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Original Research Article

A Cross-Sectional, Questionnaire-Based Assessment of the Perception and Attitude on Implementation of Pharmacovigilance Program among Junior Doctors

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Abstract

Aim: The present study aimed to evaluate the perception and attitude on implementation of pharmacovigilance program on predesigned proforma among junior doctor.

Methods: This study was a cross-sectional, questionnaire-based study involving, 100 resident doctors at Shree Narayan medical Institute and Hospital, Saharsa, Bihar.

Results: Only 52% participants gave the correct definition of Pharmacovigilance while 80% participants responded correctly that Department of Drug Administration is responsible for monitoring ADR in Bihar. More than half of the participants (65%) agreed that reporting of ADR in Bihar is voluntary. 92% believed that reporting ADR of drugs is necessary. 52% participants thought pharmacovigilance should be taught in detail to healthcare professionals. 95% participants agreed that establishment of ADR monitoring center in every hospital is essential. 96% participants had never reported an ADR case. 6% participants had got training on pharmacovigilance.

Conclusion: The present study concludes that resident doctors were lack of proper knowledge regarding pharmacovigilance, however attitude and perception were relatively better. Even though majority of the resident doctors came across ADRs and felt pharmacovigilance activity will be beneficial to the patient, reporting done by them is lower.

Keywords: Attitude, Knowledge, Pharmacovigilance, Perception

Introduction

Adverse Drug Reactions (ADR) are unwanted effects of drugs. These are responsible for prolonging hospitalisation, significant increase in economic burden and increasing death. [1] ADRs are the main reason of mortality and morbidity worldwide. [2] Monitoring of ADRs is called as pharmacovigilance. Activities in pharmacovigilance include detection, assessment, understanding, prevention of ADRs. Post marketing surveillance of drugs is very important in analysing and managing the risks associated with drugs, once, they are available for the use in the general population.

Adverse drug reactions are a complicated trouble which requires attention of patients, scientific professionals, the pharamcological industries, drug regulatory bodies. [3] ADR reporting does not appear to be part of standard practice for healthcare providers now. [4] The Uppsala Monitoring Centre (UMC) World Health Organisation (WHO), Sweden is maintaining the international database of ADR reports. Although, India is participating in the program, its contribution to UMC database is very little. Furthermore, due to a lack of knowledge and poor training on drug safety monitoring among healthcare workers, the Indian National pharmacovigilance Programme lacks continuity. [5] Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem". [6] It helps in ensuring that the patient receives safe drugs as adverse drug reactions(ADRs) are considered as one of the major reasons of mortality and morbidity in the world. [7] The reasons for underreporting of ADRs vary from countries to countries but major causes include lack of awareness about the existence of pharmacovigilance program, negative attitude towards ADR reporting and unavailability of ADR reporting forms. [8]

It is essential to enhance the knowledge, attitude, and perception of all healthcare workers for better reporting of ADRs. Among all healthcare workers, resident doctors course play a crucial role in clinical practice, as they are the future clinicians, and also will be the primary care providers for all types of ADRs. However, very few studies were conducted on resident doctors, which show that more than half of the resident doctors were lacking the knowledge and training on ADR reporting. [9]

According to WHO, ADR is defined as a response to a drug which is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for the modifications of physiological function and pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. [10] There are many reasons for under-reporting of the ADR/ ADE by the health-care providers voluntarily or as an obligation. [11,12] The reporting of ADR is under the aegis of pharmacovigilance is made compulsory. Owing to the current trend of under-reporting, drug controller of India under the supervision of Indian pharmacopoeia commission, launched a national program on ADR/ADE implementing the pharmacovigilance program/ pharmacovigilance program of India (PvPI) in 2014. [11-13]

The present study aimed to evaluate the perception and attitude on implementation of pharmacovigilance program on predesigned proforma among junior doctor.

Methods

This study was a cross-sectional, questionnaire-based study involving, 100 resident doctors at Shree Narayan medical Institute and Hospital, Saharsa, Bihar, for nine months

Inclusion and Exclusion criteria: All last year batch resident doctors were included in the study. Those who did not return the questionnaire within the given time, were excluded from the study.

Study Procedure

The participants were required to answer predesigned and validated questionnaire on KAP on pharmacovigilance, within 30 minutes. There were 20 questions that were face-validated by the professors of the Pharmacology Department for feasibility, readability, formatting, and

clarity. All resident doctors were assembled at one place to distribute the hard copies of the questionnaire. Participant's consent was assumed when they were willing to answer the questionnaire. Only one answer was supposed to be marked for each question.

Statistical analysis

The answered questionnaires were statistically analyzed by using SPSS version 20.

