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A study on incidence and clinical characteristics of adverse drug reactions at a private tertiary care hospital in north Karnataka

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ABSTRACT

It is important to identify the risks for ADRs, henceforth the common drugs causing ADRs, their therapeutic class, demographic data of patients suffered from ADRs and concomitant medications used should be known. Also ADR specific data such as type of reaction, system affected and probable causes will be of great help to minimize the ADRs. It was a prospective-observational Study. Nine patients (13.8%) were admitted due to an adverse drug Reaction compared to 56(86.15%) who were affected by ADR after hospital admission. The majority of patients who suffered from ADRs were of 30-59 years 41(63.2%). System most commonly affected were dermatological in 18(24.8%) patients, gastro Intestinal in 14(20%) patients, central nervous system in 11(19.2%) patients followed by respiratory system in 9(17.6%) patients. The drug class mostly associated with ADR was NSAIDS in 10(13.6%) cases, followed by antibiotics in 9 (11.2%) cases .In 6 (9.6%) cases the drug was withdrawn, dose altered in 9(11.2%) and no change was made in 45(79.2%) patients. Adverse reactions encountered were treated and the final outcome was measured. About 63 (98.4%) patients recovered, while in 2(1.6%) cases the ADR decreased. No fatal cases were reported. Intervention was required in all ADRs as it indirectly contributed to affect the patient's quality of life. Our ability to anticipate and prevent such ADRs can be facilitated by the establishment of standardized approaches and active reporting of suspected ADRs. Our study shows that ADRs are a significant problem in hospital in-patients contributing to morbidity and resulting in considerable financial burden. Over half are definitely at potentially avoidable and steps should be taken to introduce strategies to reduce their impact.

Keywords: Adverse drug reactions, Monitoring, Hospital, Pharmacist
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INTRODUCTION

World Health Organization defines an adverse drug reaction 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 [1]. According to the Centre for Health Policy Research, more than 50 percent of the approved drugs in the United States associated with some type of adverse effect not detected prior to approval. Previous studies indicated that ADRs account for 5% of all hospital admissions and occur in 10-20% of hospitalized patients [2-5].

In the United States, it has been reported that ADRs due to prescription and over the counter drugs during the period 1966 to 1996, affected 6.7% of patients with 3.2% death [6].

While similar figures are not available for India, it is logical to surmise that the figures in relative and absolute numbers would be much higher in view of high levels of unmonitored and indiscriminate drug use widely prevalent in the country.

There is general agreement that drugs prescribed for disease are often themselves the cause of a serious amount of disease or adverse reactions ranging from mere inconvenience to permanent disability and death. Since drugs are intended to relieve suffering, patients find it particularly offensive that they can also cause disease. It is estimated that adverse reactions cause 2–3 % of consultations in general practice, up to 3% of admissions to intensive care units and 0.3% of general hospital admissions are due to adverse drug reactions. A recent study done in Sweden has implicated ADRs as the 7th most common cause of death. Another study involving 19,000 admissions has shown that 6.5% of patient admissions were related to an ADR. Data from older studies on ADRs occurring in in-patients have suggested that 10-20% of patients experience ADRs in hospital. However these studies are decades old and with an increase in life expectancy and development in medicine over the years, there is a need for more data on the ADR in hospital in-patients. Though ADRs are of great concern to the general public, the medical profession, the pharmaceutical industry and the regulatory authorities, the concept of ADR reporting is still new in India. There are very few centers in India to monitor ADRs and hardly any detailed ADR surveys done in India are published [7].

\It is important to identify the risks for ADRs, henceforth the common drugs causing ADRs, their therapeutic class, demographic data of patients suffered from ADRs and concomitant medications used should be known. Also ADR specific data such as type of reaction, system affected and probable causes will be of great help to minimize the ADRs [8] Studies from various literatures revealed that review and monitoring of prescribed medicines by pharmacists or other healthcare professionals may help to improve the clinical condition of the patients and may reduce the cost of treatment [9-11].

The aim of the present study was planned to detect and document suspected ADRs and to study the incidence and clinical characteristics of ADRs.

MATERIALS AND METHODS

A prospective – descriptive cross sectional study was carried out for a period of six months from January 2013 to June 2013 in Navodaya Medical College Hospital and Research Center, Raichur, India. The study was carried out in all Inpatient departments of a 1000 bedded multi-specialty tertiary care teaching hospital. The hospital is well known for its service to all sections of the society, with 80% earmarked for free treatment for the underprivileged sections. The hospital has well staffed pharmacy, drug information center and pharmacovigilance center. All the patients admitted in hospital were included in the study. Outpatients and patients with Obstetric and Gynecological complaints were excluded in the study.

