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EVALUATION OF ADR – A PROSPECTIVE ANALYSIS IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Adverse drug reactions are due to hazards of drug therapy and can occur with any class of drugs. The goal of this study was to evaluate and analyze Adverse Drug Reactions in inpatients of a tertiary care hospital (SRM MCH & RC) at Kattankulathur. A prospective analysis and spontaneous reporting study was done from January 2014 to September 2014 – a period of nine months. A total number of 73 ADRs were reported during this nine months period of which 26 were males and 47 were females showing female preponderance. The highest number is from General Medicine followed by General Surgical department. Since allergic reactions most commonly occur in the skin, it is the most commonly affected organ system (52.05%) followed by gastro intestinal system (6.8 %). The most common drugs causing ADRs were antibiotics (49.3 %) of which type B reactions were more common than type A. Most of the reactions were mild (71.6%). Causality assessment was done which showed that 72.6% of the reactions were probable, possible (21.9%), certain (5.47%) and no reactions were unlikely. The study concluded that Adverse Drug Reactions are common and some of them resulted in increased expenditure due to interventions and increased length of hospital stay. Rational and judicious use of drugs is a critical step in preventing ADR as a part of patient management.

KEYWORDS: **Adverse drug reactions, Pharmacovigilance, Patient management, Expenditure.**

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INTRODUCTION

Nature is unbiased, i.e. it has no intensions towards human being though it is often adverse to them. It is humans, in their desire to avoid sufferings and fatality, who decided that some of the biological effects of drugs are therapeutic and others unwanted adverse reactions. An adverse drug reaction is 'a response to a drug that is noxious and unintended and which occurs in doses normally used for the treatment, prophylaxis, or diagnosis of disease, or the modification of physiological function' (World Health Organization)[1]. Drugs are double edged swords. Adverse reactions affect patients' improvement as well as the expenditure of health care. They are important causes of morbidity and mortality in hospitalized and ambulatory patients. So the study aim is to establish a causal relation between the drug and adverse events. The idea behind the assessment for the relationship-likelihood of case reports of suspected ADRs was that this would, in a planned way, bring about a reproducible measurement of causality. The causality assessment system proposed by the World Health Organization Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (WHO–UMC), and the Naranjo Probability Scale are the generally accepted and most extensively used methods for causality assessment in clinical practice[2].Early detection, evaluation and monitoring of ADR are needed to reduce harm to patients and to improve general health condition. High levels of unmonitored and indiscriminate drug use are widely prevalent in India. ADR monitoring and reporting activity is in its early years in our country[3]. It is the fourth largest producer of pharmaceuticals in the world with over 6000 licensed drug manufacturers and around 60,000 branded formulations. It is also emerging as a clinical trial focus exposing greater population to new drugs. It is therefore essential to identify ADRs as early as possible and to prevent them, to ensure the welfare of the patient at a sensible cost. The Central Drugs Standard Control Organization (CDSCO), New Delhi, under the guidance of Ministry of Health & Family Welfare, Government of India has initiated a nation-wide pharmacovigilance programme (PvPI) in July, 2010, with the All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordinating Centre (NCC) for monitoring Adverse Drug Reactions (ADR) in the country. Our hospital is one of the centers for monitoring and reporting ADRs through this programme.

METHODOLOGY

Before commencing the study, approval from the human institutional ethics committee (E.No.607-2) was obtained. A prospective study was conducted based on ADR reported in SRM medical college hospital and research center between January 2014 to september 2014(8 months). ADR details were obtained after getting oral informed consent from the concerned patients. we get ADR reporting by means of health care professionals, regular ward rounds and from voluntary reporting system .The ADR information collected were based on the treating physician's report .Evaluation of the data was done for patients demographics ,drug reaction characteristics, outcome of the reactions such as causality, severity, preventability, and predisposing factors by using Naranjo's probability scale. After calculating the total score, based on the score they were grouped as certain if score >9, probable if score is between 5-8 and possible if score is between 1-4. The study data were collected from case sheets, investigation reports of patients who had experienced an ADR, interviews with clinicians, patient or patient's attendant, past medical history, reports of interventions, etc. The modified Hartwig and Siegel scale classifies severity of ADR as mild, moderate or severe with various levels according to factors like requirements for change in treatment, duration of hospital stay, and the disability produced by the Adverse Drug Reaction.

