

A CROSS-SECTIONAL QUESTIONNAIRE BASED STUDY OF ASSESSING KNOWLEDGE, ATTITUDE AND PRACTICES TOWARDS PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AMONG DOCTORS



Pharmacology

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ABSTRACT

BACKGROUND: The study was conducted to access knowledge ,attitude and practices of doctors towards pharmacovigilance and for creating awareness among healthcare professionals .

MATERIAL & METHODS: A cross-sectional questionnaire based study using validated questionnaire containing 20 items was filled by doctors of SMS Medical College, Jaipur. The responses of questionnaire were analysed.

RESULTS: Out of 250 doctors , 124 were post graduate students and 126 were medical teachers. Majority of doctors (80%)were aware of the term pharmacovigilance, 32.5 % doctors had seen ADR reporting form,48% had knowledge about ADR monitoring centre . Preferable technique used by the doctors for ADR reporting was by direct contact followed by android app and toll free telephone number.

CONCLUSION: Average knowledge score was 48.2% among doctors, suggest the adequate knowledge towards pharmacovigilance but there was a significant gap between the ADR experienced in professional practice (63.8%) and ADR reported (29.4%).

KEYWORDS

Pharmacovigilance , ADR Monitoring centre(AMC), questionnaire

Introduction

Pharmacovigilance synonym to drug safety, is defined as science and activities relating to the detection, assessment, understanding, monitoring, and prevention of adverse effects or any other drug related problems.¹

Adverse Drug Reaction(ADR) is very significant and is imperative in assessing the benefit-risk ratio of each and every drug.² There is important role of doctors, in reporting and monitoring of ADRs.

Due to lack of awareness and inadequate training about drug safety monitoring among health care professionals in India, often ADRs go unnoticed or are not reported. Every health care professional should see it as a part of his/her professional duty keeping in mind about "Hippocrates admonition" at least does no harm. Sometimes ADRs are unable to identify by the physicians during hospital admission. Such hidden ADRs sometimes may be responsible for the death of patients.³ Currently, India contributes 3% of the WHO global individual case safety report(ICSR's) database.⁴

Realizing the significance of monitoring ADRs to improve public health, the Pharmacovigilance Programme of India (PvPi) was launched under the Ministry of Health and Family Welfare in July 2010 to safeguard the health of the Indian population by ensuring the safety of the marketed drugs.⁵ According to this program ADR monitoring centres (AMC) have been set up in many medical institutions all over the country including the National Coordination Centre (NCC) to estimate the frequency of ADRs occurring with various drugs among the Indians.⁶ The Indian Pharmacopoeia Commission (IPC), which is in Ghaziabad (U.P), is the NCC of PvPi programme of India. There are eight AMCs in Rajasthan including SMS Medical College, Jaipur. AMC appoints a technical associate who is responsible for collecting the adverse event information from the patients, performing follow up with them, to check the completeness of the ADR reports as per Standard Operating Procedures (SOPs), entering information in the prescribed software (Vigiflow) and sending them to NCC via the same software. A WHO global individual case safety report database (Vigi Base) is maintained and developed on behalf of the WHO by Uppsala Monitoring Centre.⁷ Final goal of PvPi is to develop smooth and effective functioning of AMC with the help of coordinator & sub-coordinators. The centre coordinator is accountable to send monthly ADR status reports to NCC, he is also responsible for increasing awareness and to guide health care professionals, students, patients about ADR reporting by taking lectures, advertisement through email, telephone, pamphlet and newsletter.⁷⁻⁸

There is very limited information available on ADRs in our country, data derived from various region within the country may have greater relevance and may help national regulatory centre for decision making.

Aim of the study

Therefore on this background, the present study was conducted to access knowledge ,attitude and practices of doctors towards pharmacovigilance and for creating awareness among healthcare professionals for the same.

Materials & Methods

Sample selection

1. It is a cross sectional questionnaire based observational study. The study was conducted in a tertiary care teaching hospital among doctors .
2. Post graduate doctors and medical teachers working in different departments of SMS Medical College and Hospital, Jaipur were randomly selected and included in the study. Doctors from departments of Medicine, ART center, Surgery, Anaesthesia and paediatrics etc. participated in the present study.
3. After due approval of Institutional Ethical Committee, this study was conducted from 01/11/2019 to 31/12/2019 for two months.

Questionnaire

The study was conducted by using a pre-designed, pre-validated questionnaire to obtain the demographic information(Question no.1 to 5) and information on the knowledge, attitude and practices(Question no.6 to 25) of doctors towards pharmacovigilance and ADR reporting. Validation of questions was done by experts of senior faculty of pharmacology , Medicine and PSM department of SMS Medical College.Details and purpose of the study was explained to 250 doctors who consented the questionnaire .

