 cases followed by drugs that come under Others category with 15 cases(21.12%) in turn followed by NSAIDs with 10 cases(14.08%). Ayurvedic drugs had 12.67% incidence with 9 cases followed by Anti-tubercular drugs and Corticosteroids having similar incidence at 8.45% with 06 cases. The least incidence was seen in the category of Anti-convulsants, Anti-diabetics and Anti-fungals ranging from 1.5-6.0% incidence with 4,2 and1 case(s) respectively.

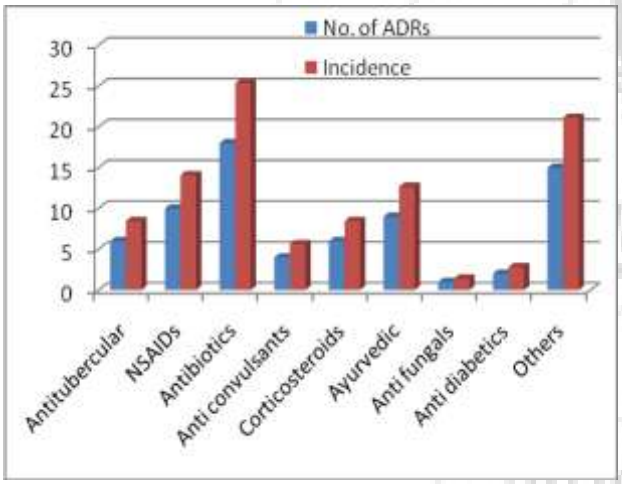


Table 2 and Figure 2: Genderwise Distribution of adrs by pharmacological drug category

Pharmacological class	Males	Incidence	Females	Incidence
Antitubercular drugs	4	12.05	2	5.1
NSAIDs	5	15.6	5	12.8
Antibiotics	6	18.7	12	30.7
Anti-convlsants	2	6.2	2	5.1
Corticosteroids	3	9.3	3	7.6
Ayurvedic medicines	4	12.5	5	12..8
Anti-fungals	0	0	1	2.5
Anti-diabetics	1	3.1	1	2.5
Others	7	21.8	8	20.5

The incidence of Gender among the drug categories is shown here. There were 04 male cases(12.05%) and 02 famale cases(5.1%) in Anti tubercular class,05 male and female cases(15.6%) each in NSAIDs class. Antibiotics class includes 06 male cases (18.7%) and 12 female cases (30.7%).

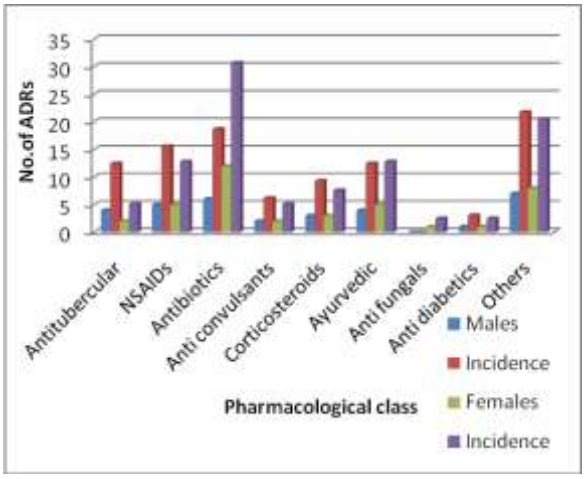


Table-3 and Figure-3: Distribution of types of adrs

Types of ADR	No.of ADRs	Incidence
Steven Johnson Syndrome	3	4.2
Drug Induced Urticaria	19	26.7
Steroid Induced Acne	8	11.2
Fixed Drug eruption	12	16.9
Local Dermatitis	16	22.5
Drug Induced Hepatitis	2	2.8
Drug Induced Gastritis	3	4.2
EMF	6	8.4
Drug Induced Hyperglycemia	1	1.4
Drug Induced Nausea	1	1.4