For obtaining the clearance certificate, an application along with study protocol was submitted to the Chairman of the Institutional Ethics Committee of Navodaya Medical College Hospital and Research Centre. The study was approved by Committee by issuing ethical clearance certificate.

A specially designed data entry format was used to enter all patients' details, which include patient information, reason for admission, past medical history, social history, laboratory investigations, medications prescribed, suspected ADRs, system affected, description of the reaction, and management of ADRs, predisposing factors.

A total of 2280 patients admitted to the medical wards of Navodaya Medical College Hospital, Raichur, Karnataka, for a period of 6 months were observed for possible ADRs, as per W.H.O. definition. Project team includes four Pharm D students. Study wards were visited daily by the project team and patients drug charts, medical and nursing notes were reviewed for evidence of an ADR. Objective markers of ADRs, e.g. laboratory results, were identifiable from the patient notes and the hospital computer system, while subjective markers of ADRs, for example headache, nausea and rash were identified through patient notes, discussion with the ward team and, where appropriate, discussion with the affected patient.

Clinical staff was informed that the study was taking place and could also refer directly either in person or through notification cards that were made available on the wards.

ADRs were identified on the basis that they were well recognized as evidenced by their inclusion in the Summary of Product Characteristics and/or the British National Formulary, Micromedex, CIMS.ADRs were identified by research team and confirmed by a physician. When there were doubts/disagreements, such cases were not included. ADRs that occurred outside the hospital and got admitted in our hospital were also included. Those who were identified to have ADRs were examined and the details recorded in a proforma where details of the drugs taken,

observed reactions, measures taken for untoward reactions, investigations and response to measures were recorded. Following completion of the ward based data-collection period, case note analysis was performed to assess patient outcomes and to ensure that all available details regarding the ADR had been collected. We determined the incidence ofADRs in the hospital by extracting the total number of hospital patients in experiencing at least one ADR and dividing this value by the total number of hospital patients. The ADR incidence was expressed as the percent of patients with an ADR. The suspected ADRs are reported to the pharmacovigilance centre. Data were expressed as percentage and kept as 95% confidence interval.

RESULTS AND DISCUSSION

A total of 65 suspected were identified in 2280 admissions during the study period. The incidence of suspected ADRs were found to be 2.85% (95%CI, 2.17%-3.53%) shown in table 1 and is comparable with study which evaluated the reports of ADRs in inpatients at south Indian hospital.[10]

Table 1: Incidence of ADRs (n=2280)

ADRs	No. of cases	Percentage (%)
Prescription with ADR	65	2.85
Prescription without ADR	2215	97.15

Pirmohamed et al, concluded from prospective analysis of about 18,820 patients in United Kingdom in which about 1225 admissions were related to ADR giving prevalence of 6.5%.[12]

The result of age categorization revealed that patients of 30-59 years experienced maximum ADRs about 41(63.2%) followed by 13 (19.2%) with patients of 60 years and above and 17.6% in 10-29 years of age group (Table 2).

Table 2: Age distribution (n=65)

Age in years	No. of patients	Percentage (%)
10-29	11	17.6
30-59	41	63.2
60 and above	13	19.2

In a study by Pirmohamed et al, similar results were observed a greater percentage of geriatric population suffering from ADRs as compared to patients within age group 30-59 years in our study [12].

Of the patients who experienced suspected ADRs during the study period 38 (58%) (95% CI,46%-70%) were male and 27(42%)(95%CI, 30%-54%) were female. Male population was more compared to female.

Figure 1: Gender distribution (n=65)

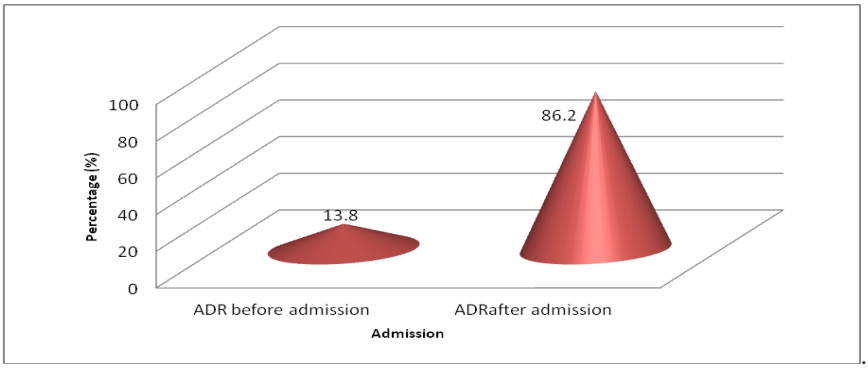

Figure 2: ADR before admission and after admission

According to the present findings the ADRs in the hospital patients were more documented in males which is consistent with the earlier reports [13]. Nine (13.8%) patients were admitted due to an ADR compared to 56(86.15%) were affected by ADR after hospital admission (Figure 2).

