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ORIGINAL RESEARCH

Knowledge of adverse drug reaction reporting in first year postgraduate doctors in a medical college

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Introduction: Poor reporting of adverse drug reactions (ADRs) by doctors is a major hindrance to successful pharmacovigilance. The present study was designed to assess first-year residents' knowledge of ADR reporting.

Methods: First-year postgraduate doctors at a private medical college completed a structured questionnaire. The responses were analyzed by nonparametric methods.

Results: All doctors were aware of the term "adverse drug reactions." Fifty percent of the doctors reported being taught about ADR reporting during their undergraduate teaching, and 50% had witnessed ADRs in their internship training. Ten percent of patients suffering an ADR observed and reported by doctors required prolonged hospitalization for treatment as a result. Only 40% of interns reported the ADRs that they observed, while 60% did not report them. Twenty-eight percent reported ADRs to the head of the department, 8% to an ADR monitoring committee, and 4% to the pharmacovigilance center. Eighty-six percent of the doctors surveyed felt that a good knowledge of undergraduate clinical pharmacology therapeutics would have improved the level of ADR reporting.

Conclusion: The knowledge of first-year doctors regarding ADR reporting is quite poor. There is a dire need to incorporate ADR reporting into undergraduate teaching, and to reinforce this during internships and periodically thereafter.

Keywords: ADR reporting, pharmacovigilance, first-year postgraduate doctors

Introduction

An adverse drug reaction (ADR) is defined as an unintended and noxious response to a drug that occurs at doses normally used for the prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function.[1] ADRs have medical as well as economic consequences, leading to increased patient morbidity and mortality.[2] This has given rise to "pharmacovigilance", which is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems.[3]

Spontaneous monitoring is the foundation of successful pharmacovigilance. In developed countries, the contribution of residents and doctors is significant and has contributed to signal detection of ADRs that were previously undetected.[4] However, in India, spontaneous monitoring has resulted in lower rates of reporting, and so the Indian contribution to the World Health Organization (WHO) Uppsala Monitoring Centre database is meager.[5]

One reason for this is lack of awareness about the detection, communication, and reporting of ADRs, and there is no intensive teaching about ADR reporting in the

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undergraduate curriculum and no periodic reinforcement of ADR monitoring in internship and postgraduate studies.[6] As well as this, doctors may underreport ADRs due to financial incentives, fear of litigation, and ambition to publish. Some doctors have inadequate ADR-related knowledge and may believe that all serious ADRs will have been documented before a drug is marketed, that an ADR should be reported only when there is no doubt about its cause, that an ADR must be serious to be reported, and there may be an attitude of indifference or ignorance to the ADR. Sometimes, doctors who are asked why ADRs were not reported give excuses like lethargy, disinterest in reporting, or a lack of time to find and complete the ADR form.[7,8]

Rates of reporting can be improved by promoting awareness of the importance of ADR reporting and the procedures for doing so, and this is best done during undergraduate teaching. Traditional forms of pharmacology teaching take place through didactic lectures and are more teacher-centered, with the main emphasis on learning facts about drugs.[9] The Medical Council of India has recommended teaching undergraduate students about ADR monitoring.

In order to improve ADR monitoring, it is imperative to assess the current knowledge, attitude, and practices of doctors. The current study was performed to assess these factors in a group of first year doctors in a private medical college. It was hoped that the results would help in the designing of an undergraduate curriculum to encourage spontaneous ADR reporting among doctors.

Methods

This was a cross-sectional questionnaire-based study performed in a private teaching and tertiary care hospital in Rajasthan, the Mahatma Gandhi Medical College and Hospital (MGMC), Jaipur, India. Approval was given by the institutional ethics committee.

The study group were first-year postgraduate doctors, who were pursuing their studies in the medical, surgical, paraclinical, and preclinical branches of medical science. A structured questionnaire was based on the work of Oshikoya et al and Tobaiqy et al.[10,11] The questionnaire sought information regarding participants' demographics, awareness about the term ADR, knowledge of ADR reporting, and ADR management in their internship positions. Also, the questionnaire sought feedback regarding ways to improve students' knowledge of ADR reporting during undergraduate training in clinical pharmacology and therapeutics. Most of the questions in the questionnaire were objective and mostly required a "yes" or "no" response (Appendix I).

