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Study on Adverse Drug Reactions and their Management At A Private Corporate Hospital

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ABSTRACT

Drug is a double edged sword, despite its benefits, is been always associated with adverse experiences. A Questionnaire Survey on the role of healthcare professionals in detecting, reporting and documenting adverse drug reactions is required for effective implementation of the program and to create awareness. A self-administered Questionnaire Survey was conducted to know the attitude, knowledge and practice oriented issues prevailing among the study site and among the healthcare professionals of Sri Ramakrishna Hospital, Coimbatore. Patients admitted to General Medicine Department over a period of 9 months were assessed for ADRs through daily ward visit by the pharmacist. A total of 51 ADRs were identified in 3722 general medicine ward admissions during the study period. Severity of the suspected ADRs assessed using Modified Hartwig and Siegel Scale, revealed that 4(7.8%) suspected ADRs were severe, 27 (52.94%) ADRs were moderate and 20 (39.21%) ADRs were mild in severity. The study revealed that 29 (56.8%) ADRs were possibly drug-related, whereas 17 (33.33%) were classified as probably or definitely related to the drug and 22(43.13%) ADRs were possibly drug-related, 16(31.41%) ADRs were probably drug-related, whereas 11(21.56%) were classified as certainly related to drug on assessment with Naranjo and WHO scale.12 patients (23.52%) were admitted due to an Adverse Drug Reaction compared to 39(76.47%) who were affected by ADR after hospital admission. The majority (40%) of patients who suffered from ADRs were above 60 years. System most commonly affected were Dermatological in -15(29.41%) patients, Gastrointestinal in 13 (25.49%) patients, CNS in 8(15.68%) patients, followed by Cardiovascular in 2 (3.92%) patients. The drug class mostly associated with ADR was Antibiotics in 16(31.3%) cases, followed by NSAID in 8(15.68%). In 41 (80.34%) cases the drug was withdrawn, dose altered in 7(15.6%) and no change was made in 3(5.8%) patients. Adverse reactions encountered were treated and the final outcome was measured. About 43(84.3%) patients recovered, while in 7(13.7%) cases the ADRs decreased. One fatal case was reported. 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 of the country. Our study revealed that pharmacists' involvement could not only greatly increase the reporting rate but also quality reporting.

Keywords: ADR, Survey Questionnaire, Pharmacovigilance

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INTRODUCTION

Adverse drug reaction is a response which is noxious and unintended that occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. ADR forms the fourth to sixth leading causes of death and representing 5% to 10% of the hospital costs[1-4]. Hence, in spite of obvious morbidity and the mortality, they also become an economic burden on health care system since it prolongs the hospital stay and increases the treatment cost.[5-8] India being the clinical trial hub of the world where larger population is being exposed to newer drug treatments definitely needs to identify ADRs as early as possible in order to ensure the safety of the patient by preventing it at a reasonable cost.[9,10]

Being the most common iatrogenic illness worldwide, morbidity and mortality due to ADRs are mainly caused because of immune and non-immune mechanisms. The risk for hypersensitivity drug reactions increases with conditions like Asthma[11], Systemic lupus erythematous[12] and use of beta blockers[11,12]. Adverse drug reactions can results in hospitalization, permanent or persistent and significant disabilities, congenital anomalies, adversely affecting the quality of life, and can result even in death[13-17].

Voluntary adverse drug reaction (ADR) reporting enables the health care professionals to report suspected ADRs and there by helps to identify new ADRs and risk factors responsible for recognized ADRs[18]. Still, only a small proportion of ADRS is reported to the concerned National monitoring centres. On a survey conducted in The Netherlands showed that the lack of time and poor access to reporting forms were major reasons for underreporting whereas a survey done among general practitioners (GPs) reported that lack of knowledge with the Dutch national reporting centre was the prominent reason for poor reporting of an ADR[19].

MATERIALS AND METHOD

Study Design

The study involves a multidisciplinary spontaneous (voluntary) reporting program that relies on both the prospective and concurrent detection of suspected adverse drug reactions. The voluntary component of the ADR reporting and monitoring system involved reporting by physicians, nurses, pharmacists and postgraduate students of pharmacy. Reports of suspected adverse drug reactions were accepted from different type of services and specialties. A self-administered Questionnaire Survey (ANNEXUR 1) was conducted to know the attitude, knowledge and practice oriented issues prevailing among the study site and among the healthcare professionals. After ascertaining the need of the study through questionnaire survey, the CDSCO's Adverse Drug Reaction reporting forms were made available with

various departments of the hospital. Adverse drug reaction reports were accepted from all the healthcare professionals of different specialties irrespective of their status and types of services offered. We adopted various modes of reporting system including use of ADR notification form, telephone reporting, direct access, referral of patients and personal meeting so as to ease the reporting of 'suspected' adverse drug reactions.