Results

Table 1: Knowledge of the pharmacovigilance among participants

S.N.	Questions on knowledge	Correct response (%)	Incorrect response (%)
1.	Pharmacovigilance is the science that relates to the detection, assessment, understanding and prevention.	52 (52%)	48 (48%)
2.	The specific aim of Pharmacovigilance is to improve patient safety.	44 (44%)	56 (56%)
3.	The scale most commonly used to establish the causality of an ADR is Naranjo algorithm.	36 (36%)	64 (64%)
4.	Scale most commonly used to establish the severity of an ADR is Hartwig scale.	38 (38%)	62 (62%)
5.	Post marketing Surveillance is the commonly employed by the pharmaceutical companies to monitor ADRs of new drugs after they are launched in the market.	40 (40%)	60 (60%)
6.	VigiFlow is the WHO online database for reporting ADR by member countries.	25 (25%)	75 (75%)
7.	In Bihar, the national center responsible for monitoring ADRs is Department of Drug Administration.	80 (80%)	20 (20%)
8.	Doctors, nurses and pharmacists can report an ADR in Bihar	62 (62%)	38 (38%)
9.	Reporting of ADR in Bihar is voluntary.	65 (65%)	35 (35%)
10.	Form used to report ADR in Bihar is ADR reporting form	34 (34%)	66 (66%)

Table 1 shows the knowledge of the pharmacovigilance among the participants. Only 52% participants gave the correct definition of Pharmacovigilance while 80% participants responded correctly that Department of Drug Administration is responsible for monitoring ADR in Bihar. More than half of the participants (65%) agreed that reporting of ADR in Bihar is voluntary.

Table 2: Attitude of the pharmacovigilance among participants

S.N.	Questions on attitude	Correct response (%)	Incorrect response (%)
1.	Do you think reporting an ADR of drugs is necessary?	92 (92%)	8 (8%)
2.	Do you think pharmacovigilance should be taught in detail to healthcare professionals?	52 (52%)	48 (48%)
3.	Do you think it is necessary to report only serious and unexpected reactions?	60 (60%)	40 (40%)
4.	Do you think of establishment of ADR monitoring center in every hospital?	95 (95%)	5 (5%)

Table 2 shows the responses of the participants towards attitude of pharmacovigilance. 92% believed that reporting ADR of drugs is necessary. 52% participants thought pharmacovigilance should be taught in detail to healthcare professionals. 95% participants agreed that establishment of ADR monitoring center in every hospital is essential.

Table 3: Perception of the pharmacovigilance among participants

S.N.	Questions on perception	Correct response (%)	Incorrect response (%)
1.	Have you reported ADR cases?	4 (4%)	96 (96%)
2.	Have you been trained to report ADR form?	6 (6%)	94 (94%)
3.	Have you ever experienced ADR in your patients during practice?	62 (62%)	38 (38%)
4.	Have you ever seen ADR reporting form?	30 (30%)	70 (70%)
5.	Have you ever yourself experienced ADR?	55 (55%)	45 (45%)
6.	Have you ever read an article related to prevention of ADR?	55 (55%)	45 (45%)

Table 3 shows the responses of the participants towards practice of pharmacovigilance. 96% participants had never reported an ADR case. 6% participants had got training on pharmacovigilance.

Discussion

It was a questionnaire-based study to assess the knowledge, attitude and perception of resident doctors on pharmacovigilance, in a tertiary care teaching hospital. As resident doctors are upcoming doctors and also the primary contact persons for patients in all teaching hospitals, awareness about pharmacovigilance among them plays significant role.

The present study reveals that knowledge, attitude and perception scores among the 100 resident doctors need to be enhanced. Majority of the resident doctors (86%) felt that, they are not sufficiently trained in ADR reporting. A similar trend is seen in the studies, conducted at Dharwad,9 Hyderabad, [14] where more percentage of resident doctors and doctors felt the need for adequate ADR training. The majority (95.7%) resident doctors believed that, all the drugs available in the market are not safe, which is in line with the Hyderabad study. [14]

Nearly half of the resident doctors (38%) have not come across ADR cases, in the present study. This may be due because they are not sufficiently trained to detect ADR. Prior clinical sensitisation for ADR will improve case detection. Few studies from Dharwad, [9] Junagadh, [15] Perambalur [16] reported a higher percentage of healthcare professional who came across ADR during their clinical exposure. Further, only half of those, who noticed ADR cases, in the present study, reported it to the ADR centre.

One needs to maintain confidentiality, while reporting ADR especially with regard to patients, but in the present study, only 50% resident doctors felt confidentiality is mandatory. Contrarily, a Nigerian study reported a high awareness about confidentiality (65.95%). [17] In the present study, unusually high number of resident doctors (48.9%) worried about legal issues while thinking of ADR reporting. These findings are not in concurrence with a Gujarat study, where, 17.8% of the postgraduate medical students are concerned about the legal issues. [18] Hands-on training and awareness will help to minimise these apprehensions. In the present study, only 8.5% felt that an incentive will improve ADR reporting. Studies from conducted in Chennai [19], Sikkim [20] also, support

remuneration for an increase in ADR reporting.

The ADRs are an unavoidable risk factors with the use of modern medicines. Studies in the USA and France, had shown that ADRs were the main contributors to morbidity and mortality. [21] As the data regarding ADRs keeps on upgrating, clinicians need to update themselves. [22] Undergraduate pharmacovigilance training may be insufficient or conducted in an ineffective manner for the duty of ADR monitoring and reporting. [23,24]

Conclusion

The present study concludes that resident doctors were lack of proper knowledge regarding pharmacovigilance, however attitude and perception were relatively better. Even though majority of the resident doctors came across ADRs and felt pharmacovigilance activity will be beneficial to the patient, reporting done by them is lower. Also, they were in opinion that training provided to them was inadequate, hence there is a need for regular training and motivation for ADR reporting. Importance should be given to various aspects of pharmacovigilance in medical curriculum. Further studies needed to strengthen effectiveness of pharmacovigilance activities.

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