The questionnaire was presented to 50 first-year postgraduate doctors who indicated that they were willing to participate in the study after the purpose of the study was explained to them. They were asked to complete the questionnaire and return it immediately; those who were too busy to complete the questionnaire were asked to return it the next day, or as soon as possible. Results were analyzed by nonparametric statistical tests.

Results

Forty-four percent of study participants were aged between 21 and 25 years, 34% were aged between 26 and 30 years, 18% were aged between 31 and 35 years, and 4% were aged over 35 years. Fifty-eight percent of participants were male, and 42% were female (Table 1).

All participants had studied ADRs in undergraduate teaching and were conversant with it. Fifty percent of participants said that they had been taught about ADR reporting in their undergraduate teaching, while the remaining 50% said that they had not. Fifty-four percent of participants said that they had not discussed ADR reporting during their internship, while 46% said that they had discussed this.

Fifty percent of participants had witnessed ADRs during their internship training, and of these, 20% reported that the likely cause of ADRs were drug–drug interactions, 18% reported medication errors, and 36% reported idiosyncratic reactions. Of the ADRs witnessed, 22% of cases did not require any hospitalization, while 34% required short hospitalization, and 10% required prolonged hospitalization. Some 84% doctors reported that they thought that ADRs are avoidable, while 14% thought that they are unavoidable. Some 74% thought that ADRs are predictable.

Eighty-six percent of doctors reported that a good knowledge of undergraduate Curriculum Practical Training (CPT) teaching would have improved the ADR reporting (Table 2). Only 40% of doctors reported the ADRs they observed, with 28% reporting these to their head of the department, 8% to the

Table 1 Demographic profile of the study population

Age (years)		Male:Female ratio
21–25	44%	58:42
26–30	34%	
31–35	18%	
>35	4%	

Table 2 Undergraduate teaching of ADRs and ADR reporting

Questions	Responses (%)
Knew the term ADR before	100
Taught about ADR reporting in UG teaching	50
Not discussed ADR reporting in internship	54
Not seen any ADR	46
ADRs are avoidable	84
ADRs are predictable	74
Good knowledge in UG teaching could have improved ADR reporting	86

Abbreviations: ADR, adverse drug reaction; UG, undergraduate.

ADR monitoring committee, and 4% to the pharmacovigilance center (Table 3).

Discussion

The current study suggests that the rate of ADR reporting is poor among first-year postgraduate doctors. Only 40% reported the ADRs they witnessed, with most reporting these to the head of the department, some to the ADR monitoring committee, and a smaller number to the pharmacovigilance center. These results are quite similar to the findings of Li et al.[12] Another study from a large tertiary care hospital in north India showed that most ADR reporting is by postgraduate doctors.

Self-reporting through questionnaires, as was done in the current study, has a number of weaknesses: the most important of these are underreporting and biased reporting.[13]

It is imperative for doctors to know how to report an ADR, and who to report to. If doctors do not know these two things this will affect spontaneous reporting, so it is important for awareness programs to be in place to educate first-year postgraduate doctors. Poor spontaneous reporting is an indicator of poor management and dissemination of ADR monitoring.

ADR reporting should be intensively taught during undergraduate study, and this should be reinforced at the start of internships as well as periodically thereafter through continuous education programs.[14] The doctors who participated in this study also suggested organizing training programs, introducing a quick and easy method of ADR reporting, and providing small gestures such as an appreciation note to keep up the motivation for pharmacovigilance activities.

It has been demonstrated that an educational intervention can increase a physician's awareness of ADRs, and enable them to incorporate the knowledge into clinical practice.[15] Another study on simplifying ADR reporting has indicated that the use of quick and easy methods of ADR reporting, such as introducing a drop box with ADR forms and alert cards, helps to promote reporting.[16] Other suggestions include compulsory teaching and lectures on pharmacovigilance and ADR reporting for undergraduates, and it has been suggested that students should be required to report at least three ADRs during their pharmacology training, and that interns be taught about ADR reporting during internship orientation programs. There should also be a strong collaboration between a hospital's department of pharmacology and other clinical departments to help ensure proper and efficient ADR reporting, and also to provide pharmacovigilance awareness programs.

