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Original Article

Incidence of Adverse Drug Events among Hospitalized Patients at a Tertiary Care Teaching Hospital

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ABSTRACT

Background: Adverse Drug Reactions **(**ADR) Monitoring and reporting activity is in its infancy in India. ADR reporting programmes on an institutional basis can support the setting up of a sound pharmacovigilance system in the country. The aim of this study is to find incidence of adverse drug events among hospitalized patients in surgical wards.

Material & Methods: This is a prospective cross-sectional study to analyze the occurrence of ADRs in hospitalized patients of Great Eastern Medical School & Hospital, Ragolu, Srikakulam, Andhra Pradesh, India. ADR data was collected by spontaneous reporting.

Results: In our study observed that the out of 45 patients 20 (44.4%) were male and 25 (55.6%) were female. Maximum patients (42.2%) belonged to the age group of more than 60 years (table 1). Gastrointestinal tract system (GIT) is the most commonly involved system in 51.7% ADR's, followed by skin (29.3%) then urinary system (5.2%) and in respiratory system 5.2% ADR's found Others (CNS) included 8.6% ADR's.

Conclusion: Adverse Drug Reactions are one of the drug related problems in the hospital setting and is a challenge for ensuring drug safety. So implementation of antibiotic guidelines for the hospital scenario and strict adherence should be ensured to promote the rational use.

KEYWORDS: ADRs, Drug Reaction, Antibiotics.

INTRODUCTION

Drugs are double edged weapons; they can save life but also can cause adverse drug reactions [ADRs] and are major cause of morbidity and mortality worldwide.[1] The World Health Organisation's definition from 1972 stated that an ADR is "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".

Recently some authors prefer the term adverse drug event [ADE] which is an injury resulting from administration of a drug.[2] An adverse event [abbreviated ADE] refers to any injury caused by the drug [at normal dosage and /or due to overdose] and any harm associated with the use of the drug. ADRs are special type of ADEs. It has been estimated that approximately 2.9-5.6% of all hospital admissions are caused by ADRs and as many as 35% of hospitalized patients experience an ADR during their hospital stay. An incidence of fatal ADRs is 0.23 - 0. 41%. At least one ADR has been reported to occur in 10 to 20% of hospitalized patients.[3]

ADR Monitoring and reporting activity is in its infancy in India. ADR reporting programmes on an institutional basis can support the setting up of a sound pharmacovigilance system in the country.[4] Although ADRs are of great concern to the general public, medical practitioners, pharmaceutical industries and the regulatory authorities.[5] The ultimate objective was to give a feedback to the prescribers that would ensure a judicious prescription and prevention of the reactions in future.[6]

MATERIALS & METHODS

This is a prospective cross-sectional study to analyze the occurrence of ADRs in hospitalized patients of Great Eastern Medical School & Hospital, Ragolu, Srikakulam, Andhra Pradesh, India. ADR data was collected by spontaneous reporting. Spontaneous

reporting is the core data generating system of international pharmacovigilance, relying on health care professionals to identify and report any adverse events to their national pharmacovigilance centre, health authority, or to the drug manufacturer, itself spontaneous reports are, by definition, submitted voluntarily.

Inclusion Criteria

- Patients receiving cancer chemotherapy
- Patient receiving new drug or established drugs.
- Patients age between 6 to 70 years.
- Hospitalized patient.
- Negative Urine pregnancy test
- Patients receiving drugs by I.V. infusion.

Exclusion Criteria

- Pregnant women.
- Seriously ill/moribund patients
- Drug abuse or addiction
- Severe psychiatric disorder
- Inability to function independently
- Non cooperative patients
- Patient aged <6 years &>70 Yrs.

The Principal of causality assessment of on ADR mainly focus on inclusion of all other causes concomitant drugs, natural progression of disease, withdrawing the suspected drug and rechallange with same drug to evaluate reoccurrence of event.

Table 1: Sex and age wise distribution of ADRs

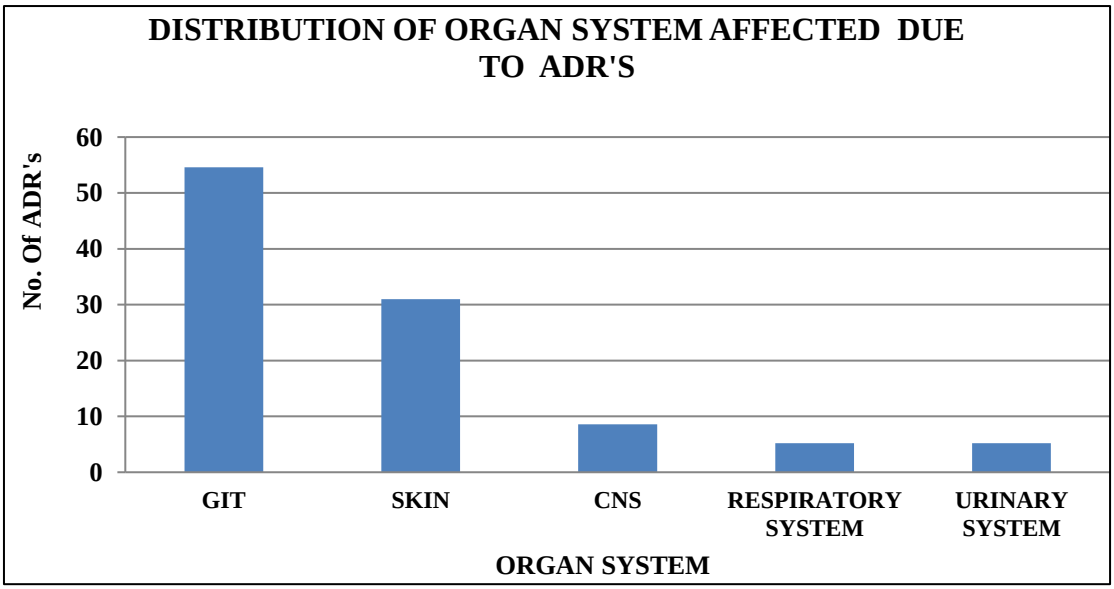
Age(years)	Male	Female	Total No. of ADRs	Percentage (%)
2.0-3.9	5	4	9	20
4.0-5.9	6	11	17	37.8
≥6.0	9	10	19	42.2
Total	20	25	45	100

