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Open Access Case Report

ANALYSIS OF PATIENT ADMISSIONS IN HOSPITAL DUE TO ADVERSE DRUG REACTION

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ABSTRACT

The present study is prospective and observational non-interventional study was conducted in tertiary care center. All suspected ADRs which are observed in hospital stay will be assessed for causality, severity, preventability and predictability. The results were presented as number and percentage. Among the 7697 cases (both males and females), a total of 240 ADRs were detected, an overall incidence of 03.11 % adverse drug reactions in inpatients. The high prevalence of ADR mostly observed in the age group between 1-10 years 48 (20.00%) From this 240 ADR's where 7.96% on continuing t, 38.36% are recovering, 47.08% are recovered.

Keywords: Adverse drug reaction, Causality, Severity, Preventability, Probability.

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INTRODUCTION

The WHO defines an "Adverse drug reactions "any response to a drug which is noxious and unintended and which occurs or doses normally used in man of prophylaxis diagnosis or therapy of disease or for the modification of physiologic function".[1]

Pharmacovigilance has been defined by the WHO as 'the science and activities relating to the "detection, assessment, understanding and prevention of adverse effects or any other drug-related problems".[2]

Adverse drug reactions (ADRs) are types of adverse drug events (ADEs). ADEs include ADRs, medication errors and other drug-related problems. ADEs are the negative consequences of drug misadventures. Henri Manasse defined drug misadventure as the iatrogenic hazard that is an inherent risk when drug therapy is indicated.

The American Society of Health- System Pharmacists (ASHP) defines significant ADRs as any unexpected, unintended, undesired, or excessive response to a drug that includes the following.[3,4,5]

- Requires discontinuing the drug
- Requires changing the drug therapy
- Requires modifying the dose
- Necessitates admission to the hospital
- Prolongs stay in a health care facility
- Necessitates supportive treatment
- Significantly complicates diagnosis
- Negatively affects prognosis or results in temporary or permanent harm, disability or death.

METHODOLOGY

Study Location

The study is carried out at Aware Global Hospital in General Medicine & all Clinical Departments.

Study Design

Prospective, Observational and Non- interventional.

Study Period

Study period for data collection was carried out for 3years (March 2015 To March 2018 **)**

Study Setting

Study includes only those patients who experience an adverse reaction to medicine used either during their stay in hospital (IPD) or visiting the outpatient departments (OPD).

Patients Selection:

Study participants were inpatients in general medicine department according to the inclusion and exclusion criteria.

Inclusion Criteria

- All patients admitted in Aware Global Hospitals.
- All suspected ADRs that conforms to WHO's definition.
- Patients of either sex receiving treatment.
- Any patient who developed ADR during the treatment period.
- Patients willing to Participate.

Exclusion Criteria

- Out Patient Dept. (OPD) patients.
- Day care surgery patients.
- Patients unable to respond to verbal questions.
- Patients who are not willing to participate.
- Emergency Patients.

ANALYSIS OF ADRs

Types of adverse drug reactions based on Rawlins and Thompson classification:

In this classification, the ADRs are categorized into two classes viz type A and type B reactions.

Causality Assessment:[7]

Different scales for assessing causality relationship between suspected drug and reaction was established by using World Health Organization **(WHO) Causality Assessment Scale .**

Severity Assessment:

The severity of reported reactions was assessed by using **Hartwig & Seigel scale** which are categorized into mild, moderate and severe

Preventability Assessment:

The preventability of reported ADRs was assessed by **using Modified Shumock and Thornton scale** and was categorized as definitely preventable, probably preventable and not preventable,

Predictability Assessment:

Criteria for determining predictability of ADRs.

RESUTLS

During the study period of total of 7697 patients were screened in the hospital. Out of which 240 patients encountered ADR's.

Among 240 cases the higher prevalence of adverse drug reactions was observed in patients having past medical history of CVS diseases 57(23.75%) followed by CNS disease 50(20.84%), Skin disease 32(13.34%), Metabolic disease 28(11.66%), Renal disease 19(07.92%), Immune disease 16(06.67%), GI disease 10(04.16%), Respiratory disease 05(02.08%) and Others 23(09.58%).

