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Identification, Evaluation, and Assessment of Suspected Adverse Drug Reactions in a Tertiary Care Teaching Hospital

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Keywords: Naranjo's causality assessment scale, Hartwig's severity assessment scale, Gynaecomastia, Hematuria, Maculopapular drug eruption, NSAIDs

ABSTRACT

Background: The World Health Organisation (WHO) defines adverse drug reactions as a response to a drug that is harmful and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of body functions. Adverse drug reactions (ADRs) are classified into Type A (Augmented), Type B (Bizarre), Type C (Continuous), Type D (Delayed), Type E (End of stage), and Type F (Failure). **Aims and Objectives:** To Identify the prescription/case sheets based on the possibility or probability of obtaining suspected Adverse drug reactions to assess the identified suspected adverse drug reactions on the basis of Naranjo's Causality Assessment scale and Hartwig's severity assessment scale. **Method:** A prospective observational study was conducted on in-patients admitted to a tertiary care teaching hospital. Data regarding the patient's demographic details, diagnosis, complete prescription, and any other information will be collected in a predesigned pro forma. The collected data were assessed and thoroughly analysed. **Results:** Among the total reported ADRs majority of ADRs were identified in the department of Medicine i.e., 53.57%, followed by 32.14% of ADRs found in the department of Dermatology. The majority of the cases (86%) were identified in the General ward. Among the various known patterns of ADRs, the most commonly reported ADRs were gynecomastia (14.28%), hematuria (14.28%%), maculopapular drug eruption (14.28%), etc. **Conclusion:** From our study, we concluded that ADRs is a common occurrence and this study strongly suggests that there is a need for streamlining hospital-based ADR reporting and monitoring system in order to create awareness and to promote the reporting of ADR among HCPs.

INTRODUCTION:

Medicines are a major component of the modern health care system and can be considered as a 'double-edged sword' having both beneficial as well as harmful effects on human beings. Concern is raised within this context worldwide about the increasing number of adverse effects that are caused by drugs. Studies have shown that adverse drug reactions (ADRs) are a major cause of hospitalization and death all over the world [2]. The study of ADRs is the concern of the field known as Pharmacovigilance. The occurrence of adverse drug reaction is a price that the healthcare professionals or rather the patients have to pay for the great benefits that have been produced by modern medicine and which are anticipated to continue to produce in the future.[1] The growing evidence on the increased frequency and severity of ADRs, associated with a negative impact on patient's health status, also reveals that ADRs entail a significant burden on healthcare facilities, increasing the length of hospital stay, and requiring sometimes additional investigations and drug therapies for the treatment of symptoms and diseases caused to the patient .

Pharmacovigilance or ADR monitoring, launched by WHO in the 1960s in the wake of 'thalidomide' disaster, is currently an integrated global effort of more than 70 countries worldwide. After the "thalidomide tragedy" many countries have established drug monitoring systems for early detection and prevention of possible drug-related morbidity and mortality. The use of traditional and complementary drugs (e.g., herbal remedies) may also pose specific toxicological problems, when used alone or in combination with other drugs.[13]

Regulatory authorities have now mandated to track the adverse drug reactions. In India Pharmacovigilance program initiated by Central Drugs Standard Control Organization (CDSCO) of Indian government which regulates the use of drugs and their effects on people. The ADRs among Indian population is monitored by NCC-PvPI and helps the regulatory authority of India (CDSCO) in taking decision for safe use of medicines.

To identify and prevent adverse drug reactions, some methods must be developed that can accurately predict those most at risk for an ADR and identify the severity of the adverse reactions. Pharmacists have an important role in drug safety by contributing to the prevention, identification, assessing, evaluating and reporting of ADRs. All healthcare professionals for that matter are responsible in maintaining a balance in the risk benefit ratio of the medication.

When a drug comes into market, it is very important to identify and assess for any adverse drug reaction caused by the drug. Once a drug is available to the public, the exclusion criteria applied in clinical trials no longer exist; making a determination about its safety is the shared responsibility of all who are a part of the prescribing process, including patients.