There are different types of ADRs that were reported which have their repective incidence rates. Highest among them was Drug Induced Urticaria with 19ADRs accounting for 26.7% incidence followed by Local Dermatitis with 16ADRs and 22.5% incidence which in turn is followed by Fixed Drug Eruption with 12ADRs and 16.9% incidence. Steroid Induced Acne and EMF accounted for 11.2% and 8.4% incidence with 08ADRs and 06ADRs repectively. Steven Johnson Syndrome and Drug Induced Gastritis had same incidence rate at 4.2% with 03 ADRs each. The least types of ADRs seen were Drug Induced Hyperglycemia and Drug Induced Nausea at 1.4% incidence with 1ADR each

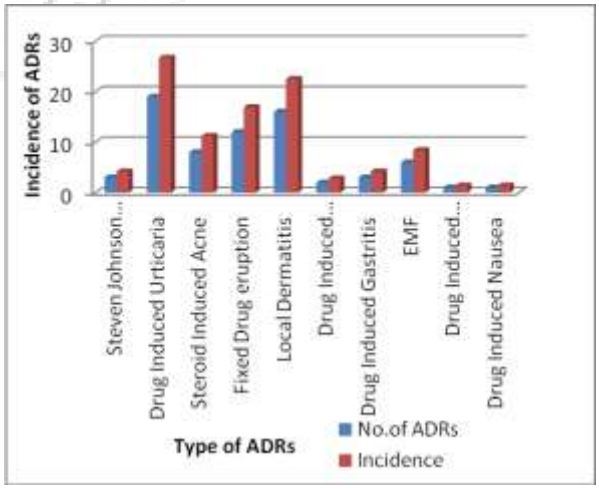


Table 4 and Figure 4: Genderwise Distribution of types of adrs

Table 4 and Figure 4: Genderwise Distribution of types of adrs

Type of ADRs	Males	Incidence	Females	Incidence
Steven Johnson Syndrome	2	6.2	1	2.5
Drug Induced Urticaria	6	18.7	13	33.3
Steroid Induced Acne	5	15.6	3	7.6
Fixed Drug eruption	6	18.7	6	15.3
Local Dermatitis	5	15.6	11	28.2
Drug Induced Hepatitis	1	3.1	1	2.5
Drug Induced Gastritis	1	3.1	2	5.1
EMF	3	9.3	3	7.6
Drug Induced Hyperglycemia	1	3.1	0	0
Drug Induced Nausea	0	0	1	2.5

The types of ADRs with repect to Gender is seen here. There were 02 male cases and 01 female case of Steven Johnson Syndrome type,06 male cases and 13 female cases of Drug Induced Urticaia,05 male and 03 female cases of Steroid Induced Acne. Same number of male and female cases i.e,06 were of Fixed Drug Eruption and also in both Drug Induced Hepatitis i.e.,01 cases and EMF i.e,03 cases each respectively. In Local Dermatitis there were 05 mlae and 11 female cases. One male case of Drug Induced Hyperglycemia and one female case of Drug Induced Nausea was seen. In Drug Induced Gastritis there was 01 male case and 02 female cases.

