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STUDY OF SUSPECTED ADVERSE DRUG REACTION AND ITS REPORTING SYSTEM

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ABSTRACT

A Prospective observational study on reporting of adverse drug reaction was conducted in Navodaya medical college hospital & Research center, Raichur. The aim of the study was to detect, document, assess and report the suspected adverse drug reaction. Suspected ADRs were analyzed for causality, severity and outcome using validated scales. A total of 15 ADRs were identified during the study period of September 2017 to February 2018 of which 7(46.6%) were male and 8(53.3%) were female. Severity of ADRs were assessed using Naranjo's causality assessment scale revealed that 9(60%) of ADRs were probable and 6(40%) ADRs were possible. The systems affected were dermatological 9(60%), gastro intestinal 2(13.3%), central nervous and cardiovascular 1(6.66%) each and others 2(13.3%). Drugs that are suspected to cause ADRs were beta lactam antibiotics 6(40%), analgesics 3(20%), antihypertensive 2(13.33%), anti-tuberculoid 2(13.33%), aminoglycoside antibiotics 1(7%) and antidepressants 1(7%). Severity of ADRs were assessed and found that 6(40%) mild, 3(20%) moderate, 6(40%) severe. Outcome of ADRs were assessed of which 7(46.6%) recovered and 8(53.3%) were recovering. Our study concludes that ADRs are significant problem in hospital in-patients contributing to morbidity and resulting in considerable financial burden.

KEYWORDS: Adverse drug reactions, drugs, Naranjo's causality assessment scale, severity, systems affected.

INTRODUCTION

Medicines have, beyond any doubt, proved to be a boon for humanity and it fights against disease and suffering associated with their use, called Adverse Drug Reaction. These reactions though mild in most cases, have the potential to cause disability and even death.[1]

As ADRs represent an important public health concern, institutions complying with the joint commission and Accreditation of Healthcare Organizations (JCAHO) are required to perform numerous steps pertaining to the surveillance and management of ADRs.[2]

The Harvad Medical Practice showed that in 1984, 3.7% of 30195 patients admitted to acute nonpsychatric hospitals experienced ADR during their hospital stay further data from this group suggested a 6% group of ADR and 5% incidence of potential ADR among 4031 medical and surgical admission over a six months period.Of all events observed, 1% was fatal, 12% life threatening, 30% serious, 57% significant.Of observed ADR, 28% was considered preventable, with a greater proportion of the life threatening and serious reactions in that category. The drug classes most frequently implicated in those reactions were analgesic, antibiotics, sedatives, cytotoxins, cardiovascular drugs, antipsychotics, antidiabetics and anticoagulants.[3]

The FDA requirement on ADR reporting varies depending on the source of the report. Pharmaceutical manufacturers are legally required to report to the FDA all ADRs, including severe reactions. The Med-Watch system should be used to report cases involving deaths, birth defects, miscarriages, stillbirths, or birth with disease, the need for medical or surgical treatment to prevent impairment; or any combination of these. It is not necessary that a direct causal relationship be demonstrated. The FDA also oversees ADR reporting for biological agents (eg; vaccine) and devices, and any reaction to these products should be reported as well.

The WHO UMC system has been developed in consultation with the natonal centres participating in the programme for International Drug Monitoring and meant as a practicle tool for the assessment of case reports. It is basically a combined assessment taking into account the clinical-pharmacological aspects of the case history and the quality of the documentatttion of the observation. Since pharmacovigilance is particularly concerned with the detection of unknown and unexpected adverse reactions, other criteria such as previous knowledge and stastical chance play a less prominent role in this system. It is recognised that semantics of the definitions are critical and that individual judgements may they are for differ. There are other algorithms that are either very complex or to specific for genaeral use. This method

gives guidance to the general arguments which shoukd be used to select one category over another.[4]

MATERIALS AND METHODS

A Prospective observational study design was carried out for a period of 6 months from September 2017 to February 2018 in Navodaya Medical College Hospital and Research Centre, Raichur.

Patients admitted in different departments of hospital were included in the study. ADRs which occurs prior to hospital admission were excluded from the study. The study was approved by Institutional Ethics Committee (IEC) of the hospital.The study was carried out in all the departments of NMCH & RC, Raichur which is 1000 bedded multi-specialty tertiary care teaching hospital with Anesthesia, Orthopedics, Pediatrics, ENT, Radio diagnosis, General medicine, TB and Respiratory diseases, General surgery, Urology, OBG, Ophthalmology, Psychiatry, Telemedicine facilities, Simulation lab and Rehabilitation.

