Knowledge, attitude, and practice of pharmacovigilance among intern doctors of peripheral medical college in Gujarat

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ABSTRACT

Background: Adverse drug reactions (ADR) are regarded as one of the major reason of morbidity and mortality all over the world. According to previous studies, 35% of the hospitalized patients experience an ADR during their hospital stay. Various studies on pharmacovigilance indicate inadequate knowledge, poor attitudes, and lack of awareness among healthcare personnel are associated with a high degree of underreporting of ADRs. Intern doctors are one of the points of first contact when it comes to ADRs. Aim and Objectives: Aim of the study was to assess knowledge, attitude, and practice of pharmacovigilance in peripheral medical college among intern doctors.

Materials and Methods: This study was a questionnaire-based cross-sectional study which was conducted at GMERS Medical College and hospital, Junagadh. Out of 90 intern doctors 70 have participated in our study. 18 questions were included in the questionnaire out of which ten related to knowledge, five related to attitude and three related to practice.

Results: Average score of knowledge about pharmacovigilance is 5 points out of 10 point. Most of the intern doctors 92.9% (n = 65) are in a general consensus the reporting of ADRs is necessary and 88.6% are in the opinion that medical students like could play a major role in reporting ADRs. Difficult to decide whether ADR is occurred or not is most common factor (51.4%) which discourages intern doctors from reporting ADRs.

Conclusion: Knowledge about pharmacovigilance can be enhanced by organizing various teaching programs on pharmacovigilance. Underreporting can be overcome by regularly arranging pharmacovigilance awareness program. Therefore, there is a necessity of undertaking educational program in every hospital to improve the attitude and knowledge toward ADRs reporting.

KEY WORDS: Pharmacovigilance; Adverse Drug Reactions; Intern Doctor; Questionnaire; Knowledge

INTRODUCTION

The World Health Organization (WHO) has defined pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Adverse effect is any undesirable or unintended consequence of drug administration. This term, includes all kinds of noxious effect-trivial, serious or even fatal effects. Adverse drug reactions (ADRs) has been defined as any noxious change which is suspected to be due to a drug, occurs at a doses normally used in man, requires treatment or decrease in dose or indicates cautions in the future use of the same drug. ADRs can lead many consequences like increase the duration of hospital stay, cost of treatment and the risk of mortality. ADRs are regarded as one of the major reason of morbidity and mortality all over the world. According to previous studies, around 2.9–5.6% of all the hospital admissions are due to ADRs and 35.0% of the hospitalized patients experience an ADR during their hospital stay. Thus,
safe use of medicine is an important aspect in healthcare practice.\[4\]

Indian pharmacopoeia commission, Ghaziabad is the national coordinating center for pharmacovigilance program of India (PvPI). In India, Pharmacovigilance was started in 1986 with a conventional ADR monitoring system, was supervised by the drug controller general of India. India had joined the WHO Program for International Drug Monitoring in 1998, but was not successful. Then, in 2005, the National Program of Pharmacovigilance was launched and was given a new name as the PvPI in 2010.\[5\] International collaborating center for pharmacovigilance known as The Uppsala Monitoring Centre (UMC, WHO), Sweden, keep the international database of the ADR reports worldwide.\[6\] India’s contribution to the UMC database is only 2%.\[7\]

The previous studies indicate inadequate knowledge, poor attitudes and lack of awareness toward pharmacovigilance among healthcare personnel are associated with a high degree of underreporting of ADRs. Hence, this study was undertaken to assess the knowledge, attitude, and practice (KAP) regarding pharmacovigilance among intern doctors in a tertiary care hospital.

Aim of our study is to assess KAP of pharmacovigilance among intern doctors at peripheral tertiary care center. It is an anticipate that the results of this study will increase existing knowledge in the field and provide relevant data that will aid in improving the practice of ADR monitoring and reporting among intern doctors.

MATERIALS AND METHODS

This study was a questionnaire-based cross-sectional study which was conducted at GMERS Medical College and hospital, Junagadh from July 2021 to August 2021 to evaluate KAP among intern doctors working in our hospital. This study was conducted after approval by the Institutional Ethics Committee of our institute. Around ninety intern doctors are working in our hospital at present in clinical departments. Out of 90 intern doctors 70 have participated in our study. Pre-designed questionnaire was made from earlier studies then first it was shown to other faculties of our department to prevalidating questionnaire. Few minor changes to questionnaire were made before distributing it to study participants.