Pharmacists clearly understand that no drug product is completely safe and that pre-marketing trials do not fully identify the risks, particularly of recently marketed drugs. So there is a greater and urgent need to create and enhance healthcare professional's awareness about detection, management, prevention and reporting of adverse drug reactions.

Hence a prospective study was done in order to promote the identification, assessing and reporting of suspected ADR's and intervening and providing educational feedback to the patient as well as the health care professionals. This study focuses identifying, assessing and evaluating the suspected adverse drug reactions that will be found in various departments of tertiary teaching care hospital and enhance the reporting of adverse drug reactions for the betterment of patient's quality of life.

MATERIALS AND METHODS:

Study duration and location: The study was conducted for a period of 6 months in all the departments of Shri. B.M.Patil Medical College, Hospital and Research Centre, Vijayapura-586103.

Sample size:

With anticipated Proportion ADRs among in patients of a hospital 96.7**%** [1] the minimum sample size is 26 patients with 1% level of significance and 10 % absolute precision.

Formula used

$$n=\frac{z^2\ p*q}{-\ d^2}$$

Where Z= Z statistic at α level of significance

d^2= Absolute error

P= Proportion rate

q= 100-p

Study Design: The present study is prospective observational study.

Inclusion criteria:

All the in-patients of either sex admitted in various departments of tertiary care hospitals.

Patients willing to provide consent

Exclusion criteria:

Case sheets with incomplete documentation.

Patients unable to respond verbally

Patients in Casualty Department

Ethical clearance: Ethical clearance has been obtained from the Institutional ethics committee.

Source of data: The data was collected from day-to-day review of patient's case files.

Methods:

The clinical pharmacists participated in the ward rounds with the physician for actively monitoring for any ADRs and the prescription / case sheet with a possibility or probability of obtaining suspected Adverse drug reactions were identified (based on factors like polypharmacy, age, co morbid conditions, history of ADR to a drug class, concurrent interactive drugs).

Data regarding patient's demographic details, diagnosis, complete prescription, and any other information was collected in a predesigned pro forma after thorough review of literature. The collected data were assessed and thoroughly analysed. Structured interview with patient was conducted and appropriate analysis was done by using Naranjo's causality assessment scale and Hartwig's severity assessment scale. The suspected ADRs were then reported to the AMC center where assessment of data was reperformed and confirmation of ADRs were done.

Table 1: The Naranjo's Causality Assessment Scale

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

Definite :> =9 or greater, probable for a score of 5-8, possible for 1-4, and doubtful if the score is 0 Report ☐ definite ☐ probable ☐ possible ☐ doubtful

Table 2: Hartwig's Severity assessment Scale:

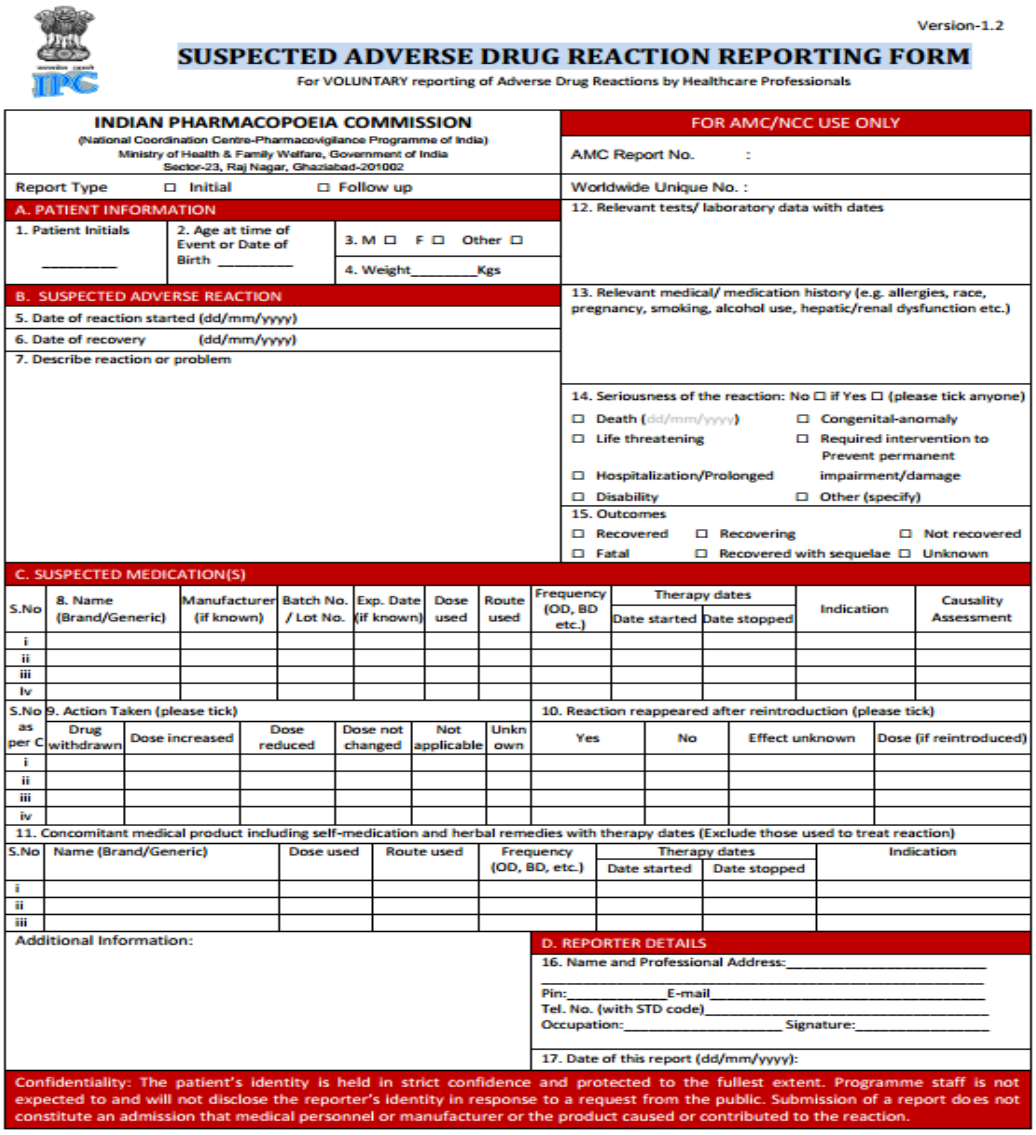
Level	Description
1	An ADR occurred but required no change in treatment with the suspected drug.
2	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. No antidote or other treatment requirement was required. No increase in length of stay (LOS)
3	The ADR required that treatment with the suspected drug be held, discontinued, or otherwise changed. AND/OR An antidote or other treatment was required. No increase in length of stay (LOS)
4	Any level 3 ADR which increases length of stay by at least one day. OR The ADR was the reason for the admission
5	Any level4 ADR which requires intensive medical care
6	The adverse reaction caused permanent harm to the patient
7	The adverse reaction either directly or indirectly led to death of the patient

Mild = level 1 and 2, Moderate=level 3 and 4, Severe=level 5,6 and 7.

Report	☐ Mild	☐ Moderate	☐ Severe

Interventional performed

☐	☐	☐	☐
Drug stopped	**drug replaced**	**supplement added**	**no change**



Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION
(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

FOR AMC/NCC USE ONLY

AMC Report No. :

Report Type ☐ Initial ☐ Follow up

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____
2. Age at time of Event or Date of Birth _____
3. M ☐ F ☐ Other ☐
4. Weight_____Kgs

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent impairment/damage
☐ Hospitalization/Prolonged
☐ Disability ☐ Other (specify)

15. Outcomes
☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Fig.no:1 Suspected adverse drug reaction reporting form

RESULTS:

A total of 28 suspected adverse drug reactions were identified, evaluated, assessed and reported to the AMC centre.

Distribution of Patients According to Gender: During the study period, a total of 28 patients were analysed, out of which 57% were male and 43% were females.

