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Research Article

AWARENESS, KNOWLEDGE, AND ATTITUDE TOWARD PHARMACOVIGILANCE AMONG MEDICAL GRADUATES IN A TERTIARY CARE TEACHING HOSPITAL IN SOUTH INDIA

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ABSTRACT

Objectives: As an ever growing scale people are using newer and more effective drugs for various medical conditions. Adverse drug reactions (ADRs) are preventable if the health-care professional pays close attention to the details of the adverse effects, following a drug administration. Awareness about ADRs can decrease the irrational use of drugs. Hence, there is an urgent need to create awareness among the prescribers about the ADR monitoring. Hence, this study is undertaken to assess the awareness, knowledge, and attitude toward Pharmacovigilance among the future health-care professionals.

Methods: Questionnaire-based study was conducted in a tertiary health-care hospital after getting approval from the Institutional Ethical Committee. The questionnaire was developed to assess the knowledge, awareness, and practice of Pharmacovigilance activity. The questions were distributed to the final year students, interns, and postgraduate's students and allowed to write down the answers independently. Each correct answer was given a score of '1,' whereas the incorrect/incomplete was given a score of "0."

Results and Conclusion: The study reported that awareness (UGs - 53.3%, interns - 54.9%, PGs - 30.75) was adequate among undergraduates and interns, in the knowledge part (UGs-65.5%, interns - 35.4%, PGs - 9.2%), undergraduates excel far than the interns and PGs. However, in the application of Pharmacovigilance (UG - 22.2%, interns - 59.8%, PGs - 63.1%) postgraduates and interns fair better than the undergraduates. Hence, there is need to increase the awareness and also increase the ADR reporting practice among medical graduates.

Keywords: Questionnaire, Pharmacovigilance, Awareness.

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INTRODUCTION

Drug disasters have played a key role in the awareness of adverse drug reaction (ADRs). The thalidomide disaster has served an important role in the improvement of drug regulation safety needs and triggered the spontaneous reporting of ADRs globally. There are 3 actions of a drug, the one you want, the one you do not want, and the one you do not know about [1]. Hence, it is crucial to monitor both the known and unknown adverse effects of medicines. This is often paraphrased by saying that all drugs are poisons, the dose alone making the difference. In various studies, ADRs have been implicated as a leading cause of considerable morbidity and mortality [2].

ADRs can arise from many sources even if a drug is correctly selected and dosed. To the patient, an unnecessary hospital admission caused by ADRs is a needless loss of health as well as an unnecessary loss of quality of life [3]. Thus, prevention of unnecessary hospitalization by ADRs is a key goal in health policy decision-making.

In a country like India, with a huge population and vast diversity, it is absolutely necessary to introduce a standard Pharmacovigilance programme in each medical college and hospitals across the country. Pharmacovigilance is by definition "the science and activities which are related to the detection, assessment, understanding, and the prevention of adverse effects or any other drug-related problems [4]. India ranks below 1% in terms of ADR reporting against the world rate of 5% [5]. To overcome this problem, the Ministry of Health and Family Welfare, Government of India, has initiated the National Pharmacovigilance programme. The purpose of this program is to gather the data, analyze it, and to use inferences to propose informing regulatory interventions, besides communicating the risks to the health-care professionals and the public. This program is coordinated by the National Pharmacovigilance Centre at the Central Drugs Standard Control Organization in New Delhi. The National Center is operating under the supervision of the National Pharmacovigilance Advisory Committee, to recommend procedures and guidelines for regulatory interventions. This committee oversees the performance of two zonal, five regional, and twenty-six peripheral Pharmacovigilance centers. The entire network works in coordination to improve the ADR reporting in our country [6].

India has become a destination for conducting clinical trials. During clinical trials, drugs are commonly studied in a safeguarded environment, for a relatively small number of patients, and usually for a limited duration. These trials at times exclude the elderly, the very young, and patients with comorbidities. Often patients on multiple drug therapy and patients with decreased renal and hepatic function are disqualified. For these patient populations, any susceptibility to ADRs may be missed. Adverse reactions may occur at such a low frequency that they are not being detected in the small numbers of patients included in clinical trials. Furthermore, it is very difficult to foretell how practitioners will really use medications in practice. Once the drug is commercially available, the exclusion criteria applied in clinical trials, no longer exist. Thus the use of drug in general population either short term or long term may increase the possibility of identifying unobserved adverse effects. In addition, widespread use of medicines in the general population can increase the chances for uncovering adverse reactions occurring at low frequency and thus not previously detected during the marketing approval process.