A questionnaire consisting of 20 questions was prepared on pharmacovigilance and ADR reporting. References from previous studies was also taken to prepare them.⁹⁻¹⁰ The knowledge based questions assessed, knowledge regarding various aspects of pharmacovigilance such as definition and purpose of pharmacovigilance programme, location of local and national ADR monitoring centres, WHO online data base for ADRs reporting, who can report and how ADR reporting done. The attitude based-questions assessed the views of the participants regarding factors which can encourage and discourage ADR reporting. Importance of pharmacovigilance awareness activities in the institution

and their impact on current system of Pharmacovigilance. The practice based-questions determined concern towards ADR reporting and also the preferable method of ADR reporting.

Sensitization of participants:

An objective of increasing awareness regarding pharmacovigilance was done by sensitizing participants at the time of collection of questionnaire. The detailed information was shared with the help of distributing pamphlets and news bulletin published by pharmacovigilance centre about Pharmacovigilance programme of India, the role of the co-ordinator of Pharmacovigilance centre, method of causality assessment of ADRs and facility of direct communication about any ADR to the technical associate appointed by that AMC. In addition all participants were demonstrated the process of uploading the case safety report in 'Vigi Base' Other information shared were : NCC PvPi has developed a mobile app in association with NSCBMC (Netaji Subhash Chandra Bose Medical College), Jabalpur, on 22 May 2015. PvPi-NCC has also launched a toll free helpline number (1800 1803024) on 11 October, 2013 for ADR reporting.

Data analysis

To investigate the knowledge and attitude and practice regarding pharmacovigilance among doctors, the collected data from questionnaire was analysed using descriptive and inferential statistics.

Results

In this study, 250 doctors from different departments participated. The average time taken by the doctors to complete the questionnaire was 15 minutes.

Description of demographic data (Question no.1 to 5): Maximum participants(31% each) were from medicine and paediatric departments followed by surgery, anaesthesia and ART centre.

71% of the total study population were of middle age between 30 years to 50 years.

Among them 49.4 % (123) were male and 50.6 % (127) were female. Most of the postgraduate doctors natively belong to other than Jaipur 60%(150). 50.4 % (126) were medical teachers and the rest 49.6 % (124) of the participants were postgraduate doctors.

Knowledge regarding pharmacovigilance (question no.6&7 showed that 88% of participants were aware of term pharmacovigilance & 79.3%(198) correctly understood the components of pharmacovigilance.

32.6% (82) doctors have seen ADR reporting form and 24.2%(60) were aware of the WHO international collaborating Uppsala monitoring centre. While only 17% (43) knew the Indian pharmacopeia commission is the regulatory body of ADR monitoring in India. The correct responses to other questions related to knowledge are summarized in Table. 1

Table 1: Questionnaire assessing Knowledge of doctors regarding pharmacovigilance and ADR

Sr. No	Questions	Correct Responses	
		%	Number
8	The important purpose of pharmacovigilance is	29.5	74
9	In India which regulatory body is responsible for monitoring ADRs	17.1	43
10	Name of "WHO online data base" available for reporting ADR?	52.5	131
11	Health care professionals responsible for reporting ADR	69.4	174
12	What do you understand by causality assessment?	60	150
13	The International centre for Adverse drug reaction monitoring is located in	24.2	61
14	Did you see an ADR reporting form	32.5	81
15	Do you know rare ADRs can be identified in the phase-4 of a clinical trial is	40.4	101
16	A serious adverse event in India should be reported to the regulatory body (DCGI) within 24 hours	54.3	136
17	An important step in the ADR monitoring is signal generation. Do you know what "signal" is	41.5	104

In our study average knowledge score was 48.2% among doctors as shown in figure 1

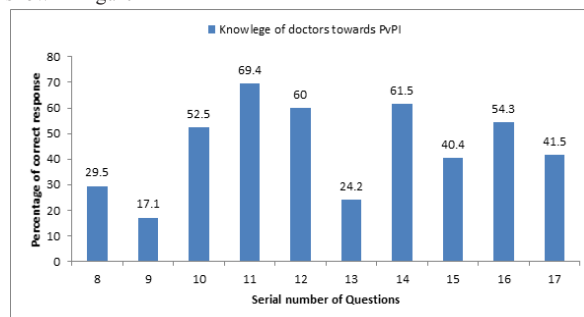


Figure 1: Showing Knowledge of doctors towards Pharmacovigilance

Attitude regarding pharmacovigilance: (Question no.18) 67.5% of doctors had the opinion that appropriate training of pharmacovigilance programme can increase ADR reporting as shown in table 2.

Table 2: Factors that may encourage you to report an ADR

Opinion of doctors	Percentage
a. Appropriate training regarding ADR reporting	67.5
b. Financial incentives for reporting	9.5
c. A very severe life threatening reaction in my patient.	13.6
d. Full proof confidentiality	9.4

Lack of time to actively look for ADRs while at work and not sure about occurrence of ADR and its relationship with the drug are the main reason for underreporting of ADR as shown in Figure 2. Attitude of doctors towards publishing ADR reports in medical journals and taking reference from journals and text books and attending CMEs/seminar and workshops was found in favour of ADR reporting (Question no.19 to 21).