Table 2: Level of severity (Hartwig Scale)

Level of severity	No. of ADR's	Percentage (%)
Mild	41	91.2
Moderate	3	6.6
Severe	1	2.2
Total	45	100

Table 3: Outcome

Parameters	No. of ADR's	Percentage (%)
Fatal	0	0
Recovering	15	33.3
Recovered	30	66.7
Unknown	0	0
Others	0	0
Total	45	100



Graph 1: Organ System affected due to ADR's

RESULTS

In our study observed that the out of 45 patients 20 (44.4%) were male and 25 (55.6%) were female. Maximum patients (42.2%) belonged to the age group of more than 60 years (table 1). Gastrointestinal tract system (GIT) is the most commonly involved system in 51.7% ADR's, followed by skin (29.3%) then urinary system (5.2%) and in respiratory system 5.2% ADR's found Others (CNS) included 8.6% ADR's (Graph 1).

In our results showed that the out of 45 ADR's reported 91.2% were mild and 6.6% were moderate and 2.2% severe in severity (table 2). 33.3% (n=15) of cases were reported recovering, while 66.7 % (n=30) fully recovered (table 3).

DISCUSSION

The present study was initiated in order to study the nature of ADRs and to identify the most frequent ADRs recognized and reported by the attending physicians, using stimulated reporting. We also focused on assessing the incidence of ADRs in hospitalized patients. A total of cases were studied during the study period. The incidence of ADRs was1.26 % in our set up. In comparison with the study by Mandavi et al[7] and Ramesh et al.[8] This can be considered as underreporting. It is a universal problem and many reasons are identified such as busy schedule of clinicians, lack of knowledge about the exact authority to report ADRs.

The demographic analysis showed female gender predominance over males, which was similar to earlier study by Arulmani et al.[9] As far as age was concerned, most of the reactions were in the adult group. This might be due to higher emotion quotient in females, which makes them more sensitive to the pharmacological actions of medicines, thus enhancing the probability of ADRs. Rational dose titration may lead to minimization of ADRs in females.[10]

Incidence of ADRs was found to be higher in older patients i.e., more than 40 years as compared to younger ones i.e., less than 40 years compromised organ functions, decreased BMR (basal metabolic rate), concomitant disease conditions and multiple drug regimens might be assigned as likely reasons for higher incidence of ADRs in older patients[10]

This result is consistent with the study carried out by Carnasos et al.[11] (1974) and Rajesh et al.[12] (2008) The documented antibiotic Adverse Drug Reactions are mainly affecting the GIT and skin and this study also pointed out the same. The study of Benjamin Horen et al.[13] also found the predominance of the gastrointestinal system followed by the skin in ADR occurrence (Pierre Jonville-Bera, 2002[14]). Other studies showed the predominane of cutaneous manifestations (Mohammed Misbahet al., 2010[15]; Oshikoya et al., 2007[16]).

Worldwide studies have proved ADRs to be a major cause of morbidity and mortality. Though Indian studies in this regard are very few, the pattern of reactions seems to be similar. There are however certain peculiarities of drug use in our situation, such as: large number of patients, poor doctor-patient ratio, self-medication, and drugs of alternative systems of medicine, malnutrition, widespread anemias, presence of counterfeit drugs and presence of the highest number of drug combinational products in the world. ADR's have recently emerged as leading killers one of the reasons for under-reporting might be a reluctance or negligence among doctors to report adverse outcomes. Particularly strong disincentives for reporting are shame, fear of liability, loss of reputation and peer disapproval.[17] The awareness that medical errors, and also surgical complications, are frequently system errors rather than an individual liability has helped abandoning a shame-and-blame culture and has harnessed the medical professional to report errors and adverse outcomes.[18] Furthermore, increasing societal demands as to safety and transparency in healthcare have created more awareness of the importance of, and willingness to contribute to, and a better quality of care.[19,20]

CONCLUSION

Adverse Drug Reactions are one of the drug related problems in the hospital setting and is a challenge for ensuring drug safety. So implementation of antibiotic guidelines for the hospital scenario and strict adherence should be ensured to promote the rational use. The development and use of clinical decision support systems can promote rational antibiotic use.

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