Pharmacovigilance is now accepted to be an uninterrupted practice of evaluation accompanied by steps to improve safe use of medicines which involve pharmaceutical companies, regulatory authorities, health professionals, and patients. Pharmacovigilance is particularly important since most of the adverse effects are reversible by modifying the dosage

or omitting the offending medicine. All medicines (pharmaceuticals and vaccines) have side effects. In a vast country like India with a population of over 1.2 Billion with vast cultural blend, different disease occurrence patterns, practice of different systems of medicines, different socioeconomic status, it is important to have a standardized and healthy Pharmacovigilance and drug safety monitoring program for the nation. Concern for ADRs in highly vulnerable populations is of even greater concern.

Pharmacovigilance programs have played a major role in detection of ADRs and banning of a number of drugs from the market. However, underreporting of ADRs is one of the major problems associated with Pharmacovigilance programs. Although Pharmacovigilance programs are victorious in improving drug use patterns, underreporting of ADRs is felt as a major problem. ADR may not be reversible or may escalate into severe consequences. In the long run, this ADR may spread out in different parts of the world with the same symptoms as no professional engaged in prescribing the doses takes pain in reporting the matter to the concerned agency. Such a casual approach may prove fatal to the large population and at times be cost-effective and result into loss of valuable workforce. At last medicine, despite promising ingredients to cure the disease, is discarded and the other alternatives are searched upon [7]. The Herculean task is to foster a culture of reporting among the clinicians, especially among the junior doctors, as they are more closely associated with the patient care. The present low level of ADR reporting is mostly due to a lack of awareness and training and time constraints [8]. The way in which a doctor takes the clinical record of a patient can be improved if he has a sound knowledge of the drug safety issues, with an importance on the patient's medication history. It also helps him in understanding the action of the drug better. It thus decreases the irrational use of medicines, adverse drug-drug interactions, and inappropriate polypharmacy [9]. To expand the reporting rate, it is vital to improve the knowledge, attitude, and practices (KAP) of the health-care professionals regarding ADR reporting and Pharmacovigilance. Before carrying out any intervention, it is necessary to evaluate the baseline KAP of the health-care professionals regarding ADR monitoring and Pharmacovigilance [10]. Pharmacovigilance plays an important role in the rational use of medicines by providing information about ADRs in the general population. Communicating the potential harm of drug use to patients is a matter of high priority and should be carried out by every prescriber [11]. One of the important long-term goals of this program is to develop a reporting culture among health-care professionals and make ADR reporting mandatory for health-care professionals [12,13]. Studies from different settings indicate inadequate knowledge about Pharmacovigilance among health-care professionals as well as attitudes that are associated with a high degree of underreporting [13] detection, recording, and reporting of ADRs is of vital importance and health experts should be encouraged to execute this appropriately.

Table 1: Awareness of pharmacovigilance among respondents

Grading	Final year students (%)	Interns (%)	Postgraduates (%)
Poor (below 25%)	11.1 (10/90)	18.3 (15/82)	18.4 (12/65)
Average (25-50%)	24.4 (22/90)	31.7 (26/82)	49.2 (32/65)
Good (51-75%)	53.3 (48/90)	54.9 (45/82)	30.75 (20/65)
Excellent (above 75%)	3.3 (3/90)	2.4 (2/82)	1.5 (1/65)

Table 2: Knowledge of pharmacovigilance among respondents

Grading	Final year students	Interns	Postgraduates
Poor (below 25%)	6.6 (6/90)	10.9 (9/82)	24.6 (16/65)
Average (25-50%)	28.8 (26/90)	43.9 (36/82)	64.6 (42/65)
Good (51-75%)	65.5 (59/90)	35.4 (29/82)	9.2 (6/65)
Excellent (above 75%)	6.7 (6/90)	2.4 (2/82)	1.5 (1/65)

Table 3: Application of pharmacovigilance among respondents

Grading (%)	Final year students (%)	Interns (%)	Postgraduates (%)
Poor (below 25)	24.4 (22/90)	9.75 (8/82)	3.1 (2/65)
Average (25-50)	52.2 (47/90)	28.1 (23/82)	27.7 (18/65)
Good (51-75)	22.2 (20/90)	59.8 (49/82)	63.1 (41/65)
Excellent (above 75)	1.11 (1/90)	2.4 (2/82)	6.2 (4/65)

METHODS

Study population

This was a noninterventional study which was done among the final year MBBS students, interns, and the postgraduates who were studying at Sree Balaji Medical College, Chennai, after getting consent from them. Those who did not return the questionnaires in the stipulated time were excluded from the study. The study was conducted after getting approval from the Institutional Ethical Committee.