ADR Notification Form

As a first step to the implementation of ADR reporting and monitoring system, a suitable "ADR notification forms" (*'Yellow card')* was designed. This was prepared based on a format similar to the 'Yellow card' of the Committee on Safety of Medicines (CSM), United Kingdom (UK) and Australia's Adverse Drug Reaction Advisory Committee (ADRAC)'s 'Blue card', with necessary changes, to suit the present study. This notification form contained only the basic and essential information such as patient demographic details, information about the suspected medication, description of event, date and signature of the reporter. The ADR notification form was made available at all nursing stations, outpatient departments and physician's chamber for easy access to all healthcare professionals.

ADR Documentation Form

Similarly, a suitable ADR documentation form was designed to gather and document as much relevant data as possible pertaining to the reported reaction. The designed ADR documentation form contained the specific details regarding patient demography, description of event, medications suspected, medication used prior to the reaction with their complete dosing regimens, co-morbidities, risk factors involved, patient allergic status, causality category, severity, predictability, preventability, management of reported adverse reaction, outcome of management and follow up details.

Study Patients

Patients admitted in the hospital of either sex of any age who developed an ADR during the study period (9 months) were considered for the study. Out of 3722 patients admitted in the hospital, 51 patients were identified to have ADR's. Patients who developed an ADR due to intentional or accidental poisoning, ADR to fresh blood/blood products, ADR due to overdose, patients with drug abuse and intoxication were not included in the study.

The study was approved to be conducted at Sri Ramakrishna Hospital, Coimbatore by the hospital ethical committee. Informed consent form was obtained from patients or a legal representative before enrollment.

Study Outcomes

The primary outcome was detection and documentation of the suspected adverse drug reactions. We issued adverse reaction reporting forms to healthcare professionals and alert

card to patients who experienced ADR, as active reporting of suspected adverse drug reactions can minimize the incidence of ADRs in hospital inpatients. An assessment of suspected ADRs for Severity (Modified Hartwig and Siegel Scale), Preventability (Modified Schumock and Thornton) and Causality (WHO & Naranjo scale) by using standard scales. Study group also conducted questionnaire survey on role of Healthcare professionals in reporting adverse drug reactions and to check the feasibility of implementing an ADR monitoring centre in the hospital.

RESULTS AND DISCUSSION

Many physicians report that they have detected ADR during their practice but a significant proportion do not report the ADR to a regulatory body. Common reasons for not reporting may be lack of knowledge about the drug causing the ADR, difficulty in accessing reporting forms, lack of awareness of the requirements for reporting, lack of understanding of the purpose of reporting and lack of time.

In this study a total of 51 patients had been reported with ADR, out of that 29(57%) were male and 22 (43%) were female,20(39%) of age above 60, 18 (35%) between 30 to 59 and 13 (24%) between 18 to 29. The older people are more liable to adverse drug reactions as the elderly receive more drugs, illnesses in the elderly tend to be treated with drugs with a poor therapeutic ratio, drug interactions occur due to poly-pharmacy, poor compliance, altered pharmacokinetics and pharmacodynamics. In this 12 (24%) had ADR before admission and 39 (77%) had ADR before admission TABLE (2). The systems involved in the ADR are given in FIGURE (1) , dermatological reactions were more that is 15 (29%) compared to others.

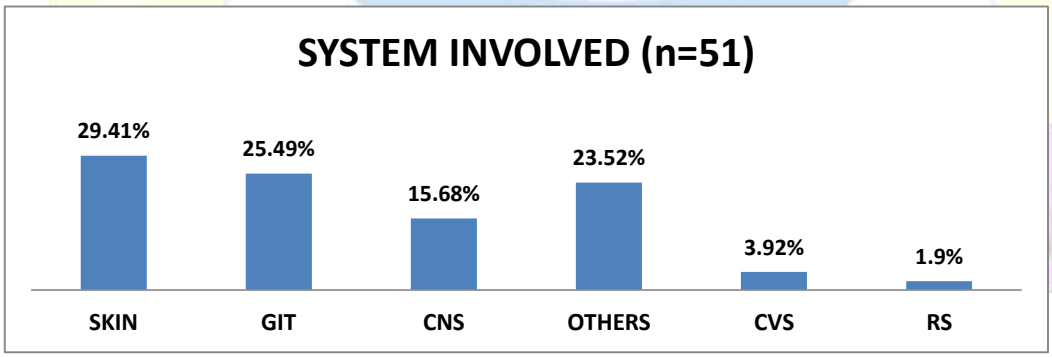

Figure 1:System commonly affected (n= 51)

Table 2: ADR before admission and ADR after admission (n= 51)

Admission	No of patients	Percentage (%)
ADR before admission	12	23.52
ADR after admission	39	76.47

The drug class mostly associated with ADR was Antibiotics in 16(31.3%) cases, followed by

NSAIDs in 8(15.68%).In 41 (80.34%) cases the drug was withdrawn, dose altered in 7(15.6%) and no change was made in 3(5.8%) patients. Adverse reactions encountered were treated and the final outcome was measured. About 43(84.3%) patients recovered, while in 7(13.7%) cases the ADR decreased and 1(1.9%) fatal case was reported.

