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RETROSPECTIVE ANALYSIS OF SERIOUS ADVERSE EFFECTS IN A TERITARY CARE CENTRE IN CHENNAI

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ABSTRACT

Objectives: Adverse effects are still one of the major problems in the therapy of many diseases and SAE [serious adverse effects] constitutes more economic burden to patients and therein to society as it might lead to prolonged hospital stay and requires active treatment. Hence this study was undertaken to analyse the incidence of SAE in a tertiary care centre. **Methods:** This is a retrospective study which analyses the ADRs in inpatients of Sri Ramachandra Medical College for a period of 1 year (May2013 to April 2014). ADR reports was collected, among those patients with SAE were picked out using WHO criteria for SAE and the particulars of these patients were analysed in detail. **Results:** There were five patients with SAE in this one year period. Out of these, one patient had severe cutaneous reactions all over the body which was produced by cefoperazone and sulbactam. Four were anaphylaxis, each one was caused by cefazolin, cefotaxime, contrast agent and Paclitaxel. All the patients were given symptomatic treatment according to the guidelines and were recovered completely. There were no mortalities. **Conclusion:** Only very less number of SAE inclusive of anaphylaxis was reported. The patients recovery was also significant as immediate treatment is possible in a tertiary care hospital, still reporting of all adverse effects particularly of SAE by the physicians should be encouraged , so that can lead to more insight of identifying, treating and trying hard to avoid future SAE.

KEYWORDS: Hospital, serious, anaphylaxis.

INTRODUCTION

Adverse drug reactions (ADRs) are one of the major cause for morbidity, increased health expenditure and even death.[1] ADRs account for 0.7% of total admissions and 1.8% of total deaths in South Indian hospitals.[2] Cutaneous ADRs (CADRs) are among the most frequent ADRs. An adverse cutaneous reaction caused by a drug is any undesirable change in the structure, function of the skin and mucous membranes.[3] This includes all adverse events related to drug eruption, regardless of the aetiology. They manifest with varied and diverse morphological pattern ranging from trivial urticaria to severe form of vasculitis or toxic epidermal necrolysis and cutaneous necrosis. The drugs causing serious reactions are not common, but reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS-TEN) and exfoliative dermatitis may result in death even if eruption is the only manifestation.

OBJECTIVES

Adverse effects are still one of the major problems in the therapy of many diseases and SAE [serious adverse effects] constitutes more economic burden to patients and therein to society as it might lead to prolonged hospital stay and needs active treatment. Hence this study was undertaken to analyse the incidence of SAE in a tertiary care centre.

METHODOLOGY

This is a retrospective study which analyzes the serious ADRs in inpatients of Sri Ramachandra Medical College for a period of 1 year (May 2013 to April 2014).Reported ADRs was collected by the pharmacologists from the respective departments and maintained in a register in the pharmacovigilance centre. Causality assessment was done using WHO (UMC) Uppsala Monitoring Centre scale. In the WHO (UMC) scale an adverse drug reaction can be classified as certain, probable, possible, unlikely, unclassifiable and unclassified. ADR severity was classified into mild, moderate or severe based on the subjective assessment. Patients of all age group are included in this study. The data for the study were taken from this register which has the details filled in the adverse drug reaction form[4]

RESULTS

Analysis of ADRs during the study period revealed a total number of adverse drug reactions of 136 for a period of one year and adverse drug reaction due to antibiotics in our hospital

was 97(Fig 1). Skin was the most commonly involved organ and respiratory system was involved to some extent. Reporting of ADR was maximum in the surgery department – 42, followed by 26 in medicine department, 14 in paediatrics department, 10 in OBG department, 5 in other departments (Fig 2).

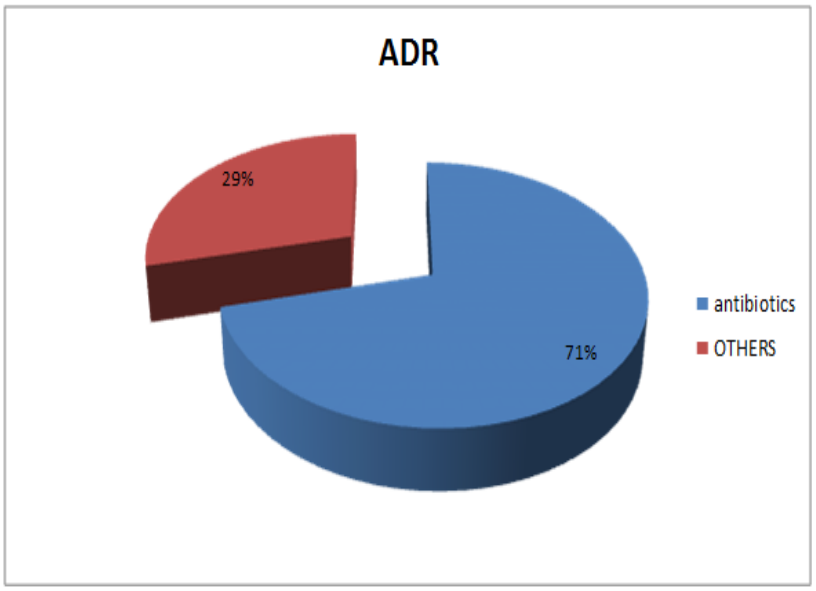

Fig 1: Drugs and ADRs.