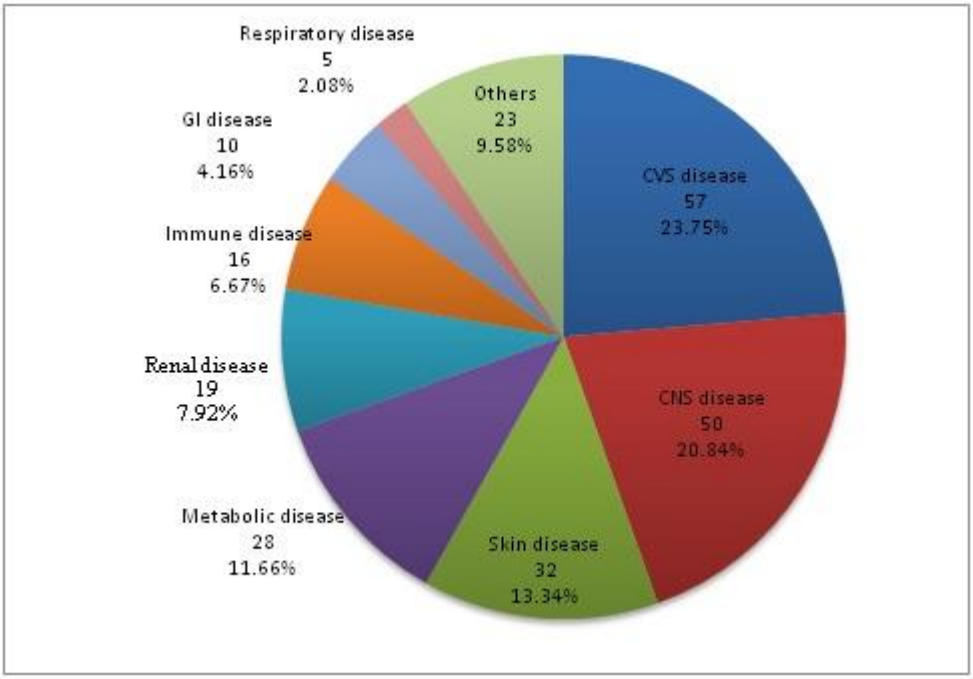

Figure 1: Distribution according to Past Medical History

2) ADRs were distributed according to the WHO ART system codes

It includes different systems and number of ADR'S found in each system: most of ADRs were experienced by Gastrointestinal 72 (25.71%) reactions followed by Dermatology 31 (21.78%) reactions, Central nervous 32 (11.42%) reactions, Endocrine 27 (09.64%) reactions, Hepatic system and Haematology17(06.07%) reactions, Cardiovascular 12 (04.28%), Otic system 10(03.57), Renal System 09 (03.21%), Muscular skeletal 7(02.50%) ,Ophthalmic 03(01.07%) and General disorders-13(04.64%).