Data were collected using predesigned data entry form, which include patient information, reason for admission, past medical history, social history, laboratory investigation, medications prescribed, suspected ADR, counseling assessment scales, severity of the reactions. A specially designed questionnaire was used which includes two sections. Section A deals with socio-demographic details of respondents (Age, Gender, Highest level education, working status) and Section B deals with answers to questions pertaining awareness on ADR reporting.

Study tools used in this study are Suspected ADR reporting form (Yellow card), CDSCO ADR reporting form, ADR documentation form, Causality assessment scale, Naranjo scale and WHO scale.

RESULTS

A total of 15 ADRs were identified from different wards of hospital. Female population was more compared to male and the most affected age group was 15-35yrs i.e.,9(60%) were among the patients, followed by 35-55yrs 4(26.6%) and 55-75yrs 2(13.33%) In which mild and severe is 6(40%) and moderate is 3(20%).

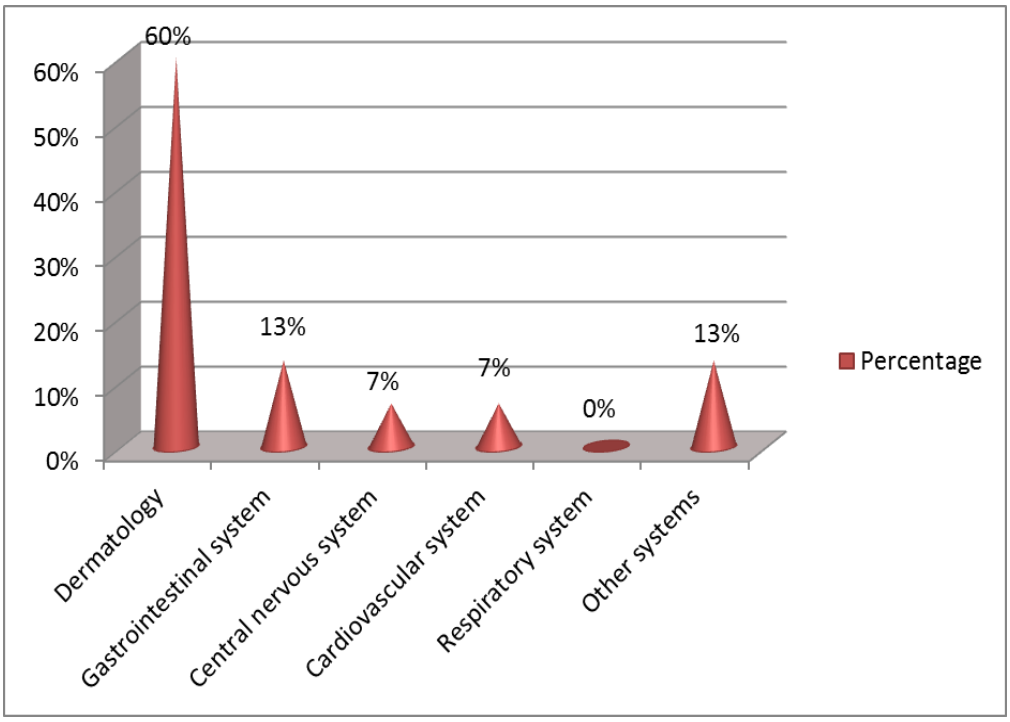

Fig 1: Distribution according to system commonly affected (n=15).

As shown in fig 1 which explains about the systems that are most commonly affected by ADR.which shows dermatological reactions were more i.e. 9(60%), followed by gastro intestinal system and other systems (musculo-skeletal and ENT) in 2(13.3%) each, central nervous system and cardiovascular system in 1(6.66%) each.