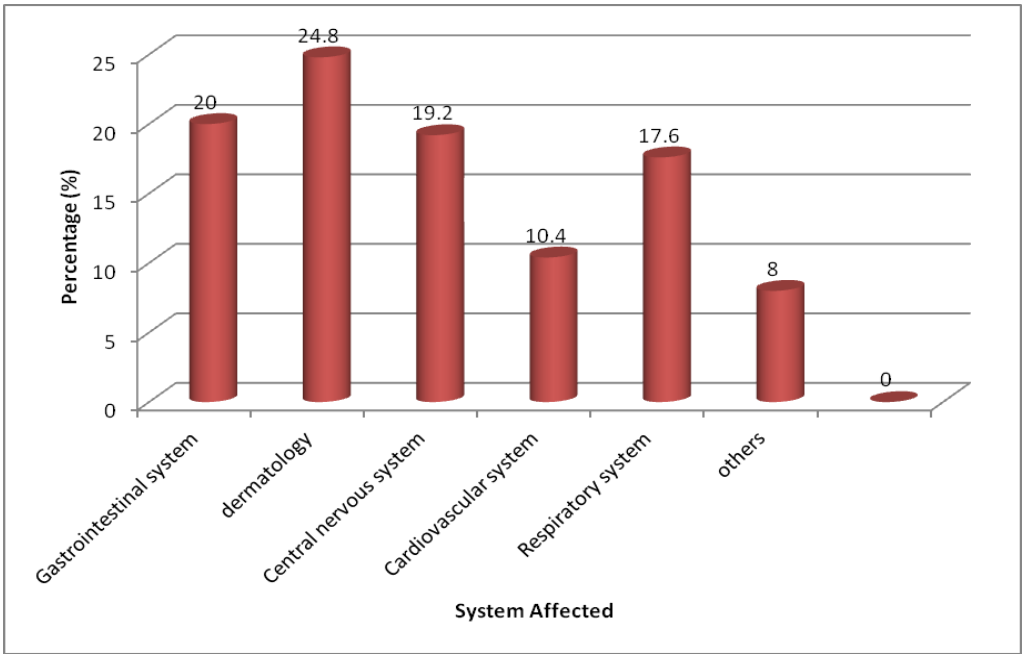

Figure 3: System commonly affected (n=65)

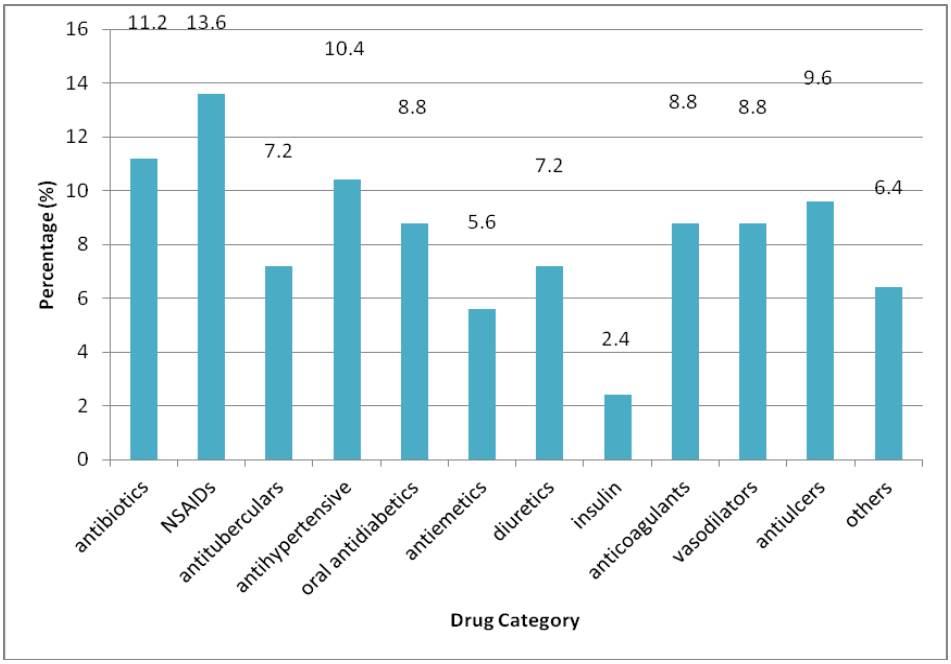

Figure 4: Common drug category causing ADR (N=65)

