RESEARCH ARTICLE

A novel way to overcome the challenge of under-reporting of adverse drug reactions in a tertiary care hospital: A pharmacovigilance study

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ABSTRACT

Background: Adverse drug reactions (ADRs) constitute a major clinical problem in terms of human suffering and increased health-care costs all over the world. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects, or any other drug related problems. Thus, the information generated is useful in educating doctors about ADRS as well in the official regulation of drug use. However, the pharmacovigilance program faces the challenge of under reporting of ADRs and one needs to find the ways to overcome it. Aim and Objectives: The aim of the study was to improve the reporting of ADRs from the hospital and overcome the problem of under-reporting of ADRs. Materials and Methods: A prospective observational study was conducted as part of pharmacovigilance program over 6 months between June 2021 and December 2021. Undergraduate students were trained to collect cases of ADR from hospital during their clinical postings. The details of cases obtained by such active surveillance were filled into suspected ADR–CDSCO forms and submitted to pharmacovigilance unit. Causal relationship was assessed and categorized by Naranjo algorithm and WHO-UMC causality scale. All values were expressed in percentages. Results: A total of 120 cases were reported over 6 months compared to just 20 cases during the past year. Among them, 66% were in males and 55% were in females. The majority of ADRs were due to antimicrobial agents (40.78%) followed by hematinics (12%) and anti-epileptics (10%). The maximum number of patients (30.25%) reported with dermatological manifestations. The highest number of ADRs was reported from the Department of Medicine (45%). As per Naranjos scale, 54% reports were assessed as probable and 46% as possible. Conclusion: This new way of training and involving undergraduates significantly improved the number of ADR cases being reported to the pharmacovigilance center. This helped overcome the problem of under reporting of cases and has strengthened the pharmacovigilance activity in our institute.

KEYWORDS: Adverse Drug Reactions; Under Reporting; Adverse Drug Reaction Reporting Systems; Pharmacovigilance

INTRODUCTION

Adverse drug reactions (ADRs) constitute a major clinical problem in terms of human suffering and increased health-care costs not only in developed but in developing countries. ADRs are responsible for 5–11% of hospital admissions of which 60–70% are preventable.[1-3]

The World Health Organization (WHO) defines an ADR as “any noxious unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease.”[4] Post-marketing surveillance of drugs is very important in analyzing and managing the risks associated with drugs once they are available for use in the general population. Spontaneous reporting systems have contributed significantly to the success of pharmacovigilance. In this regard, the
contribution of health professionals to ADR databases is very important. In spite of these benefits, under-reporting remains a major draw-back of spontaneous reporting.\(^5\) It is estimated that only 6–10% of all ADRs are reported.\(^6\) A systemic review by Hazell and Shakir found that a median rate of under-reporting is 94%.\(^7\) This high rate of under-reporting can delay safety signal detection and consequently cause negative impact on public health in a longer term.\(^8\)

Need for the study

Ours is a tertiary care government hospital; with capacity to accommodate 750 in-patients. It is an ADR monitor center since 2014. However, just 20 cases report with ADRs were reported in 2014. It was speculated that inadequate knowledge about pharmacovigilance among clinicians, nursing staff, and pharmacists would be associated with a high degree of underreporting.\(^9\) Also, lack of awareness and high patient load could be other contributing factors. To overcome these challenges and impart adequate inclination toward ADRs reporting a baseline change in knowledge and attitude is expected. Thus, this study was conducted to observe change in reporting frequency post awareness and knowledge calibration.

Objectives

The objectives of the study are as follows:

To improve the reporting of ADRs in a tertiary care hospital.

Overcome the impediments to under-reporting of ADRs.

MATERIALS AND METHODS

After obtaining the Institutional Ethics Committee clearance, a prospective observational study was conducted between June 2021 and December 2021 in a tertiary care hospital of Bidar Institute of Medical Sciences, Bidar, Karnataka. Second Phase/Year MBBS students were trained during pharmacology practical sessions for active surveillance and reporting of ADR cases during clinical postings. For this purpose, CDSCO spontaneous ADR reporting forms were used. Further practical sessions were also utilized to train and assess the progress. Filled ADR forms were submitted to pharmacovigilance unit. Completeness of forms and cases were assessed and discussed with postgraduate students. Causal relationship between reported adverse events/reactions and suspect drug/s was assessed and categorized by Naranjo’s algorithm and the WHO – UMC causality scale.