The inclusion criteria were enrolment of intern doctors posted in various clinical departments at our institute who were willing to give written consent. Those intern doctors refused to give written consent were excluded from the study.

About 18 questions were included in the questionnaire out of which ten related to knowledge, five related to attitude and three related to practice. Each correct answer related to knowledge was given a score of 1 whereas incorrect answer and negative response was given a score of 0; KAP was assessed and calculated by adding up the KAP scores for all the provided questions.

The participants were contacted and after explaining the aims of the study, they were invited to participate in study. A written consent form was obtained from them ensuring their confidentiality and anonymity. The participants were given sufficient time to complete the questionnaires. Some of the participants were filled questionnaires instantly on the same day but some of them were filled on another day because of the busy of their tight schedules. Collected data were entered on Microsoft office excels and it was analyzed.

RESULTS

Assessment of Intern Doctors Knowledge of Pharmacovigilance

Assessment of knowledge of pharmacovigilance showed that out of the 90 intern doctors assessed, 70 (78%) intern doctors had responded to questionnaire. On assessing knowledge of pharmacovigilance 85.7% (n = 60) given correct answer regarding major risk factor for occurrence of maximum ADR is use of irrational drug use and 76% (n = 51) of participant were aware of drug banned in INDIA. Results for what is pharmacovigilance showed that 81.4% (n = 57) of intern doctors could correctly answered term pharmacovigilance, though a higher proportion 78.6% (n = 55) of respondents were not aware within how many days they have to report serious drug events to the regulatory body. On asking Method commonly employed by the pharmaceutical companies to monitor ADRs of new drugs once they are marketed for general use 72.9% (n = 51) answered correctly, however only 22.9% (n = 16) correctly stated scale most commonly used to establish causality of an ADRs. Majority of intern doctors 55.7% (n = 39) were don’t know about body functioning as national coordination centre (NCC) for PvPI. Only 37% (n = 26) participants knows there is pharmacovigilance committee in their institute. Large number of participant 53% (n = 37) answered incorrectly that pharmacovigilance includes all drug, blood and herbal product related ADRs. Average score of knowledge about pharmacovigilance is 5 points out of 10 point. (one point belongs to one correct answer) Table 1.

Assessment of Intern Doctors Attitude Towards Pharmacovigilance

Majority 68% (n = 48) of intern believes doctor, pharmacist and nurses all are responsible for reporting ADRs in a hospital. Most of the intern doctors 92.9% (n = 65) are in a general consensus the reporting of ADRs is necessary. 98.6% (n = 69) are in opinion about establishing ADR monitoring in
every hospital. Only 10% \((n = 7)\) of intern doctors were not in favor of teaching pharmacovigilance in details while 90% \((n = 63)\) thinks that pharmacovigilance should be taught in details to healthcare professionals. Large number of students \(n=62\) (88.6%) are in the opinion that medical students like could play a major role in reporting ADRs Table 2.

Assessment of Intern Doctors Practice Towards Pharmacovigilance

Result on assessment of practice of intern doctors shows that difficult to decide whether ADR is occurred or not is most common factor 51.4% \((n = 36)\) which discourage them from reporting ADRs followed by lack of time to report ADRs 18.6% \((n = 13)\), non-renumeration for reporting ADRs 15.7% \((n = 11)\) and thinking that a single unreported case may not affect ADRs data base 14.3 % \((n = 10)\). On asking Have you ever been trained on how to report ADR 68.6% \((n = 48)\) answered yes and 31.4% \((n = 22)\) said no. 70% \((n = 49)\)

![Figure 1](image1.png)  **Figure 1:** The healthcare professional responsible for reporting adverse drug reactions in hospital

![Figure 2](image2.png)  **Figure 2:** Factors discourage intern doctors from reporting adverse drug reactions

![Figure 3](image3.png)  **Figure 3:** Have you ever been trained on how to report adverse drug reactions

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes (%)</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you think reporting of ADR is necessary?</td>
<td>92.90</td>
<td>7.10</td>
</tr>
<tr>
<td>What is your opinion about establishing ADR monitoring center in every hospital?</td>
<td>98.60</td>
<td>1.40</td>
</tr>
<tr>
<td>Do you think Pharmacovigilance should be taught in detail to healthcare professionals?</td>
<td>90</td>
<td>10</td>
</tr>
<tr>
<td>Are you of the opinion that medical students like could play a major role in reporting ADRs?</td>
<td>88.60</td>
<td>11.40</td>
</tr>
</tbody>
</table>

ADR: Adverse drug reactions
Figure 4: Have you ever seen any adverse drug reactions in patient due to drug

Intern doctors have come across ADRs in patient due to drug Figures 1-4.