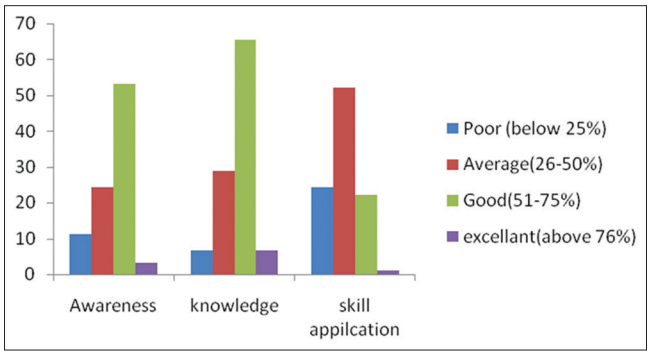

Fig. 1: Pharmacovigilance score of undergraduates

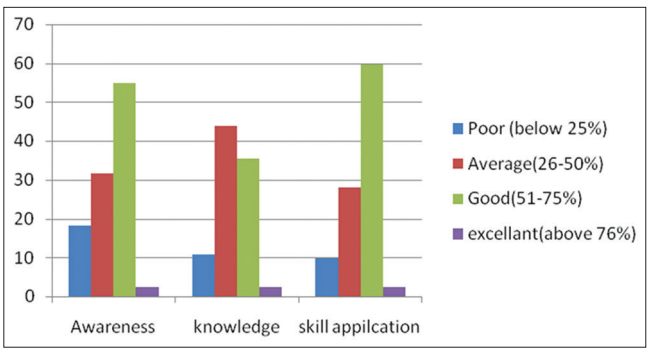

Fig. 2: Pharmacovigilance score of interns

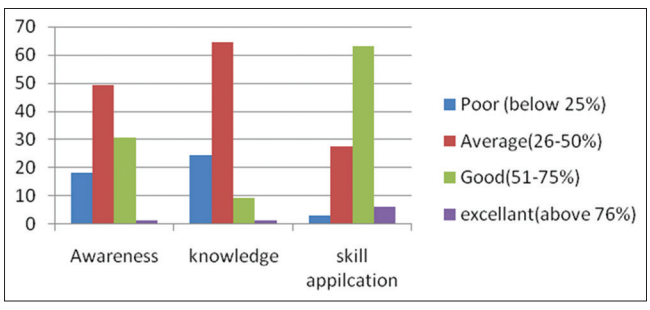

Fig. 3: Pharmacovigilance score of postgraduates

The study instrument

The study instrument was a predesigned questionnaire which was prepared by following the preference which was set by related studies. It was validated. The study questionnaire was designed to assess the awareness, knowledge, and the methods of application of Pharmacovigilance among the study population. The questionnaire is comprised 30 questions (awareness - 6, knowledge - 10, and methods of application - 14).

The study conduct

The questionnaire was administered to 250 final year MBBS students, interns, and postgraduates (from all specialties) of Sree Balaji Medical College. The participants were personally briefed about the questionnaire and they were requested to return the duly filled in forms. The participants were given 45 minutes to answer the questions and they were not allowed to consult anyone during that time. They could maintain ambiguity with regard to their names, but they had to write their designations. The questionnaire was designed in such a way that each question had only one correct answer. The questionnaires were then evaluated. One point was given to each answered question (max total - 30 points). All the 3 groups were categorized as poor if the score is below 25%, as average if the score is 26-50%, as good if the score is 51-75%, and as excellent if the score is above 75%. The questionnaires were then analyzed by grading the respondents into data from the completed questionnaires are charted categorically in MS Excel sheet, analyzed and the results are expressed using suitable pictorial representations and percentages.