Table 3: Distribution of patients according to Gender.

Gender	No: of cases	Percentage (%)
Male	16	57
Female	12	43
Total	28	100

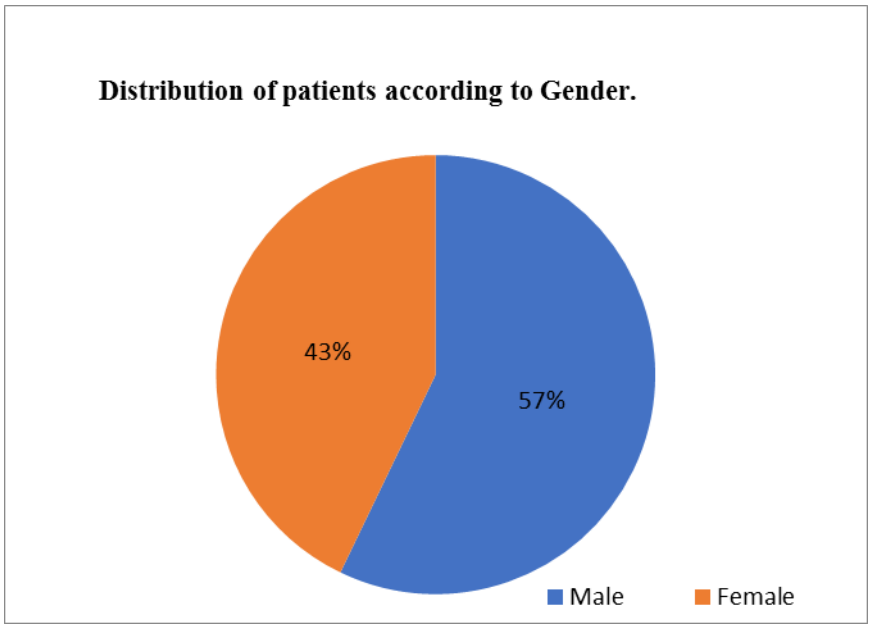


Fig.no:2. Distribution of patients according to gender

DISTRIBUTION OF PATIENTS WITH RESPECT TO AGE (YEARS):

Out of 28 patients studied the majority of the patients belonged to the age group of 18 to 64 years (64%), followed by geriatrics (25%) and 0-18 years (11%) of age groups.

Table 4: Distribution of Patients with respect to Age (Years)

Age group	No. of cases	Percentage (%)
Pediatrics (≤ 18)	3	11
Adults (19-64years)	18	64
Geriatrics (≥ 65)	7	25
Total	28	100

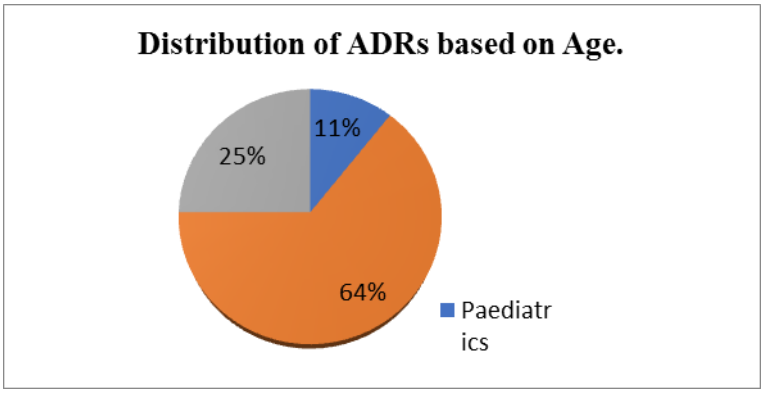


Fig.no:3. Distribution of ADRs based on Age

Distribution of ADRs based on Departments.

A total of 28 ADRs were reported among which majority of ADRs were identified in the department of Medicine i.e., 53.57%, followed by 32.15% of ADRs found in the department of Dermatology.

Table 5: Distribution of ADRs based on departments.

