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PHARMACOVIGILANCE STUDY IN MEDICINE WARDS AT A TERTIARY CARE HOSPITAL IN INDIA

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ABSTRACT

Background: Pharmacovigilance monitoring and assessment of medications in hospitals are very important task for prevention of adverse drug reactions and patients harm. **Objectives:** The aim of the study was to determine the prevalence of adverse drug reactions at a tertiary care hospital in India and to determine the most common Therapeutic Class of Drugs causing ADR and to determine the most common organ system affected by ADRs. **Materials and Methods**: The Prospective, observational study was conducted at a tertiary care hospital in India, between September 2016 and February 2017. All In-patients admitted in medicine wards were monitored for ADRs. **Results and Discussion:** Over the study period of 6 months, a total of 97 ADRs were reported in 140 patients. The ADRs observed were higher in male patients [52 (53.60%)]. Based on the reported ADRs, gastro-intestinal adverse drug reactions [28 (28.86%)] were among the highest number of ADRs. The most common therapeutic classes of drugs which were involved with ADRs were antibiotics [24 (24.74%)] followed by antihypertensive agents [19 (19.58%)] and antidiabetics [5 (5.15%)]. Most of the adverse drug reactions [72 (74.22%)] were managed by discontinuing the suspected drug. The causality assessment of the ADRs were carried out using the Naranjo's Scale algorithm and the majority of the ADRs were found to be definite [31 (32%)]. **Conclusion:** Presence of clinical pharmacists for regular monitoring and assessment for adverse drug reactions in hospitals is a crucial task which will reduce the adverse drug reactions occurrence and harm to patients and consequently improve the patient safety.

KEYWORDS: Pharmacovigilance, Adverse drug reactions, Naranjo scale, Antibiotics, Patient safety.

INTRODUCTION

World Health Organization defines an adverse drug reaction (ADR) as "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function".

Adverse drug reactions (ADRs) are a major cause of hospital admissions, but recent data on the incidence and clinical characteristics of ADRs which occur following hospital admission, are lacking. The purpose of documenting adverse drug events is to prevent future injuries for patients. New adverse drug reactions are often discovered when drugs are used in larger or in different populations than studied during initial clinical trials. Therefore, documentation and reporting becomes a crucial element in clarifying the side effect profile of a drug. But recent data on the incidence and clinical characteristics of ADRs which occur following hospital admission are lacking.[1]

It is clear that adverse drug reactions adversely affect patients quality of life and can also cause patients to lose confidence in healthcare system and reduce the patient therapeutic outcome and medication adherence because of the related ADRs of each medicine that the patient experience. Apart from that there is a significant impact through increase costs of patient care and the potential to lengthen hospital stays.

Primary objective of the study was to determine the prevalence of adverse drug reactions in a tertiary care hospital. Secondary objectives were to determine the most frequent Therapeutic Class of Drugs causing ADR and to determine the most frequent organ system affected by ADR.

MATERIAL AND METHODS

A prospective, observational study was carried out in the wards of St. Philomena's Hospital, Bangalore for a period of 6 months between" September 2016 to February 2017". All In-patients of both genders who admitted in medicine wards and experienced an ADR were enrolled for the study, with the approval of Institutional Ethics committee and the consent of the study population. Inclusion criteria were all In-patients

of both gender who experienced ADR during their admission to medicine wards and the exclusion criteria were those patients admitted to hospital in OBG, Surgery, ICU and Paediatrics wards.

The severity of adverse drug reactions was assessed using Naranjo's scale. The Naranjo's causality assessment scale contains a score value ≥ 9 indicated a definite causal relation between the drug and the ADR; 5-8 as indicated a probable relation; 1-4 indicated a possible relation and a score of ≤ 0 indicated an unlikely relation.

RESULTS AND DISCUSSION

Over the study period of 6 months, a total number of 97 ADRs were reported in 140 patients. ADRs were higher in male patients [52 (53.60%)]. A predominance of gastro-intestinal reactions [28 (28.86%)] was observed followed by fluid and electrolytes imbalance [18 (18.55%)], neurologic [15 (15.46%)] and dermatological reaction [12 (12.37%)]. The result of the study was similar to study conducted by Eisazaei et al.[2] Evans et al also showed the prevalence of gastrointestinal tract adverse events (abdominal pains, constipation, diarrhoea, nausea and vomiting) was 64%.[3] Details are shown in Figure 1.