System most commonly affected were dermatological in 18 (24.8%) Patients, GI in 14 (20%) patients, CNS in 11 (19.2%) followed by respiratory system in 9 (17.6%) patients (Figure 3).The results are comparable matches with the international study conducted by Suh et al ,which reveals that the system most badly affected was the dermatological and GIT system [14] Skin seems to be most common organ system affected followed by GIT. It is likely that patients being extra cautious about glaring ADR of skin have come rushing to hospital. People also may

be worried about GIT problems and CNS symptoms due to drugs, nevertheless commonly used drugs like antimicrobials and analgesics cause ADR. It is seen that ADR may be related to any system [15-17].

The drug class mostly associated with ADR was NSAIDs in 10(13.65) cases, followed by antibiotics in 9(11.12%), anti hypertensives in 7(10.4%), cases each (Figure 4). Our study results comparable with other studies like those done by Classen DC et al., which indicated that NSAIDs have cost extensive damage to human health [18].

In 6(9.6%) cases the drug was withdrawn, dose altered in 9(11.2%) cases and no change was made in 45(79.2%) patients (Figure 5). ADRs were treated and the final outcome was measured. About 63(98.4%) patients were recovered; while in 2(1.6%) cases the ADRs decreased. no fatal cases were reported (Table 3).

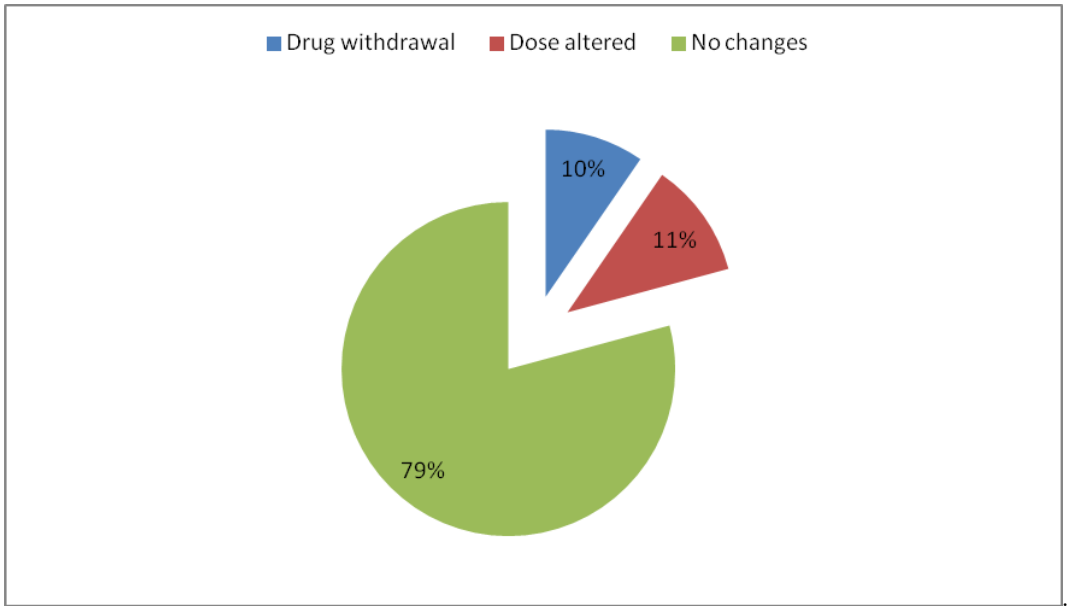

Figure 5: Management of suspected ADRs(n=65)

Table 3: Outcome of ADR (n=65)

Outcome	No. of patients	Percentage (%)
Recovered	63	98.4
Decreased	2	1.6
Fatal	0	0

Interventions were required in all ADRs indirectly contributed to affect the patient quality of life. A study conducted by LI Qing et al showed that the main reasons for under reporting by health care professionals was lack of knowledge of ADRs and voluntary reporting procedure [19] Under reporting is even a major problem in western countries where the pharmacovigilance centre is fully established. In India the major problem is the lack of proper system in pharmacovigilance. In this study pharmacist have reported majority of cases which are confirmed by physicians.

CONCLUSION

In conclusion our study shows that ADRs are a significant problem in hospital in-patients contributing to morbidity and resulting in considerable financial burden. Over half are definitely at potentially avoidable and steps should be taken to introduce strategies to reduce their impact. Our 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 of the country. Measures to improve detection and reporting of ADR by all health care professionals should be undertaken, to ensure patient's safety. The present study hints that pharmacists' involvement may not only greatly increase the reporting rate but also quality of reporting.

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