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ADVERSE DRUG REACTIONS IN THE INTENSIVE CARE UNIT OF A SOUTH INDIAN HOSPITAL

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ABSTRACT

Background & Objectives – Adverse drug reactions (ADRs) continue to be of concern to all health professionals. The objective of the study was to study the pattern of occurrence of ADRs among patients in intensive care unit of a South Indian hospital. **Methodology** -It was a prospective, descriptive study conducted over a period of nine months (Nov 2005 to July 2006) involving 916 patients in the ICU. The study was initiated after getting approval from Institutional human Ethics Committee (IHEC). Factors like age and sex distribution, most common drug classes involved in ADRs and the most common ADRs were analysed. **Results-** Thirty eight adverse drug reactions were reported spontaneously in 9 months of study in the intensive care unit. Cutaneous reactions were the commonest side effect reported in (34.2%) of patients. Liver dysfunction was the next common side effects reported in (15.8%) of patients. Antibiotics were the common class of drugs involved in ADRs(60.5%). Twenty one (55.3%) ADRs were reported in males and seventeen (44.7%) reports were in females. **Conclusion-** Awareness about adverse reaction monitoring, can be improved by conducting CME programmes and workshops for the ICU staff which could increase the ADR reports from the ICU, which in turn could reduce the morbity and mortality of the patients.

KEYWORDS: Adverse drug reactions (ADRs), Spontaneous reports, Intensive care unit, Cutaneous reactions, Antibiotics.

INTRODUCTION

An adverse drug reaction (ADR) has been defined as *any noxious, unintended and undesired effect of a drug which occurs at a dose used in humans for prophylaxis, diagnosis, therapy or modification of physiological functions.*[1]

Adverse drug reactions (ADRs) continue to be of concern to all health professionals. ADRs contribute significantly to patient morbidity and mortality as well as to costs for health care systems. Even serious ADRs seem to be routinely under reported in hospitals, both in the west and in India.

Drug safety monitoring is very much necessary and feasible in ***intensive care units***.[2, 3] There have been very few Indian studies on the pattern of ADRs among patients in Intensive care Units. What is fascinating about Adverse Drug Reactions Monitoring is that 30-80% of them are preventable[4] Incidence of adverse drug events (ADEs) and adverse drug reactions (ADRs) is higher in the intensive care unit (ICU) than other areas of the hospital[5] This is because patients in ICU have multiorgan dysfunction as well as altered pharmacokinetic parameters. Hence they are susceptible to adverse drug reactions (ADRs). Predisposing factors like age, gender, number of drugs taken have been reported as significant risk factors for the development of ADRs.[6,7] Co-morbidity with advancing age becomes a risk factor. Awareness of those co-morbid conditions which predict Adverse Drug Reactions can help clinicians to identify which older adults are at greater risk, therefore, who might benefit from closer monitoring.[8] Few institutions in the world currently track ICU-specific ADE/ADR data. ICU-specific ADR detection and prevention methods may improve the safety of critically ill patients.. Hence this study was undertaken to find the incidence of ADR in the ICU. Factors like age and sex distribution , common drug classes involved in ADRs and the most common ADRs would be analysed.

Aim

To study the pattern of occurrence of adverse drug reactions among patients in the Intensive Care Unit of a South Indian Hospital.

Methodology

This was a prospective, ***spontaneous reporting*** study conducted over a period of 9 months (from Nov 2005 to July 2006) involving 916 patients in the Intensive Care Unit of PSG Hospitals, Coimbatore. The study was initiated after getting approval from Institutional

human Ethics Committee (IHEC). The WHO definition of ADR[1] was adopted. Only spontaneous ADR reports were noted.

The doctors and duty nurses in the ICU were requested to report all ADRs. Existing as well as new patients at the start were included in the study. ADR reporting cards were provided in the ICU for the doctors and nurses to report. After the initial notification from the doctors and nurses, detailed report about the ADR was collected by interviewing the patient and from the patient case reports.[9]

The information was then transferred to the proforma which was adopted from the one used by Central Drugs Standard Control organization (CDSCO)[10] Statistical analysis was done by using Excel spreadsheets. The incidence of ADRs in the ICU like age & sex, most common group of drugs involved in ADRs and the most common ADRs were analysed.