RESULTS

During the study period, 73 ADRs were reported. Of these, 47(64.3%) were females and 26(35.6%) were males(Table 1). The male to female ratio according to occurrence of ADRs was 0.55. The number of patients below 18 years who experienced ADRs were 9(12.32%), adults 47(64.38%), and geriatrics (>60 years) 17 (23.28%)(Table 2). Majority of the reactions were type B (Bizarre) reactions. In figure 1, According to the Naranjo algorithm scale, 53 (72.6%) reactions were assessed to be probable, 16(21.9%) as possible and 4(5.47%) as certain. Assessment of Severity showed that the majority of the reactions were mild (56, 76.71%), followed by moderate (12, 16.43%) and severe (5, 6.8%). In 64(87.6%) ADRs, complete recovery were achieved. Nine (12.3%) ADRs were classified as 'unknown outcomes' since the outcomes could not be assessed as the patients wanted voluntary discharge from the hospital. This is represented in Figure 3. In 48(65.7%) patients, the offending drug was stopped. The offending drug was substituted with another drug in 5 (6.8%) patients and the dose was reduced to improve the symptoms in 12 (16.4%) patients. No change in treatment was done in 8 (10.9%) patients(Figure 4). As in table 3, antibiotics were associated with about half of all the ADRs reported (36, 49.3%). Diclofenac produced the highest number of reactions (13, 17.8%) followed by paracetamol (9, 12.32%) and Ciprofloxacin (8, 10.9%). Rashes (17, 23.28%) were the most common ADR reported followed by itching (21, 28.76%) and difficulty in breathing (8, 10.9%). The most commonly affected organ system was found to be the skin (38, 52.05%) followed by respiratory system (11, 15.06%) (Figure 5)

Table 1
Gender distribution

Gender	Number of patients
Female	47
Male	26

Table 2
Age group distribution

Age group	Number of people
<18 years	9
Adults	47
>60 years	17

Figure 1
Causality assesment. Causality assessment was done according to Naranjo et al[4]

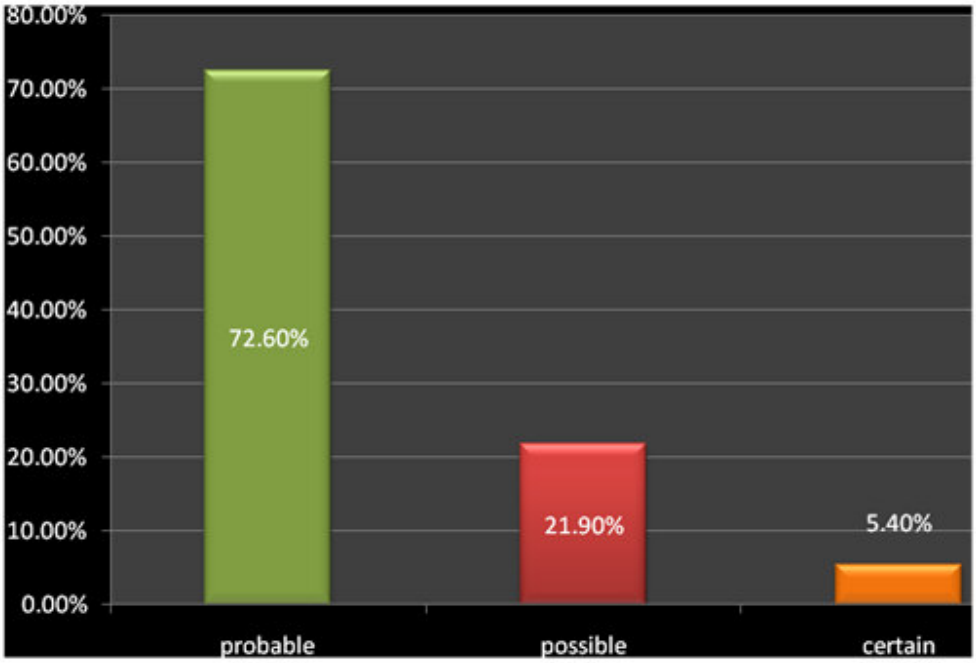

Figure 2
Onset of ADRs .acute onset denotes reactions occurring <1 hour, subacute:1-24 hours, latent:>2days