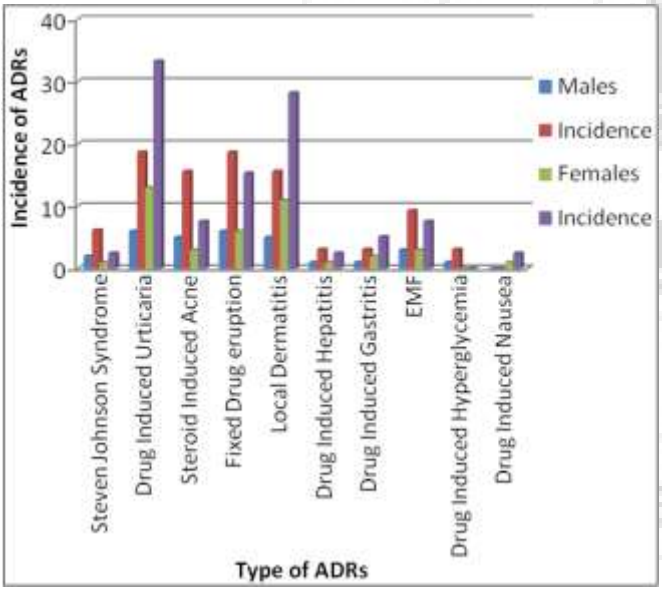
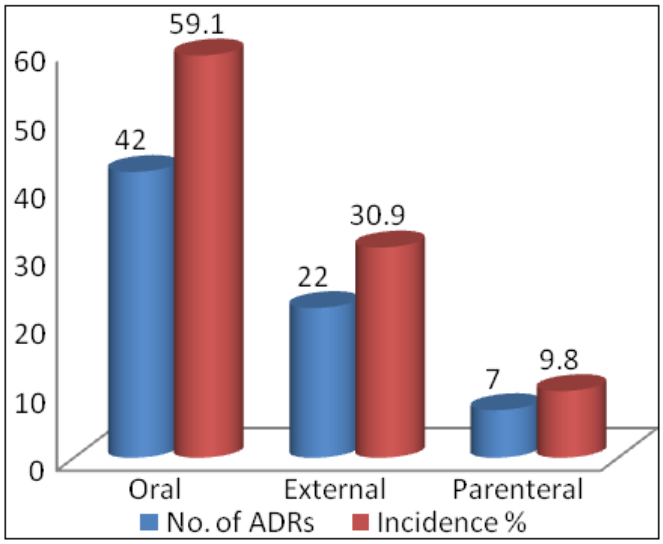


Table 5 and Figure 5: Distribution of ADRs based on Route of Administration

Route of Administration	No. of ADRs	Incidence %
Oral	42	59.1
External	22	30.9
Parenteral	07	9.8

Based on Route of Admnistration, most of the ADR cases were seen with Orally administered drugs with 42 cases at 59.1% incidence followed by External route with 22 cases at 30.6% incidence. Of all the least cases were through Parenteral route with 07 cases at 9.8% incidence



4. Discussion

The study was done by screening a number of subjects. In a total of 232 screened patients, the incidence of Antibiotics was highest at 25.35% affecting 18 patients which also accounted for highest number in females with 12 cases followed by drugs of Others category at 21.12% incidence affecting 15 patients which accounted for highest number in males with 7 cases which is in turn followed by NSAIDs at 14.08% incidence. Among the types of ADRs most of the cases were Drug Induced Urticaria with 19cases at 26.7% incidence. Next most were Local Dermatitis with 16cases at 22.5% incidence followed by Fixed Drug eruption type with 12cases at16.9% incidence. Based on route of Administration the highest number of cases seen were of Oral route with 42cases at 59.1% incidence followed by External and Parenteral routes with 22 and 07 cases at 30.9% and 9.8% incidences respectively.

5. Conclusion

In this study, ADRs were systematically reviewed from selected published studies. Cutaneous reactions were the most common manifestations of ADRs. (Martin and Li, 2008) 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 ADRs in the dermatology and general medicine departments. Among the reported 71 ADRs males accounted for 32cases with 45.07% incidence and females for 39cases with 54.92% incidence

Among the prescriptions with various Pharmacological Drug categories that were assessed, the incidence of ADRs was highest with Antibiotics and drugs that come under Others category in turn followed by NSAIDs. Ayurvedic drugs were also prominent. Anti-tubercular drugs and Corticosteroids had similar incidence. The least incidence was seen in the category of Anti-convulsants, Anti-diabetics and Anti-fungals. Most of the cases were Drug Induced Urticaria and Local Dermatitis followed Fixed Drug Eruption. Whereas the Oral route was the most common route followed by External route and the least route was Prenteral route.

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