**DISCUSSION**

The major goals of pharmacovigilance program are the early detection of the ADRs, monitoring the frequency of the ADRs and identification of the risk factors for the ADRs which is required to improve the prescription of drugs. A proper coordination among the health care professionals and the medical institutions is the most required for a successful pharmacovigilance program. Intern doctors are one of the points of first contact when it comes to ADRs. There are many studies conducted to assess knowledge of health care providers regarding pharmacovigilance; however, very few studies involved the medical interns. Hence, this study was undertaken in interns doctors posted in various clinical departments in a medical college of periphery of Gujarat.

In the present study, we observed that the knowledge of pharmacovigilance among seventy (70) intern doctors is around 50% (score 5/10). That means only 50% intern doctors have knowledge of pharmacovigilance above average. Previous study done on intern doctors in Dharwad Karnataka shows that in their study knowledge of pharmacovigilance was less than 50%.[8-10] Hence, this study was undertaken in interns doctors posted in various clinical departments in a medical college of periphery of Gujarat. In our study, 81.4% intern doctors were aware of term pharmacovigilance which is quite good. In a study done by Shetti and Limaye at Sangli around 72.6% of intern doctors were aware of the term pharmacovigilance.[12] Majority of intern doctors 55.7% (n = 39) were don’t know about body functioning as national coordination centre for PvPI. In contrast to study done by Aithal et al. were majority of intern doctors have knowledge related to national coordinating centre for pharmacovigilance.[13] Only 37% (n = 26) participants knows there is pharmacovigilance committee in their institute. These results were comparable and par with other studies conducted by Gurung et al.[14] More than 50% intern doctors have knowledge regarding banned drug in India. This result is similar to a study done at Jalandhar Punjab.[15] Inappropriate knowledge of pharmacovigilance may misguide the healthcare professionals in recognizing and hence reporting an ADR.

One previous study done by Garg et al. documented that 80% of the intern doctors were of the view that ADRs can be reported by pharmacists, nurses as well as doctors.[15] This result is very close to our result were 69% intern doctors having similar views. In our study, 92.9% intern doctors believes that reporting of ADRs is necessary which is equivalent to a study done by Shetti and Limaye at Sangli in 2021.[12]

One of the previous study shows that continuous medical education and training on ADRs reporting would like to improve ADR reporting.[16] This result is similar to our study in which 63% believes that pharmacovigilance should be taught in details. In our study, 32% intern doctors were not trained on how to report ADRs So all interns doctors should be trained to pharmacovigilance in details during their internship and more focus should be given to ADRs reporting at undergraduate curriculum. Regulatory authorities at the United States have developed online training program on ADR reporting. Such programs may increase the reporting of ADRs in institutions.[17] Therefore, there is a necessity of undertaking educational program in every hospital to improve the attitude and knowledge toward ADRs reporting.

The most common reason for discouraging reporting of ADRs was difficult to decide ADR in patients (51.4%) followed by lack of time to report ADRs (18.6%), non remuneration (15.7%), and believing that a single unreported case may not affect ADR database (14.3%). In a study conducted at Devengere, Karnataka India by Aithal et al. found that most common reason for discouraging reporting of ADR was fear of reporting (55%) followed by difficult to decide ADR in patients (50%).[13]

**CONCLUSION**

Results of this study reveals that intern doctors have average knowledge about pharmacovigilance which can be enhance by organizing various teaching programs related to pharmacovigilance. Underreporting of ADRs can be overcome by regularly arranging pharmacovigilance awareness program and sensitizing intern doctors about importance of ADRs reporting. In our study, most of intern doctors revealed their interest to participate in training program-related ADR reporting in future which is a satisfactory perception toward pharmacovigilance.
REFERENCES


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