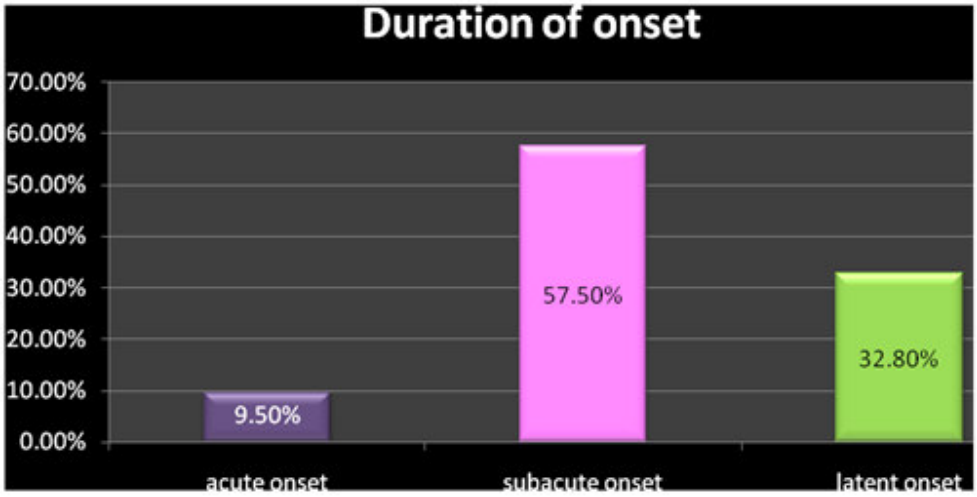

Figure 3
Recovery outcomes .Outcomes were assessed according to Hartwig et al[5]