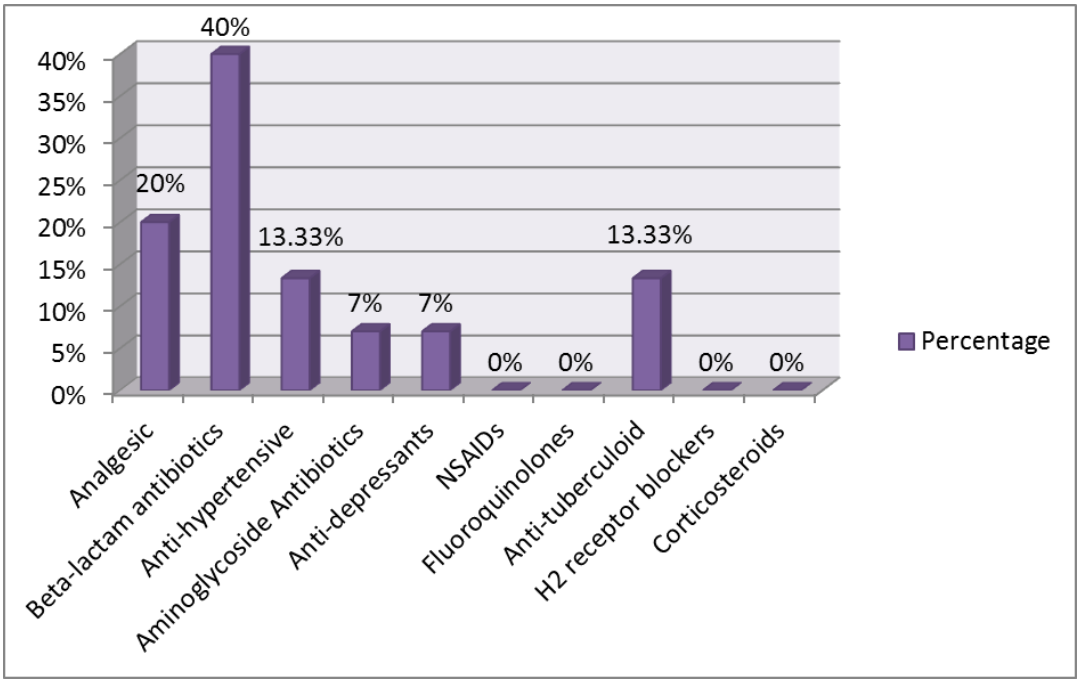

Fig 2: Distribution according to drugs causing ADRs (n=15).

As shown in fig 2:the drug class associated mostly with ADRs was Beta lactam antibiotics 6(40%) followed by anti hypertensives and anti-tuberculoid 6(13.3%) each, analgesics 3(20%),aminoglycoside antibiotics and anti-depressants 1(7%) each.

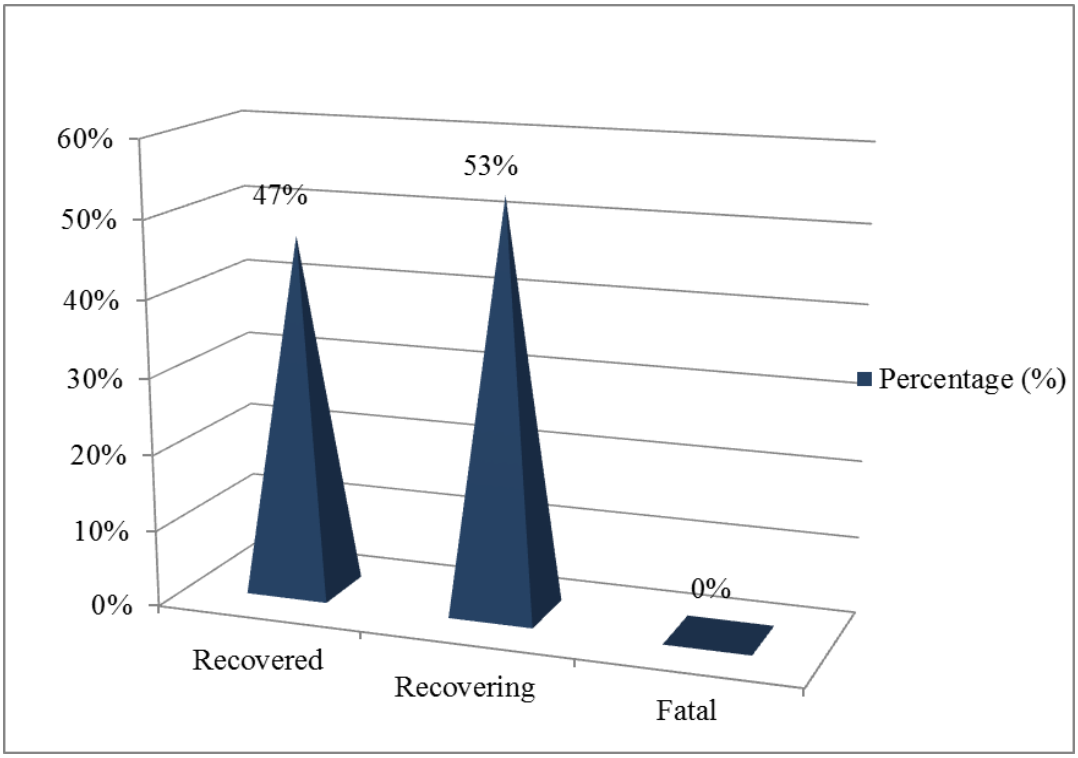

Fig 3: Distribution according to outcome of ADRs (n=15)