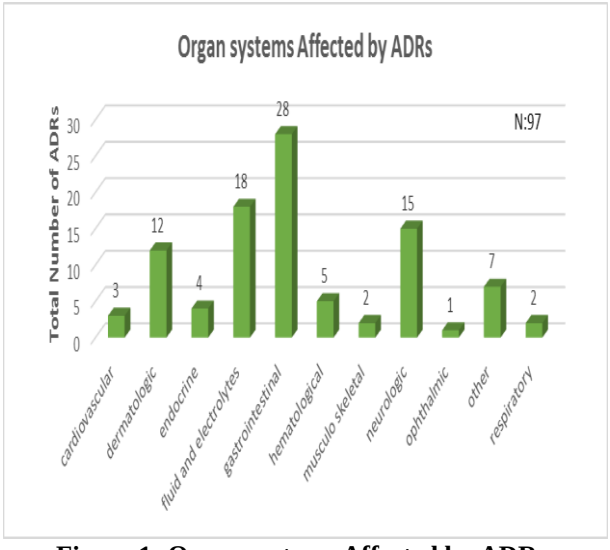

Figure 1: Organ systems Affected by ADRs.

Therapeutic classes of drugs frequently associated with ADRs were antibiotics [24 (24.74%)] followed by antihypertensive agents [19 (19.58%)]. Details are shown in Figure 2.

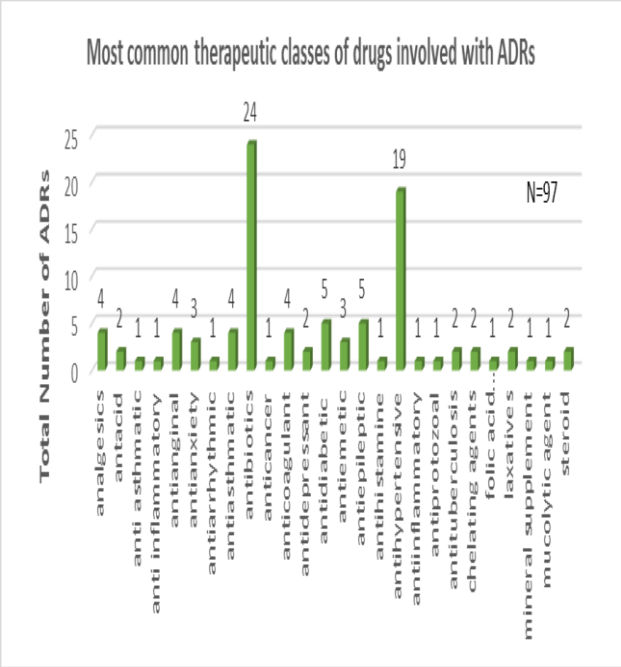

Figure 2: Most common therapeutic classes of drugs involved with ADRs.

The most common drugs involved in causing ADRs were Furosemide and Levofloxacin which was similar to the study conducted by Julie Dupouyet al.[4] The most commonly reported ADR was Diarrhoea [8 (8.24%)].

Majority of the ADRs [72 (74.22%)] were managed by withdrawing the suspected drug. The causality assessment of the ADRs were carried out using the Naranjo's Scale algorithm and the majority of the ADRs were found to be definite [31 (32%)]. The result of the study was different with the study conducted by Renuka et al.[5] in which the most common ADRs were found to be probable.

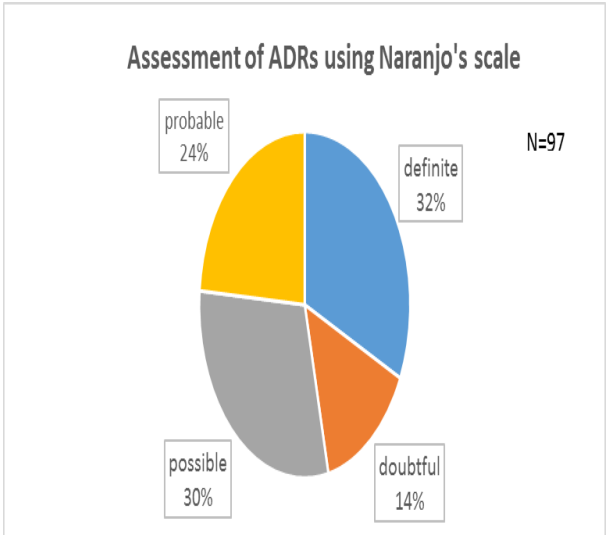

Figure 3: Causality assessment of ADRs

CONCLUSION

Pharmacovigilance study has positive impact for reducing the adverse drug reactions occurrence and prevention of its harm to patients and bringing notice for rational prescribing of the most common medication which were involved with adverse drug reactions. Presence of clinical pharmacist for regular monitoring and assessment of adverse drug reactions in hospitals will definitely improve the patient safety.

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