RESULTS

A total of 38 suspected ADRs were reported and evaluated. A total of 4% of the ICU patients experienced some form of an ADR. When we consider the patient demographics, as shown in table 1, ADRs were reported in 21 (55.3%) in males as compared to 17 (44.7%) reports in females. ADRs were more common in the elderly. There were 15 reports in patients above 60 years (39.47%), 7 reports in patients between 51 to 60 years (18.4%), 5 reports in patients between 41 to 50 years (13.1%). This could be due to polypharmacy and change in the pharmacokinetics in the elderly.

Table1. Age-Sex Distribution

AGE GROUP (Yrs)	SEX		Total (%)
	Female (%)	Male (%)	
11-20	0 (0)	2 (100)	2 (5.3)
21-30	5 (62.5)	3 (37.5)	8 (21.1)
31-40	1 (100)	0 (0)	1 (2.6)
41-50	2 (40)	3 (60)	5 (13.1)
51-60	2 (28.6)	5 (71.4)	7 (18.4)
61-70	2 (33.3)	4 (66.7)	6 (15.8)
71-80	4 (50)	4 (50)	8 (21.1)
> 81	1 (100)	0 (0)	1 (2.6)
Total	**17 (44.7)**	**21 (55.3)**	**38 (100)**

Skin was the organ / system most commonly involved with ADRs (34.21%) as shown in Table 2 & Fig 1. Out of the 38 reported ADRs there were 13 reports of cutaneous reactions.

There were 7 reports of itching, 7 reports of rashes and 1 report of blister. Liver was the next common organ involved (15.8%). There were 4 reports of hepatitis, 1 report of jaundice and one report of raised liver enzymes.

Table2. ADVERSE DRUG REACTIONS

ADRs Reported	Frequency	Percent
Cutaneous reactions [1]	13	34.2
Liver Dysfunction [2]	6	15.8
Renal Failure	3	7.9
Rigors	2	5.3
Thrombocytopenia	2	5.3
Others [3]	12	31.6
Total	**38**	**100**

1 – Include Itching (7), Rashes (5) and Skin Blisters (1)

2 – Include Hepatitis (4), Jaundice (1) and Raised Liver Enzymes (1)

3 – Include Agranulocytopenia, Bonemarrow depression, Diarrhoea, Disorientation, Haemorrhage, Hypotension, Junctional rhythm, Palpitation, Restlessness, Seizures, Unconsciousness and Ventricular ectopics (1 each)

Fig 1 ; Commonly Reported ADRs

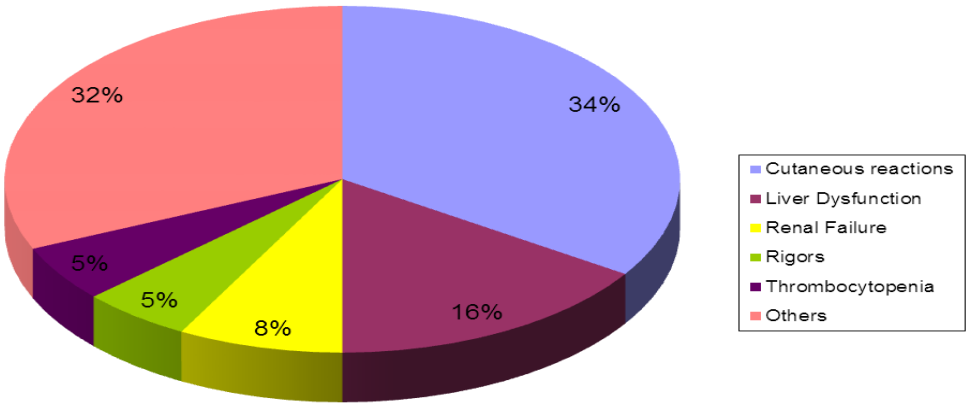
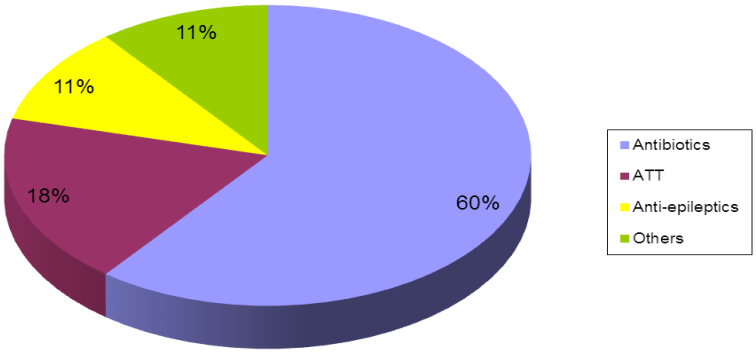