Department	No. of cases	Percentage (%)
Paediatrics	1	3.6
Medicine	15	53.6
Dermatology	9	32.1
Orthopaedics	1	3.6
Obstetrics and gynaecology (OBG)	1	3.6
Urology	1	3.6
Total	28	100

Types of suspected adverse drug reactions

Among the various known patterns of ADRs, the most commonly reported ADRs were gynaecomastia (14.28%), hematuria (14.28%%), maculopapular drug eruption (14.28%), etc.

Table 6: Tables showing types of suspected adverse drug reactions.

Types of suspected ADR's	No. of cases	Percentage (%)
Gynaecomastia	4	14.3
Erythroderma	2	7.1
Bullous Fixed drug eruption	1	3.6
Hypersensitivity reaction	1	3.6
Hyperkalemia	1	3.6
Hepatitis	2	7.1
Headache, back pain and chest pain	1	3.6
Constipation	1	3.6
Angioedema	1	3.6
Pruritis	1	3.6
Angioedema	1	3.6
Anaphylaxis	1	3.6
Pitting edema	1	3.6
Hematuria	4	14.3
Urticarial	1	3.6
Nausea and diarrhea	1	3.6
Maculopapular drug reaction	4	14.3
Total	28	100

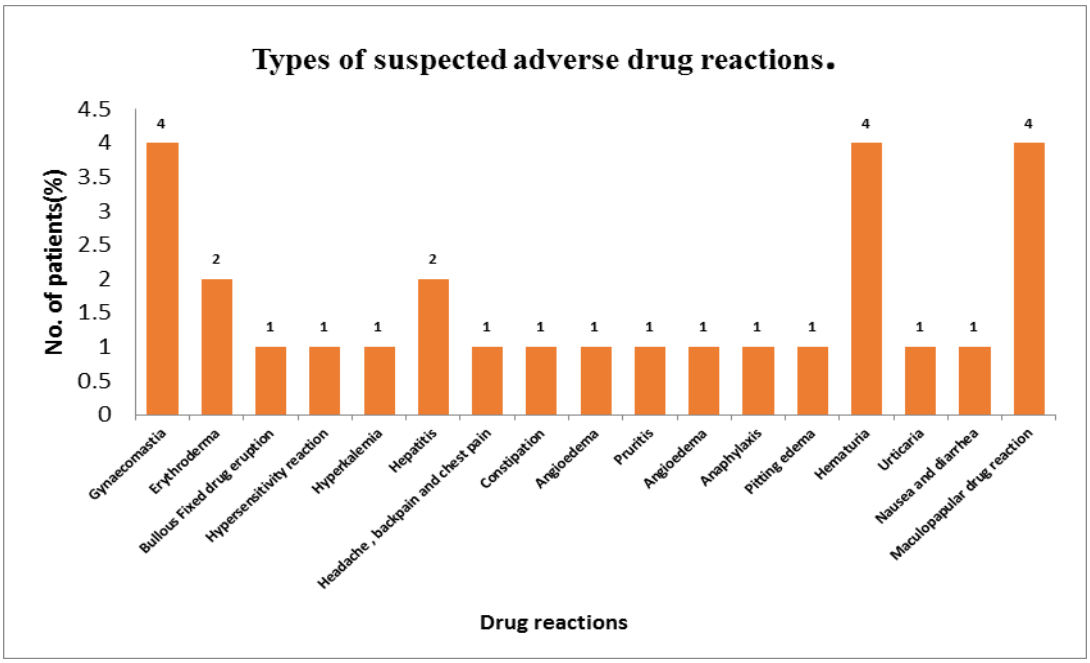


Fig.no:4. Types of suspected adverse drug reactions.

Distribution of ADRs Based on Drug Class:

From the total of 28 ADRs reported, 6 (21.4%) ADRs were associated with antibiotics followed by NSAIDs 4(14.28%), and the least were associated with Antiprotozoals (3.57%), Hormones (3.57%), Iron supplements (3.57%).

Table 7: Distribution of ADRs Based on Drug Class.