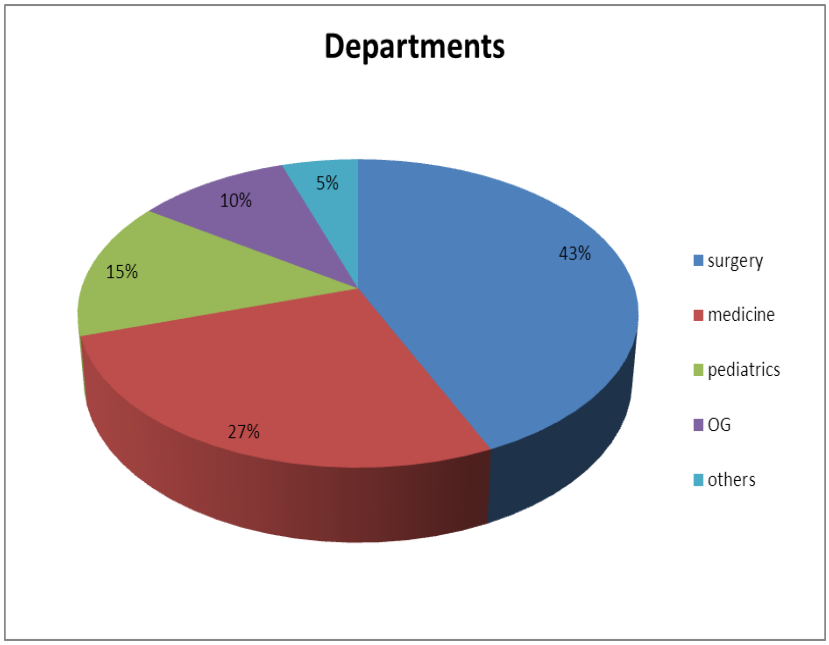

Fig 2: Departments and ADRs

Severities of the adverse drug reactions were classified by subjective assessment and most of the reactions were mild (96), moderate reactions was 35 in number and severe reactions was 5 (Fig 3).

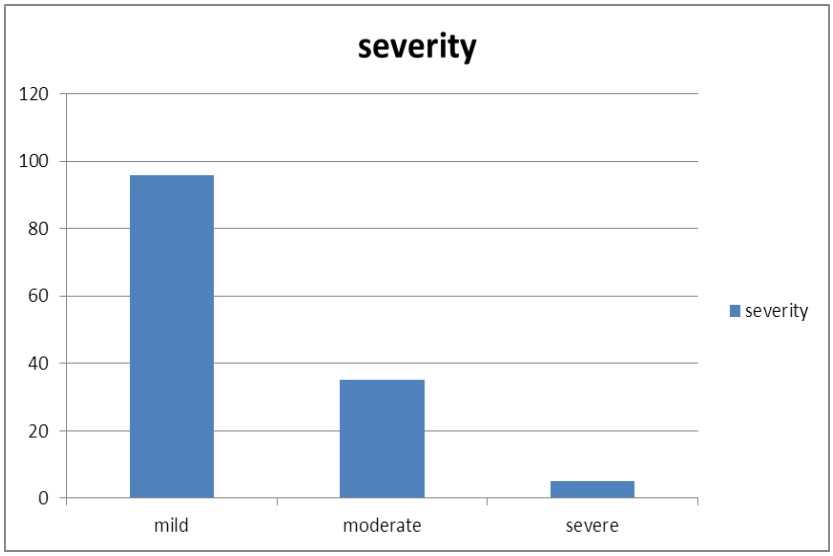

Fig 3: severity in ADR

Out of these, one patient had severe cutaneous reactions all over the body which was produced by cefoperazone with sulbactam, four were anaphylaxis, out of which one was with cefazolin, one with cefotaxime, one was with a contrast agent and another was with Paclitaxel, an anticancer agent. All patients were given symptomatic treatment according to the guidelines and recovered completely. There were no mortalities.

DISCUSSION

World Health Organization (WHO) defines an adverse drug reaction (ADR) as "one which is noxious and unintended, and which occurs in doses normally used in human for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological functions[5]"

The American Food and Drug Administration defines a serious adverse event[6] as one when the patient outcome is one of the following

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability - significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life.
- Congenital anomaly
- Requires immediate intervention to prevent any permanent impairment or damage

The ability to predict and avoid adverse drug reactions and optimize a drugs therapeutic index is an increasing focus of pharmacogenetic and personalised medicine.

Some adverse reactions like drug interactions, over dosage and excessive effects can happen in anyone. Reactions occurring only in susceptible patients include idiosyncrasy (mostly genetic in origin), intolerance and allergy (immunologically mediated). During clinical trials and before FDA approval all serious, disabling, life threatening and unexpected reactions must be reported. Even after FDA approval this reporting must continue for any adverse events of the drug. Events when serious or unexpected must be reported to the FDA within 15 days.

Hence, there is an urgent and important need to create and enhance awareness among physicians regarding detection, management, prevention and reporting of ADR.

CONCLUSION

Only very less number of SAE inclusive of anaphylaxis were reported. The patient's recovery was also significant as immediate treatment is possible in a tertiary care hospital, still awareness among the patient regarding drug allergy should be enhanced and reporting of all adverse effects particularly of SAE by the physicians should be encouraged. That can lead to more insight of identifying, treating and trying hard to avoid future SAE.

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