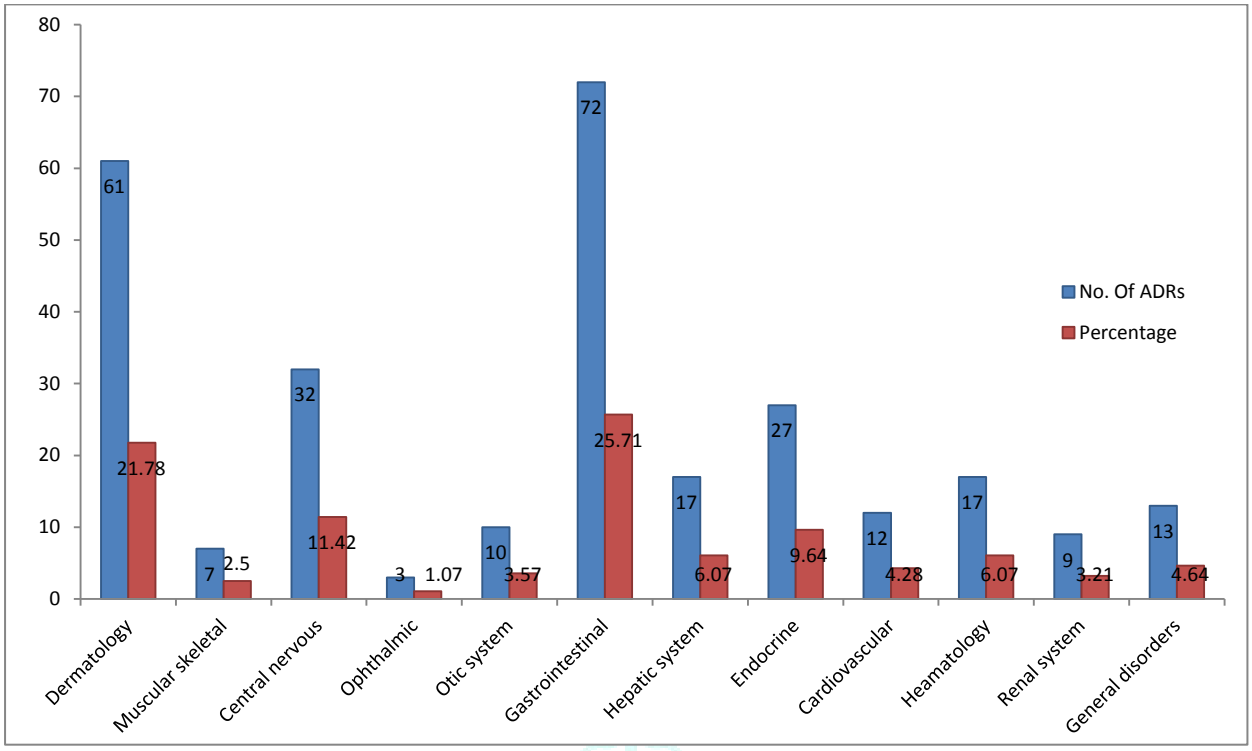

Figure 2: ADRs were distributed according to the WHO ART system codes

3) Causality assessment adverse drug reactions according WHO probability scale.

Sl.no	WHO probability scale	No.of ADRs	Percentage
1	Certain	06	2.5 %
2	Probable	88	36.66 %
3	Possible	113	47.08 %
4	Unassessable / Unclassifiable	22	9.16 %
5	Unlikely	07	2.91 %
6	Conditional/Unclassified	04	1.66 %
	Total	240	100 %

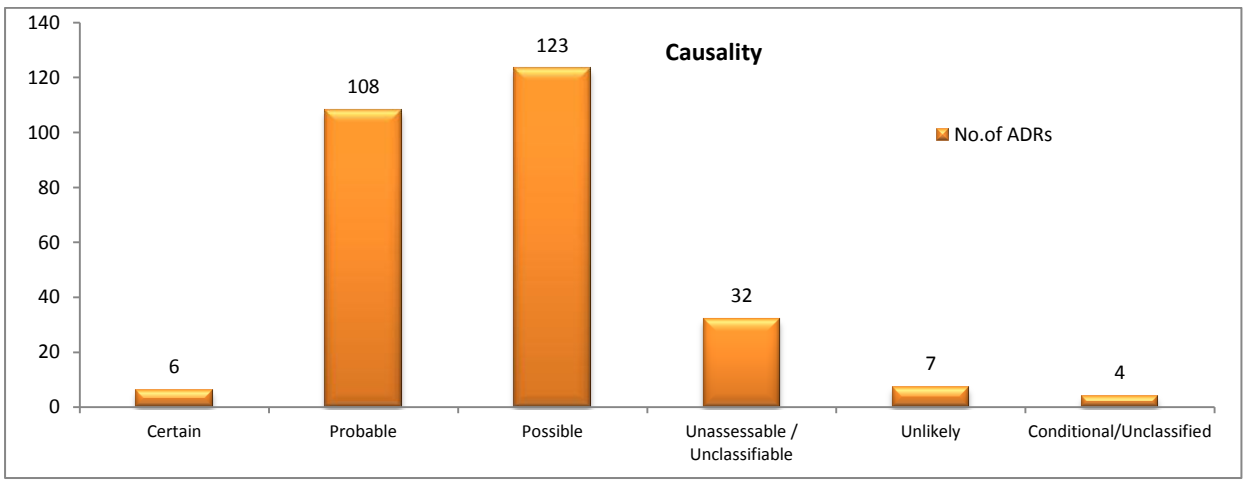

Figure 3: Causality assessment adverse drug reactions according WHO probability scale.

4) Assessment of severity of adverse drug reactions according Modified Hartwig and Siegel scales

The 240 ADRs severity was assessed, most of the patients are at level-4A 94 (39.16%) followed by lavel-4B 79 (32.91%), at level-5 17 (07.03%) of patients, 25 (10.41%) patients at level-3 and 06 patients severity at mild 7 (02.91%) and 6 (2.5%) patients are at level-1 and level-2 respectively. 2 (00.71%) patients have permanent harm at level-6.