Drug Class	No. of cases	Percentage (%)
Antibiotics	6	21.4
Antituberculosis	2	7.1
Iron supplements	1	3.6
Anticonvulsants	2	7.1
Antiplatelet	4	14.3
Cardiac glycosides	2	7.1
Diuretics	3	11
Hormones	1	3.6
NSAIDs	4	14.3
Antivirals	2	7.1
Antiprotozoals	1	3.6
Total	28	100

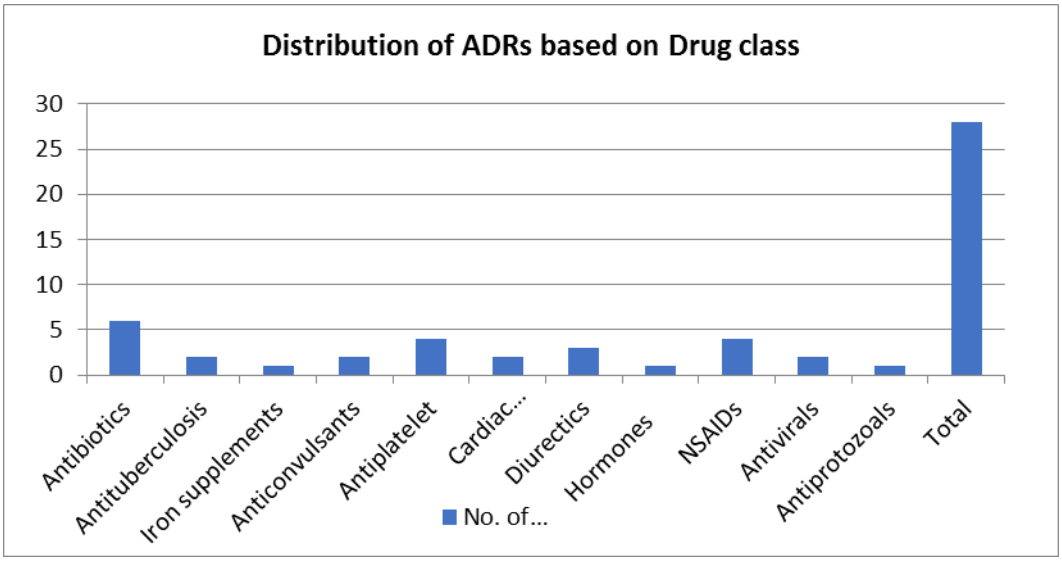


Fig.no:5. Distribution of ADRs based on Drug class

Causality Assessment:

- Naranjo's Causality Assessment
- According to Naranjo's scale majority of the ADRs were probable 14 (50%) followed by possible 9 (32.14%) and definite 5 (17.85%).

Table 8: Naranjo's Causality Assessment

Naranjo's Algorithm	No. of ADRs	Percentage (%)
Definite	5	17.8
Probable	14	50
Possible	9	32.1
Doubtful	0	0
Total	28	100

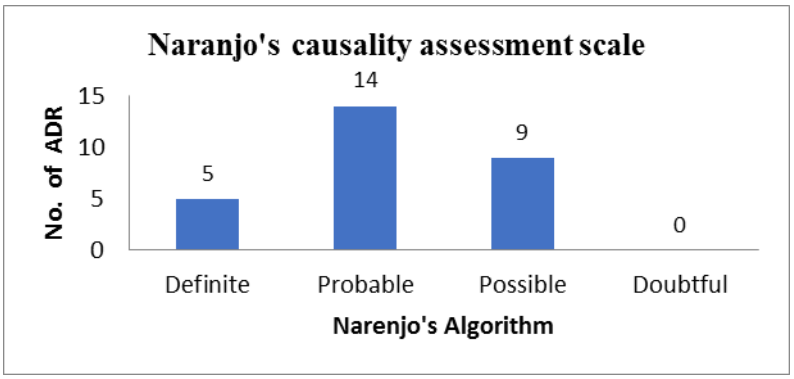


Fig.no:6. Naranjo's causality assessment scale

Severity Assessment based on Hartwig and Siegel's scale:

Of the total of 28 cases 18 were moderately severe (64%) followed by 9 (32%) ADRs of mild severity and 1 (4%) ADRs of severe severity.