It is interesting to note that 60% of the interns who participated in this study did not report ADRs they witnessed, which suggests that the practice of reporting the ADRs is poor among doctors. A recent study assessed doctors' knowledge, attitude, and practices associated with ADR reporting and found that these were inadequate,[17] while another study found that while prescribers were aware of ADRs, underreporting and a lack of knowledge of the reporting system were clearly evident.[18] The findings of these studies suggests that doctors and the medical fraternity in general need to incorporate more study of ADRs and ADR reporting into the undergraduate curriculum.

In India, a nationwide pharmacovigilance program has been put in place to protect the health of patients by assuring drug safety, monitoring ADRs, and creating awareness of the importance of ADR reporting among health professionals. This program aims to make every medical college, private hospital, and autonomous institute an ADR monitoring center, and will collaborate with the WHO Uppsala Monitoring Centre in Sweden.[19] In India, ADR reporting by clinicians relies on spontaneous monitoring, and this has been the basis of the early warning system for regulatory action relating to drugs. All health care professionals including doctors, nurses, and pharmacists can report an ADR by completing an ADR form from the Central Drugs Standard Control Organization

Table 3 Reporting of ADRs by first-year postgraduate doctors

How many reported the ADRs			How many did not report
40%			60%
28% to head of department	8% to ADR monitoring committee	4% to pharmacovigilance center	

Abbreviation: ADRs, adverse drug reactions.

and submitting this to the pharmacology department. The pharmacology department then analyses the cause of the ADR and submits data to the WHO center.

Conclusion

The current study indicates that there is an urgent need to create awareness about ADR reporting in undergraduate teaching, with this being reinforced during internships. This would lay a solid foundation for doctors to ensure pharmacovigilance in their future practice. A close relationship also needs to be created between doctors and pharmacovigilance centers, and the attitudes of residents and doctors to ADR monitoring must change so that they perceive this as an integral part of their clinical activities.

Disclosure

The authors report no conflict of interest that might bias the outcome of the paper.

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Appendix 1

Demographics

1. How old are you?
   (a) ≤20 years (b) 21–25 years
   (c) 26–30 years (d) 31–35 years
   (e) ≥35 years
2. What is your sex?
   (a) Male (b) Female
3. Where did you do your undergraduate medical training?
   (a) Mahatma Gandhi Medical College, Jaipur (b) Other
4. If other, please name the institution? ……..

Knowledge of adverse drug reactions (ADRs) and ADR reporting

5. Did you know the term ADRs before?
   (a) Yes (b) No
6. Have you witnessed any ADRs?
   (a) Yes (b) No
7. The likely cause of the ADRs was:
   (a) drug–drug interaction (b) medication error (c) idiosyncratic reaction (d) others (please specify) ……
   …….....
8. If the above is yes, which of the following did it result in?
   (a) No hospitalization (b) Short hospitalization
   (c) Prolonged hospitalization (d) Morbidity
   (e) Death
9. Do you consider the ADRs avoidable?
   (a) Yes (b) No
10. Do you consider the ADRs predictable?
    (a) Yes (b) No
11. Did you report the ADRs?
    (a) Yes (b) No
12. If the above is yes, whom did you report to?
    (a) ADRs monitoring committee of the hospital (b) National Pharmacovigilance Centre
    (c) Head of department (d) Other (please specify) …….....
13. Were you taught how to report ADR in your undergraduate CPT teaching?
    (a) Yes (b) No
14. Do you think a good knowledge of undergraduate CPT teaching would have improved the ADR reporting?
    (a) Yes (b) No
15. Has anybody ever discussed about ADR reporting with you in internship training?
    (a) Yes (b) No
16. Do you know about the Pharmacovigilance programme of India?
    (a) Yes (b) No
17. Any suggestions on improving ADR reporting knowledge by undergraduate training in clinical pharmacology and therapeutics?