Preventability of suspected ADRs were assessed by using Modified Schumock and Thornton scale and the results revealed that 40(78.4%) ADRs were definitely preventable while 5(9.8%) ADRs were probably preventable. This study revealed that an increased risk of ADRs is suspected in elderly patients, and that almost 80% of reactions were preventable. The causality assessment of suspected ADR's were done by WHO scale is given in Table .2 The major factors that discourages one from reporting are not being aware of how and where to report (33.7%), difficult to decide whether an ADR has occurred or not (30.6%), lack of time (13.7%) and false perception that a single unreported case may not affect ADR database (11.6%) respectively 57 (60%) out of 95 HCPs have enough time to fill ADR monitoring form, 77.9% demands the assistance of pharmacy PGs/interns to retrieve the fullest possible data to ensure effective Pharmacovigilance program. All health care professionals (100%) think that ADR reporting is necessary and that it can ensure patient safety and improve rational drug use. The need for education and training on ADR reporting is felt by 97.9% of health professionals and 85.3% agreed to have a Pharmacovigilance center at their hospital. 94.7% of HCPs felt that it is important to foster a culture of reporting ADRs in hospital and 85.3% reported that they are aware of the term Pharmacovigilance. Prescribing medicine is a very important responsibility for the healthcare professional but reporting suspected ADRs and participation in ADR monitoring systems must also be promoted as a fundamental professional duty. Education is the cornerstone for good quality reporting, but both the quantity and quality of reporting for suspected ADRs are important and must become part of continuing medical education and clinical governance

96.8% of HCPs felt that an ADR database is required and 91.6% demands the easy access of CDSCO form. Only 29.5% knows that IPC Ghaziabad as National Coordinating Centre (NCC) for ADR monitoring in India which clearly indicates the need of awareness of National Pharmacovigilance Programme among HCPs.82.1% of HCPs are aware that all health care professionals can report an ADR. Even though 95% of the HCPs felt that it is important to foster a culture of reporting ADRs, 12.6% revealed that ADR reporting will create a negative impact on the quality of treatment. Regarding CME of ADR, 98.9% of HCPs documented that, discussion of ADR cases on clinical meeting will help to improve quality of patient care and 76.8% of HCPs felt that circulation of identified ADR through newsletters, is essential. . Further studies are required to assess the impact of under-reporting

on public health decisions and to evaluate recent initiatives to improve reporting such as online reinitializes to improve reporting such as online re-porting, pharmacist and nurse reporting, greater feedback to reporters and potential links with continuing education and training.

A total of 51 suspected ADRs were identified in 3722 general medicine department admissions during the study period. The incidence of suspected ADRs was found to be 1.37 % and is comparable with the study done by Padma GM Rao (2006), which evaluated the reports of ADRs in the inpatients at a south Indian hospital for their incidence and pattern and found that the incidence of ADRs was 2.8% in hospitalized patients Fifty four nurses with special drug responsibilities were invited to participate in the study.

During the study period, a total number of 23 reports with 39 ADRs were sent to the regional centres by the nurses. Seventeen (74%) of the reports were assessed as serious. Eight of the 39 ADR were unlabelled and all reports were considered appropriate. The reporting rate from the physicians during the study period was similar to the previous year, indicating that the nurses contributed with additional reports.

A large number of powerful drugs, often with a narrow therapeutic window, have reached the market and this makes close monitoring necessary to avoid adverse drug reactions. The most appropriate approach of medication control to minimize the incidence of ADR is screening the total medication of the individual patient by a hospital pharmacist and by taking history of allergy as well as past medication & medical history. Developing and maintaining electronic documentation of patients' medical records may serve as a valuable tool to detect early signals of potential ADRs. In addition, creating intra net facilities within a hospital may help in easy access for healthcare professionals to the updated patients' medical records resulting in possible detection of ADRs. Also, the implementation of computerized reporting in hospital set-up may hasten reporting of ADRs.

GENERAL GUIDELINES FOR THE PREVENTION OF ADVERSE DRUG RECTIONS

Adverse drug reactions may be prevented as follows:

- Never use any drug unless there is a good indication. If the patient is pregnant do not use a drug unless the need for it is imperative.
- Allergy and idiosyncrasy are important causes of adverse drug reactions. Ask if the patient had previous reactions.
- Ask if the patient is already taking other drugs including self-medication drugs; Interaction may occur.

- Age and hepatic or renal disease may alter the metabolism or excretion of drugs, so that much smaller doses may be needed. Genetic factors may also be responsible for variations in metabolism, notably of Isoniazid and the Tricyclic Anti depressants.
- Prescribe as few drugs as possible and give very clear instructions to the elderly or any patient who are likely to misunderstand complicated instructions.
- When possible use a familiar drug. With a new drug be particularly alert for adverse reactions or unexpected events.
- If serious adverse reactions are liable to occur warn the patient.

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