Table3. Drug Classes for which ADRs were reported

Drug Class	Frequency	Percent
Antibiotics	23	60.5
ATT	7	18.5
Anti-epileptics	4	10.5
Others	4	10.5
Total	**38**	**100**

Antibiotics were the most commonly implicated drug class (60.5%) as shown in Table 3 & Fig 2, a finding consistent with other studies.[11] There were 2 reports of thrombocytopenia & 1 report of diarrhea with cefoperazone sodium. Antituberculous drugs were the next commonly implicated drug class (18.5%). There were 2 reports of hepatitis with isoniazid and 2 reports of hepatitis with rifampicin.

Fig 2 ; Drug Classes



The findings of the current study are similar to previous studies on ADRs reported from North[12] and South[13, 14] Indian Hospitals. The overall picture is similar to what is being reported in western literature.

DISCUSSION

A total of 38 suspected ADRs were reported and evaluated. A total of 4% of the ICU patients experienced some form of an ADR. The incidence is low when compared to the high of 29.7% in some of the medical centers in the west.[15] Underreporting could be the reason. Conducting workshops and CMEs on ADR reporting for the physicians and nurses would increase awareness about pharmacovigilance which could increase the number of reports in the ICU. The health care professionals could be requested to report even non serious Adverse Drug Reactions.

When we consider the patient demographics,as shown in table 1, The incidence of ADRs was more in the men when compared to the women. ADRs were reported in 21(55.3%) in males as compared to 17(44.7%) reports in females. ADRs were more common in the elderly. There were 15 reports in patients above 60 years (39.47%). This could be due to polypharmacy and change in the pharmacokinetics in the elderly. Adherence to pharmacotherapy may be improved by tailored and individual means of referring to the patient's needs and

expectancies.[16] Elderly patients had comorbid conditions like diabetes mellitus and systemic hypertension**,** which could have also contributed to the ADRs.

Skin was the organ / system most commonly involved with ADRs (34.21%) as shown in Table 2 & Fig 1.. Out of the 38 reported ADRs there were 13 reports of cutaneous reactions. There were 7 reports of itching, 7 reports of rashes and 1 report of blister. Liver was the next common organ involved (15.8%). There were 4 reports of hepatitis, 1 report of jaundice and one report of raised liver enzymes. Antibiotics were the most commonly implicated drug class(60.5%) as shown in Table 3 & Fig 2, a finding consistent with other studies.[11] There were 2 reports of thrombocytopenia & 1 report of diarrhea with cefoperazone sodium. Antituberculous drugs were the next commonly implicated drug class (18.5%). There were 2 reports of hepatitis with isoniazid and 2 reports of hepatitis with rifampicin.

Before we prescribe a drug to elderly patients if we consider the pharmacokinetic aspect, drug interactions and metabolic derangements, most of the ADRs in the ICU could be prevented. This could be achieved by improving the awareness of pharmacovigilance among the physicians and nurses in the ICU.

CONCLUSION

The incidence of Adverse drug reactions is less when compared to other institutions in the west. Before prescribing a drug to elderly patients if we consider the pharmacokinetic aspect, drug interactions and metabolic derangements, most of the ADRs in the ICU could be prevented. This could be achieved by improving the awareness of pharmacovigilance. Awareness of pharmacovigilance in the ICU could be improved by conducting training programmes and workshops for the staff on adverse reaction monitoring. This could increase the number ADR reports from the ICU which in turn could reduce the morbity and mortality of the patients.

Conflict of interest - None

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