As shown in fig 3 explains outcome of the ADRs and was found that about 7(46.6%) ADRs were recovered, and about 8(53.3%) ADRs were recovering.

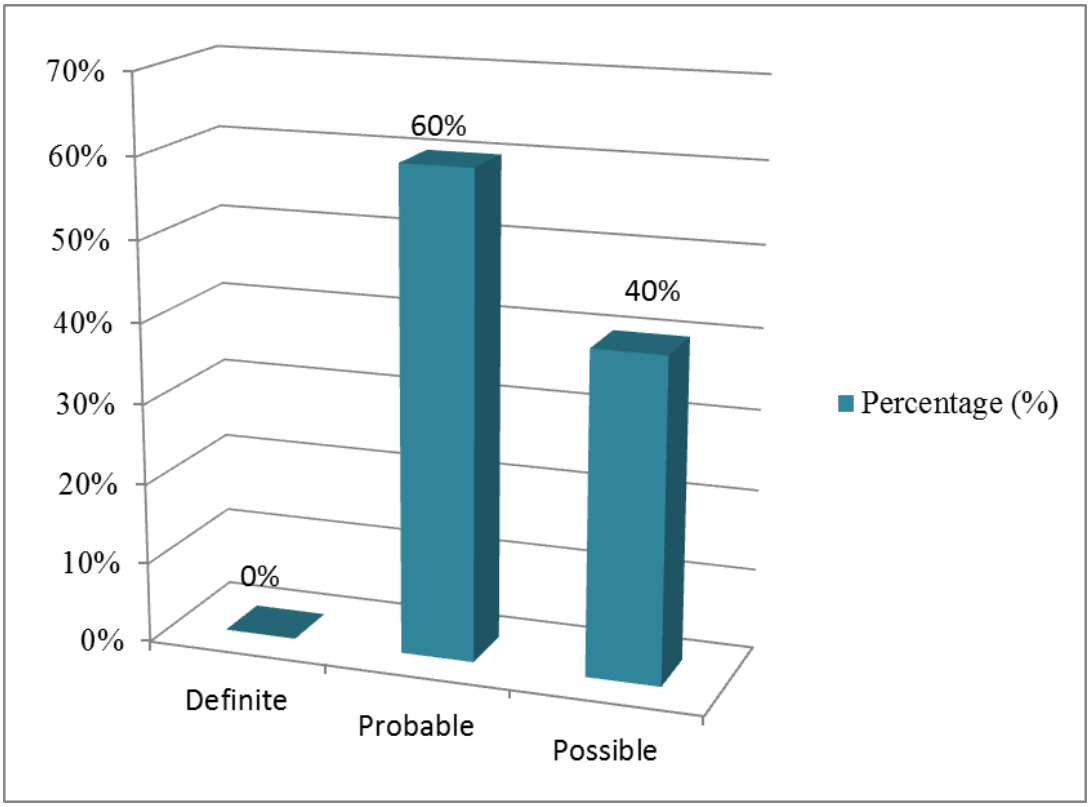

Fig 4: Causality assessment of suspected ADRs by Naranjo's scale (n=15).

In fig 4 the causality assessment of suspected ADRs was done using Naranjo's scale and the result shows that about 9(60%) cases were probable, and 6(40%) cases were possible.

CONCLUSION

The study strongly suggests that there is greater need for streamlining of hospital based ADR reporting and monitoring system to create awareness and to promote the reporting of ADR among healthcare professionals. Only such centers can greatly influence in bringing culture among healthcare professionals throughout the country. Our study reveals that pharmacist involvement could not only greatly increase the reporting rate but also quality reporting. Thus pharmacist have the greater role to play in areas of pharmacovigilance to strengthen the national pharmacovigilance program. Pharmacist participation with the medical team contributes to a significant finding of preventable adverse reactions.

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CONFLICT OF INTEREST: Nil.

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