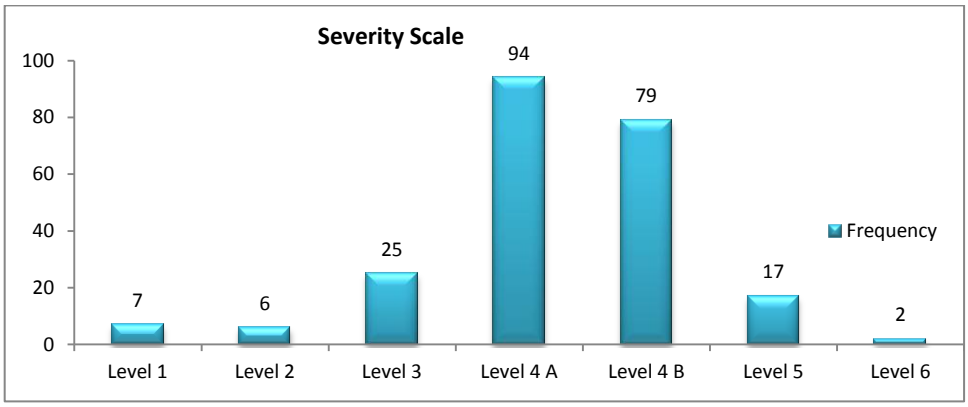

Figure 4: Assessment of severity of adverse drug reactions according Modified Hartwig and Siegel scales.

5) Assessment adverse drug reactions Predictability

S. No	Preventability	No. of ADRs	Percentage
1	Definitely Preventable	142	59.16 %
2	Probably Preventable	87	36.25 %
3	Not Preventable	11	4.58 %
*****	**Total**	240	100 %

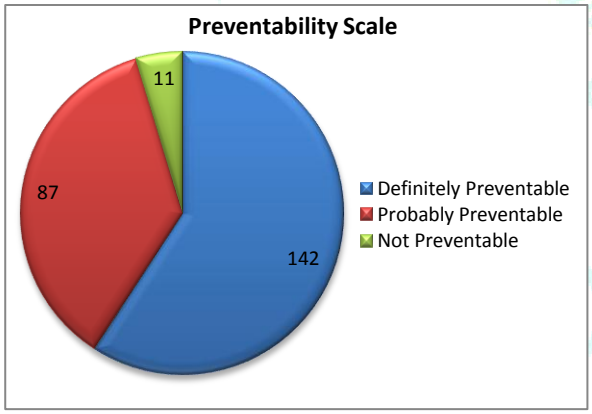

Figure 5: Assessment adverse drug reactions Preventability

CONCLUSION

Among age groups adults were predominant over children andgeriatric in terms of prevalence, while males have higher risk to develop ADRs among children and adults and in geriatrics both the genders have high risk in developing ADRs. Among the 240 cases documented 60.83% were male and 39.17% were female, showing 1.55 times higher risk for males to develop ADRs and shown 1.105 times higher risk for ADRs in individuals of urban area compared to rural area. Among all the individuals regardless of sex the distribution of ADRs is significant over rural areas. Among 240 cases the higher prevalence of adverse drug reaction was observed in patients having past medical history of CVS diseases and CNS disease. And most of ADRs were experienced by Gastrointestinal and Dermatology. The risk factors which are highly involved among ADRs are Self-medication with non-prescribed medications followed by Inappropriate Lack of knowledge (About ADRs)Poly Pharmacy or Multiple Drug Therapy Wrong time and administration, Age, Hypersensitivity and drug with narrow therapeutic index. Most of ADRs were identified by Doctors or Prescribers.

ADR reporting and monitoring in a multi super specialty tertiary care hospital must be continuous and ongoing process and it should be record for both old and newly marketed drugs and medicinal products. This will provide baseline data regarding the safety and efficacy of various drugs which are continuously and rarely used drugs.

Serious ADRs responsible for prolonged hospitalization enhance morbidity and also cause economic burden on patient and hospital. So ADR monitoring is considered very important task in hospital, as it justifies the benefit versus risk ratio of drugs to direct patient.

Hence, it can be concluded from the present study that high level implementation of ADR monitoring and reporting should be done so as to provide optimum and safe patient care for obtain required therapeutic outcome.

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