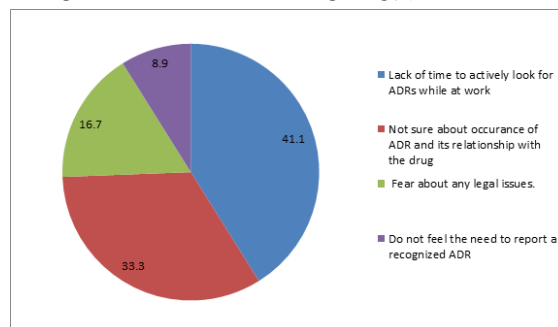


Figure 2: Showing reasons for underreporting of ADR

Practices regarding pharmacovigilance : Only 29.4 % of doctors reported ADR in their practice and 47.6 % doctors were knowing about ADR monitoring centre in their institution (Question no.22 to 24).

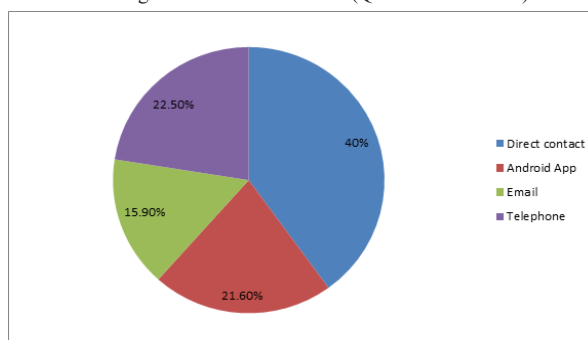


Figure3: Reporting methods to send adverse drug reaction to ADR monitoring centre

In our study preferable technique for ADR reporting (Question no.25) is direct contact (40%) by Technical Assistant appointed by AMC who visits hospital and enquires for ADR and other technique for ADR reporting used were android app as shown in figure no.3.

Discussion:

In our study, nearly 80% participants were aware of the term pharmacovigilance, while in a study by Gupta P et al¹¹ done among resident doctors at two government teaching, tertiary care hospitals in the state of Maharashtra observed that only 43% (135/ 314) were aware of the pharmacovigilance, in another study done by Srinivas M et al¹² observed that 64% of doctors knew the correct definition of PV.¹⁰ In our study 48% doctors are knowing about of ADR monitoring centre at their institution which is almost similar(49.5%) to the study done by Gupta P et al.¹¹

In our study 51% doctors knew important purpose of ADR reporting & 69.4% were aware of who can report ADR and average knowledge score was 48.2% among doctors, in contrast to study done by Hindoliya M et al only 44% doctors were aware of the main objective of reporting, 92% of doctors were aware of who can report ADR and average knowledge score was 64% among doctors.¹³

In our study 32.6 % doctors have seen ADR reporting form, similarly 31% have seen ADR reporting form in a study by Dhananjay K et al.¹⁴

Our study also highlighted the various reasons for under reporting of ADR. 33.3% doctors have opinion that lack of time to actively look into ADR while at work was the main reasons for under-reporting of ADRs. Another study done by Adhikari A et al¹⁵ given same reason by 27.91% for underreporting.¹³ In a study by Hindoliya M et al,¹¹ 23% doctors did not report as it was difficult to decide whether ADR occurred or not, in contrast 52.8 % doctors were not sure about occurrence of ADR and its relationship with the drug in our study. In our study 67.5% of doctors have opinion that appropriate training regarding ADR reporting of health care professionals should be done, while in questionnaire based study done by Modi P et al¹⁶ very high percentage (94%) of doctors had the same opinion. In our study only 9.5% of the total responses supported that financial incentives from regulatory agencies can encourage ADR reporting, study done Adhikari A et al¹⁵ also emphasized the same reason for encouraging ADR reporting by 19.38%.

In our study preferable technique for ADR reporting is direct contact (40%) along with toll free telephone number and android app, while in a study which was conducted on Nurses by R Rajalakshmi et al¹⁷ also reported direct contact for ADR reporting as a preferable method and other techniques were used in lesser number.

Conclusion:

Average knowledge score was 48.2% among doctors suggest adequate knowledge of doctors towards pharmacovigilance, but there was a significant gap between the ADR experienced in professional practice (63.8%) and ADR reported (29.4%), might be due to lack of time as great burden of patients in govt. hospitals and not sure about reporting. ADR reporting can be enhanced by incorporation of appropriate training of pharmacovigilance in medical curriculum as well as by better understanding of Pharmacovigilance Programme of India and by using modern techniques of sending of ADRs. Thus there is a need to emphasise health care professionals that reporting of adverse reactions is their moral and professional obligation.

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