RESULTS

The questionnaire was administered to 250 participants, of whom 70 were postgraduates from various departments, 90 were interns, and 90 were final year MBBS students. A total of 237 questionnaires were returned. (65 - postgraduates, 82 - interns, 90 - final year M.B.B.S students). Data from the completed questionnaires are charted categorically in MS Excel sheet, analyzed and the results are expressed using suitable pictorial representations and percentages. All the 3 groups were categorized as poor if the score is below 25%, if the score is 26-50% as average, if the score is 51-75% as good, and if the score is above 75% as excellent. The questionnaire was analyzed by giving 1 for the correct response and 0 for the incorrect one. From this study, the following results were obtained.

Final year students (53.3%) and interns (54.9%) (Table 1) are better in the awareness of Pharmacovigilance than the postgraduates (30.75%). This is because they were educated about detection, assessment, understanding, and prevention of ADR to a certain extent in their syllabus.

In the knowledge regarding the existence of various programs, regional center, the yellow card system, schedule Y, when to report the adverse event in a clinical trial, etc., the undergraduates performed better than the interns and postgraduates (Table 2).

In the application of methods, the scores were considerably higher among the postgraduates (63.1%) and the interns (59.8%) as compared to the final year students (22.2%) (Table 3). This is because they use their meagre Pharmacovigilance knowledge into application, by their clinical exposure, handling drugs, and managing ADRs in the hospital. Even though they report adverse reactions to the Pharmacovigilance cell, they are less aware of the National programs available [14].

Even though the interns have very good awareness about Pharmacovigilance (Fig. 3), their knowledge is less when compared to final year students. Even though the undergraduates had very good awareness and knowledge, they performed poorly in the methods of application. This is because they were educated (Figs. 1 and 2), but they lack the performance skill or hands on training. Fortunately, attitudes are potentially flexible variables and the level to which medical students are informed about the principles of Pharmacovigilance and their practice has a large impact on ADRs reporting.

The data analyzed highlighted that even though the postgraduates lack in the knowledge part of pharmacovigilance programme, since they are actively involved in reporting adverse effects to the pharmacovigilance cell they are far better in the application skill of the same.

DISCUSSION

The incidences of adverse events are alarmingly increasing, with the increase in the entry of new drugs. The problem is further exacerbated by the inadequate training that clinicians receive in the basic principle of applied pharmacology and therapeutics. The adverse drug events may be attributable to the drugs, diagnostic agents, biologicals, nutrients, fluids, electrolytes, pharmaceutical excipient, or even the common components of the drug delivery systems. Occasionally, more than one agent is involved in causing the ADRs regardless of the route and mode of drug administration [15]. Monitoring of ADRs should be an essential constituent of patient care. It is now a well-established fact that health-care professionals play a vital role in ADR reporting [16]. The awareness of the occurrence of adverse effects for drugs should be created and taught even from the medical student period. This awareness can to some extent lead to rational use of drugs. Hence, this study is undertaken to assess the awareness among the undergraduate, interns, and postgraduate medical students, who are the future pillars of this medical field. The numerous mutual and fiscal consequences of ADRs develop a need to vigorously involve health-care professionals in the pharmacovigilance programme. The main aims of the pharmacovigilance programme are the early detection of adverse effects, interactions and reporting the same to the concerned authorities. It is much more vital for the recognition of the risk factors for the adverse reactions and dissemination of the information which is essential to get better in the prescription of drugs. Hence, the main requirement of Pharmacovigilance is the reporting of suspected ADRs [17]. An appropriate harmonization among the health-care professionals and medical institutions is the most vital for a roaring Pharmacovigilance programme. Many factors are related with the ADR underreporting among the health-care professionals. However, basically, to improve the reporting rate, it is essential to appropriately educate health-care professionals as regards ADR reporting/Pharmacovigilance. The most fitting time to do so is during the undergraduate and the postgraduate training of the doctors. This study endeavored is to assess the extent of the awareness, knowledge, and methods of application of Pharmacovigilance of the final year MBBS students, interns, and postgraduates of a tertiary care hospital. This is because students, interns, and post graduates can play a key task in interacting with patients in the clinical departments.

CONCLUSION

The present study revealed that the medical students are better in awareness and knowledge than the interns and postgraduates. However, the interns and postgraduates are more skilled in the application which they perform using their meagre knowledge. Therefore, it is a necessity of the hour to implement Pharmacovigilance as part of the medical curriculum and also chances of application of knowledge into practice. There is a need to conduct workshop and conferences regarding the Pharmacovigilance programme.

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