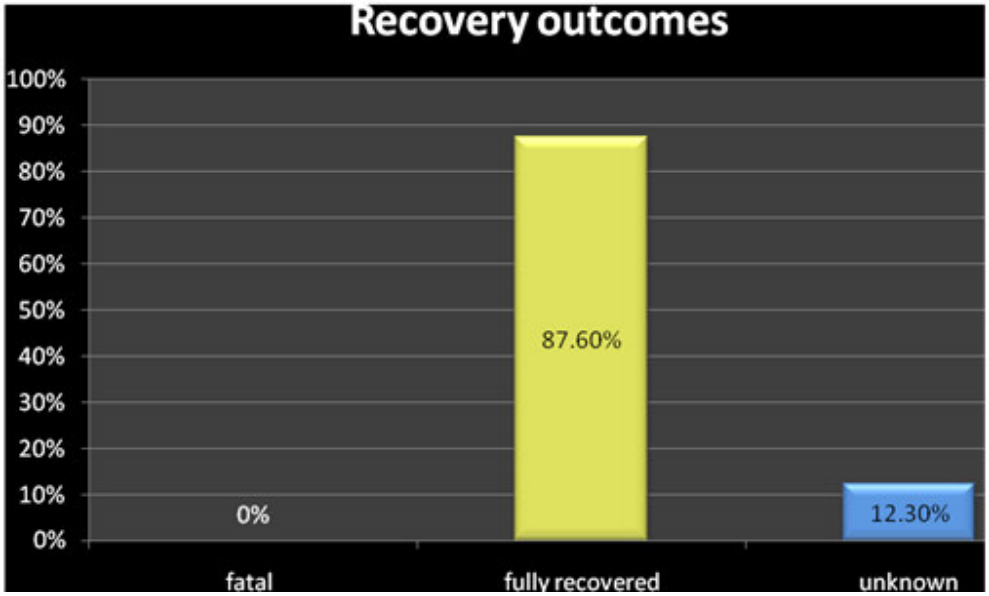

Figure 4
Management of ADRs

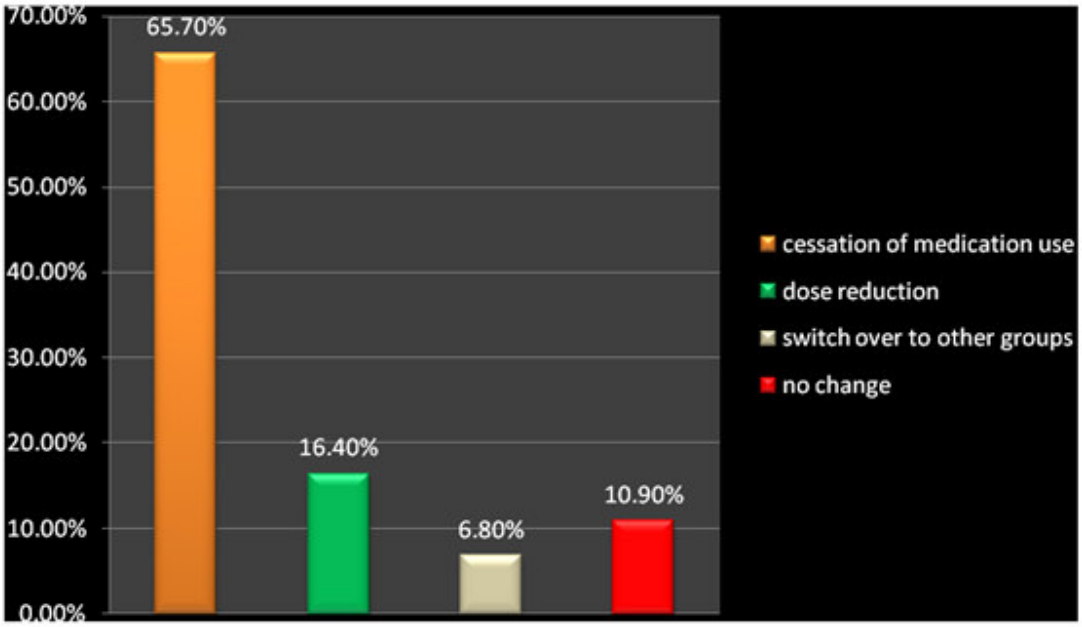

Table 3
Most commonly involved groups of drugs in ADRs

DRUGS	TOTAL NUMBER OF ADRs (%)
Antibiotics	36
Analgesics	24
PPIs	03
Antiepileptics	04
Insulin	02
Antiseptics	04

The reactions reported in each groups of medication are summarized here

Figure 5
Organ systems affected due to ADRs. The numbers represent the total number of ADRs that involved the corresponding organ system