RESULTS

Post training of second MBBS students, a total of 120 cases were reported over 6 months. This was observed as significant increase in ADR reporting (600%) compared to just 20 cases during the past year. All the result values were expressed in percentages.

The reported case reports had 66% males and 55% female patients [Figure 1]. The majority of ADRs were due to antimicrobial agents (40.78%) followed by hematins (12%) and anti-epileptics (10%) medications [Figure 2].

As per Naranjo’s scale, causality was assessed as probable in 54% reports and possible in 46% case reports [Figure 3].
The maximum number of patients (30.25%) reported ADRs as dermatological manifestations [Figure 4]. The highest number of ADRs was reported from the Department of Medicine (45%) [Table 1].

**DISCUSSION**

A total of 120 cases were reported over a period of 6 months compared to just 20 cases during the past year. Among them, 66% were in males and 55% were in females. The majority of ADRs were due to antimicrobial agents (40.78%) followed by hematincs (12%) and anti-epileptics (10%). The maximum number of patients (30.25%) reported with dermatological manifestations. The highest number of ADRs was reported from the Department of Medicine (45%). As per Naranjo’s scale, 54% reports were assessed as probable and 46% as possible. Our study showed a significant increase in reporting of ADRs following the conduct of knowledge calibration and awareness sessions about perception and importance of reporting ADRs.

In our study, the majority of ADRS were reported among middle age between 21 and 40 years, followed by >60 years and pediatrics (particularly age 1–10 years). This finding was similar to the studies carried out by Yu et al. and Martin et al. who showed the similar reporting as in middle age and adults.[10,11] Similarly, the maximum ADR reporting among various class of drugs was seen with antimicrobials followed by drugs acting on CNS and least with NSAIDs, also the study by Shehab et al. revealed the same inference from the other class of drugs.[12,13] Department-wise medicine department reported maximum ADRs, followed by obstetrics and gynecology and least by dermatology, ENT, and orthopedics. A study by Ramandeep kaur et al. showed ADRs in OBS&G department even after precautioned prescription.[14] Furthermore, the most common system organ class affected by ADRs was skin and connective tissue followed by gastrointestinal system and least with respiratory system. Pruritus and gastritis were the most common ADRs. Marzano et al. study also showed the same skin and connective tissue system related ADRS reporting.[15] Kourorian et al. showed the similar ADR reporting with the organ system.[16]

Pharmacovigilance science mainly relies on detection and reporting of suspected ADRs by physicians and health-care professionals. The reported ADRs, their frequency, and outcome help in early identification of signals. These signals provide updated reference safety informations which helps the clinicians to prevent future ADRs. The under reporting of ADRs is influenced by not only the prescriber but also reporter’s knowledge and approach to give adequate significance of ADRs.

Many factors are associated with inadequate ADR reporting. The major factors include (1) lack of knowledge, (2) poor attitude, and (3) time required to fill the ADR reporting forms. The lack of knowledge and poor attitude can be improved with proper training and imparting importance of ADRs reporting and its beneficial long-term effects. The additional health-care workers (nurses and pharmacists) could help in filling ADR reporting forms.[17] In our study, the participants were trained which led to gain of knowledge and improved their attitude toward pharmacovigilance activity thus led to increase in reporting of ADRs.

The limitations of the study include that the majority of the ADRs were reported by MBBS students or assisted by them. Thus, they continue to denote under reporting by other clinicians and health-care professionals. Furthermore, mild-to-moderate severity/intensity ADRs might not be reported or expressed by patients to physicians.

**CONCLUSION**

This new way of training and involving undergraduates significantly improved the number of ADR case reports being reported to the pharmacovigilance center. This helped overcome the problem of under reporting of cases and has strengthened the

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ADRs: Adverse drug reactions
the pharmacovigilance activity in our institute. However, there is a need to find out more innovative and practical methods to overcome the problem of under reporting in clinical settings and strengthen the pharmacovigilance system worldwide.

REFERENCES


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