Table 9: Severity Assessment Based on Hartwig and Siegel's Scale.

Severity	No. of ADRs	Percentage (%)
Mild	9	32
Moderate	18	64
Severe	1	4
Total	28	100

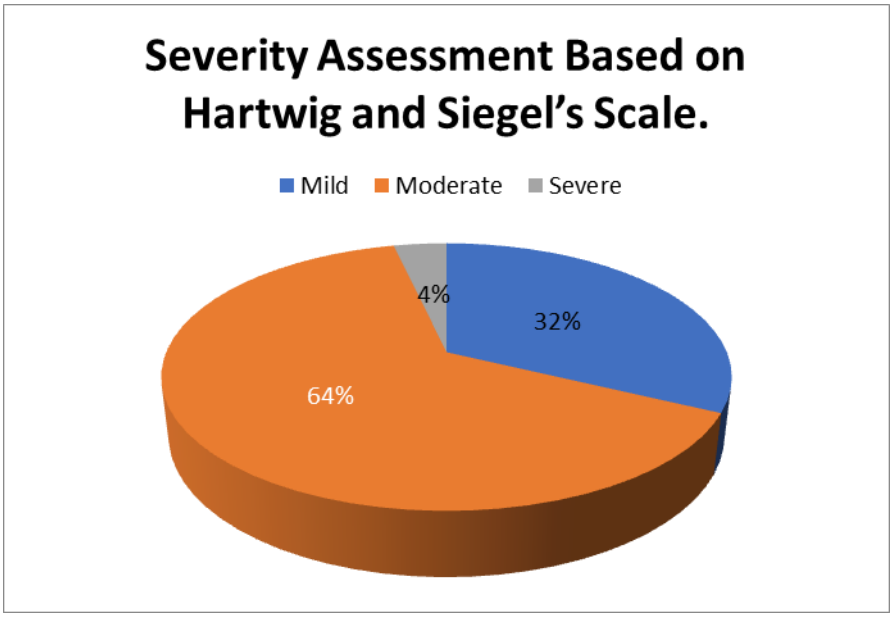


Fig.no:7. Severity Assessment Based on Hartwig and Siegel's Scale.

Interventions provided for the suspected adverse drug reaction

Observations were accepted and the following actions were taken by the physicians. Of the total of 28 cases, in the majority of the cases, the intervention was performed by stopping the drug, 18 (64.28%) and replacing the drug,5 (17.85%).

Table 10: Interventions provided for the Suspected adverse drug reaction

Interventions Performed	No. of ADR's	Percentage (%)
Drug stopped	18	64.3
Drug replaced	5	17.8
Supplement added	1	3.6
No change	3	14.1
Total	28	100

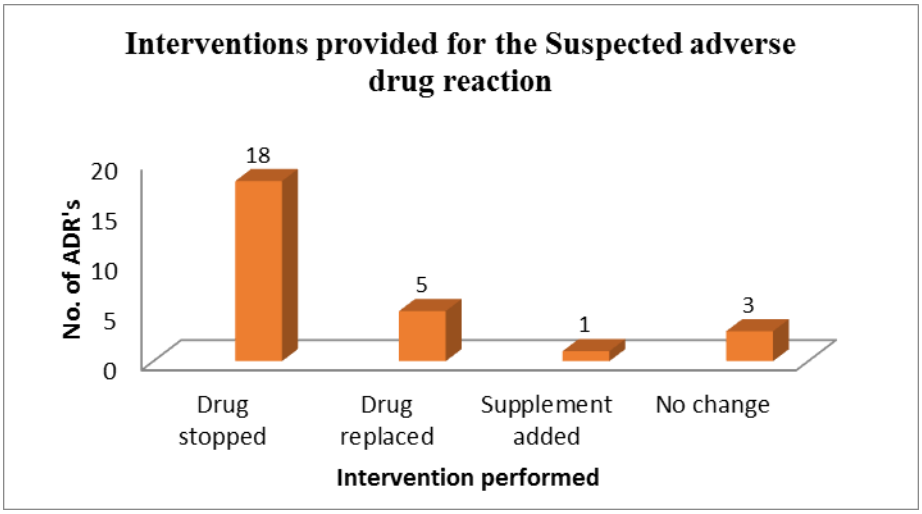


Fig.no:8. Interventions provided for the suspected adverse drug reaction

DISCUSSION:

A prospective observational study was conducted on in-patients admitted in a tertiary care teaching hospital. Data regarding patient's demographic details, diagnosis, complete prescription, and any other information was collected in a predesigned pro forma. The collected data were assessed and thoroughly analysed. A structured interview with patient was conducted and an appropriate analysis was done by using Naranjo's causality assessment scale and Hartwig's severity assessment scale. During the period of 6 months, a total of 28 cases were reported with ADRs.

Data regarding demographic details of patients in our study shows that the suspected ADRs were more commonly seen in male patients 16(57%) than female patients 12(43%) which was in accordance with the conducted by Shivanandy Palanisamy et al., [1]. This incidence of ADRs depends on the population involved in the study and that incidence of ADR(s) does not significantly differ with men or women and some researchers have found that ADRs were unrelated to gender. Suspected adverse drug reactions were found to be more prevalent in the adults (19-64years) i.e, 64% cases, which was found to be in accordance with the study conducted Theresa Anu* et al.,[9]. The reason why higher incidence is observed in adults could be that they have more awareness and accessibility to medical health care. Among the total reported ADRs majority of ADRs were identified in the department of Medicine i.e., 53.57%, followed by 32.14% of ADRs found in the department of Dermatology which was in accordance with study conducted by Theresa Anu* et al., [9]. Among the various known patterns of ADRs, the most commonly reported ADRs were gynaecomastia (14.28%),

hematuria (14.28%%), maculopapular drug eruption (14.28%), etc. In most of the studies, dermatological symptoms were observed in the majority and in this study also dermatological symptoms are one of the major suspected ADRs in accordance with Shivanandy Palanisamy et al., [1], Theresa Anu* et al., [9] **Anita Gupta et al., [19]**

The most common offending drug classes antibiotics. The studies of V**enkaraddi Magannavar Chandrashekhar et al.,[12]** Theresa Anu* et al.,[9] Shivanandy Palanisamy et al., also showed that the most common offending drug classes were antibiotics.

According to Naranjo's scale majority of the ADRs were probable 14 (50%) followed by possible 9 (32.14%) and definite 5 (17.85%) and according to Hartwigs Siegal's severity assessment scale majority of cases were moderately severe (64%) followed by 9 (32%) ADRs of mild severity and 1 (4%) ADRs of severe severity, which was in accordance with the study conducted by Santosh Chandrashekar et al., [11] In this study, of the total of 28 cases, in majority of the cases, the intervention was performed by stopping the drug, 18 (64.28%) and replacing the drug,5 (17.85%). None of the drugs causing ADR led to mortality among the recorded cases.

In hospitals, there is an increasing need to identify, assess, evaluate and report the ADRs to the AMC centers. The health care's professionals are directly involved in the patient care and it becomes their responsibility to monitor the patients and facilitate ADR follow-up and report the identified ADRs to the manufacturer or regulatory authorities.

CONCLUSION:

Adverse drug reactions are an unavoidable risk factor associated with the use of modern medicines. However, careful attention to dosage, age, and renal function can minimize the risk of developing ADRs in many patients. The predominant causative drugs were antibiotics and NSAIDs. Majority of ADRs were probable in causality assessment and moderate in severity assessment. From our study we concluded that ADRs is a common occurrence and this study strongly suggests that there is a need for streamlining hospital-based ADR reporting and monitoring system in order to create awareness and to promote the reporting of ADR among HCPs.

ABBREVIATIONS:

ADR- Adverse drug reaction

NSAIDs- Non-steroidal anti-inflammatory drugs

WHO- World health organization

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Nil

CONFLICT OF INTEREST:

The authors declare no conflict of interest.

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