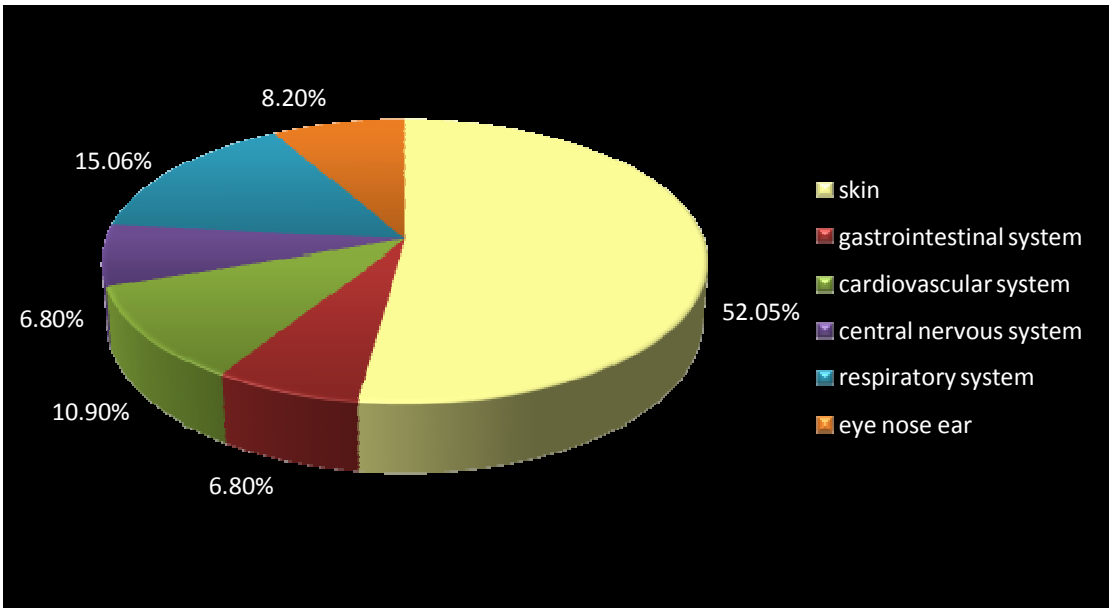

Table 4
Number of ADRs received from various departments

DEPARTMENT	NUMBER OF ADRs (%)
General medicine	23(31.5%)
General surgery	12(16.4%)
Obstetrics and gynecology	16(21.9%)
Nephrology	5(6.8%)
Neurology	4(5.47%)
Dermatology	3(4.1%)
Otorhinolaryngology	3(4.1%)
Orthopedics	3(4.1%)
ICU	2(2.73%)
Cardiology	1(1.3%)
Pediatrics	1(1.3%)

Table 5
Antibiotics associated with ADRs

Drugs	Mode of administration	Number of ADRs
Ciprofloxacin	IV/PO	8(22.22%)
Cotrimoxazole	PO	7(19.4%)
Cefotaxime	IV	5(13.8%)
Metronidazole	IV/PO	4(11.11%)
Ampicillin	IM	4(11.11%)
Ceftriaxone-Tazobactam	IV	3(8.33%)
Cefoperazone-Sulbactam	IV	2(5.55%)
Clindamycin	IV	2(5.55%)
Vancomycin	IV	1(2.77%)

DISCUSSION

The maximum number of ADRs (64.38%) was seen in adult age group which was in contrast with the previous study by Arulmani et al., where pediatric and geriatric patients experienced a higher percentage of ADRs[6]. The most frequent ADRs were due to the usage of antibiotics in 36(49.3%) patients which could be due to increased frequency of antibiotics prescription .The highest number of ADRs were from General Medicine and General Surgery departments since there is increased use of antibiotics in these departments where the patients got admitted with multiple co-morbid conditions requiring polypharmacy[14]. The ADRs reported showed high incidence of skin manifestations similar to previous study by Jose, 2008[7]. This was in contrast to the study of

Benjamin Horen et al. The ADRs reported were classified according to Rawlin and Thompson scale which exposed Type B predominance[8]. This result is in concordance with the study by Suthar and Desai but on the contrary, study conducted by Shamna et al.and Stavreva et al. showed a preponderance of Type A reactions[9,10,11]. The fate of the suspected drugs showed that the drug was stopped in most of the cases and the dose was reduced in some while there was no change in others in view of the risk benefit ratio in particular patients. Drug rechallenge was not done in any of the patients. Most patients recovered completely since most of the reactions were mild. But, it was in contrast to the study done by Oshikoya et al. reporting more severe reactions[12]. In correlation with the study of Priyadharsini et al., the causality assessment according to the Naranjo scale showed that most of them were probable with a lesser number of possible and certain ADRs and no reactions were unlikely[4,13].

CONCLUSION

This study creates awareness to the healthcare professionals and patients on the significance of scrutinizing and reporting adverse drug reactions. In order to ensure the safety of the drugs the health care system should promote the spontaneous reporting and documenting of Adverse Drug Reactions.

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