

Assessment of knowledge, attitudes and practice among the post graduate students of dentistry and physiotherapy towards adverse drug reactions reporting and pharmacovigilance at a tertiary care centre at Indore, India

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ABSTRACT

Background: Pharmacovigilance knowledge and training in post graduate student doctors is key factor for proper implementation of PvPI. Often the dentists and physiotherapists who are also one of the main stakeholders for ADR reporting are neglected for training and knowledge regarding pharmacovigilance. This study was planned to evaluate the knowledge and awareness of pharmacovigilance in post graduate students in tertiary care centre in Indore.

Methods: It was a single point cross sectional questionnaire-based study conducted in a tertiary care Institute MGM Medical College and M.Y. Hospital in the state of Madhya Pradesh at Indore. It was conducted among post graduate student doctors from dentistry and physiotherapy. Total of 55 questionnaires were distributed, 50 of them were returned back and were analysed.

Results: Overall knowledge level was average. 90% knew about ADR while 80% were aware about PVPI. 10% knew about local AMC at Indore while only 04% knew global centre for Pharmacovigilance is at Sweden Uppsala. 88% thought Med watch as global database for ADR against only 12% knew its Vigibase. 90% thought ADR reporting is necessary. 96% thought it should be included in UG curriculum. 98% had not reported any ADR till date while 84% had not seen an ADR form.

Conclusions: Post graduate doctors are the prime candidates to impart the importance of pharmacovigilance. The study strongly suggested that there was a great need to create awareness and impart training among the post graduate doctors to improve the reporting of ADRs.

Keywords: ADRs, Dentists, Pharmacovigilance, Physiotherapist

INTRODUCTION

One of the major reasons of morbidity and mortality all over the world is adverse drug reactions (ADRs). Hence, proper monitoring of ADRs is a necessity. Adverse drug reactions can be defined as an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or

specific treatment, or alteration of the dosage regimen, or withdrawal of the product.¹

According to World Health Organization (WHO) definition, an ADR is any noxious, unintended, and undesired effect of a drug, which occurs at the doses which are used in humans for prophylaxis, diagnosis, or therapy.²

Whenever any new drug is approved by any authority in any country, little facts are known about its adverse drug

reactions and side effects known by information from the drug trial and its development.

Here comes importance of pharmacovigilance in which all healthcare professionals and other stakeholders in healthcare like para clinical nursing and also physiotherapists and dentists too are supposed to report the ADR that they encounter or observe in due course of treatment.³

The success of a pharmacovigilance program depends upon the active involvement of the all healthcare professionals such as doctors, physiotherapists, dentists, pharmacists even nurses.^{4,5}

The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%.⁶ To increase this rate of reporting we should educate the all stakeholders of healthcare professionals.

Often, we tend to neglect or ignore the physiotherapists and dentists as reporting stakeholders for pharmacovigilance. So, this study was carried out in the post graduate students of dentists and physiotherapy for assessment of Knowledge, Attitudes and Practice among the Post graduate Students of dentistry and physiotherapy towards Pharmacovigilance.

METHODS

This was a cross sectional, questionnaire based survey which was conducted in a tertiary care Institute MGM Medical College and M.Y. Hospital in the state of Madhya Pradesh at Indore.

The study instrument was a pre designed 20 questionnaires which were structured to obtain information on the knowledge of the ADRs reporting and the attitudes towards the reporting. 13 questions were designed to test knowledge, 4 for attitude and 3 for practice. The doctors were requested to complete the questionnaire and to return it within 1 day to their respective departmental offices.

Inclusion criteria

All post-graduation pursuing students of MPT [masters in physiotherapy] and MDS [masters in dentistry] across various specialities in this Institute.

Exclusion criteria

Passed out Post graduate students and senior residents in the respective speciality.

Statistical analysis

The questionnaire was analysed and question-wise percentage values were calculated with the help of Microsoft excel spread sheet in MS Office 2010.

RESULTS

Total of 55 questionnaires were distributed, 50 of them were returned back and were analysed. The percentage based calculation of all the responses were made by taking 55 (the total no. of responders) as the denominator.

Percentage of responders: $(50/55) \times 100 = 90.90\%$.

It shows most of the participants were keen towards subject of pharmacovigilance.

There were 13 knowledge based questions mentioned in Table 1. The overall knowledge level of participants was average. The percentage based calculation of all the responses were made by taking 50 (the total no. of responders) as the denominator.

90% participants knew definition of ADR [45/50].

80% participants were aware about PvPI [40/50].

70% knew about CDSCO as regulatory body of pharmacovigilance in India [35/50].

30% knew about national ADR monitoring centre is at IPC Ghaziabad [15/50].

Mentioned four findings show that participants have learnt and aware about the basic concept of pharmacovigilance programme of India and adverse drug reactions.

Only 20% knew purpose of Pharmacovigilance is to identify unrecognised ADRs. [10/50].

Only 7% knew actual definition of pharmacovigilance. [07/50].

04% knew about location of international apex coordination centre [02/50] and 10% knew about local ADR monitoring centre [05/50].

10% knew that its duty of ALL health stakeholders to report ADR [05/50].

Only 12% knew about vigibase; the reporting online portal of ADR of WHO [06/50].

Findings show that participants have absolutely poor knowledge about the more deeper aspects of PvPI and ADR reporting.

There were 04 attitude based questions mentioned in Table 2. The percentage based calculation of all the responses were made by taking 50 (the total no. of responders) as the denominator.

90% thought ADR reporting is necessary [45/50].

90% thought it should be made mandatory for all health care professionals [45/50].

96% thought it should be included in UG curriculum and also our hospital should be made AMC [48/50].

Above findings show that participants had a positive attitude and approach towards the Pharmacovigilance and also eager to implement it in their practice.

Table 1: Percentage responses to knowledge based questions.

Questions	Most frequently answered %	Correct answer %	Most commonly wrong answered %
1. Do you know what an ADR is?	Adverse Drug Reaction 45/50	Adverse Drug Reaction 45/50	Acute Drug Reaction 05/50
2. Define Pharmacovigilance?	The science of monitoring ADR's happening in a Hospital 43/50	The detection, assessment, understanding and prevention of adverse effects 07/50	The science of monitoring ADR's happening in a Hospital 43/50
3. Are you aware of Pharmacovigilance Programme of India?	Yes: 40/50	Yes: 40/50	No: 10/50
4. The important purpose of Pharmacovigilance is	To calculate incidence of ADR's 40/50	To identify unrecognized ADR's 10/50	To calculate incidence of ADR's 40/50
5. Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market?	Meta-analysis 41/50	Post Marketing Surveillance (PMS) studies 09/50	Meta-analysis 41/50
6. In India which Regulatory body is responsible for monitoring of ADR's?	Central Drugs Standard Control Organization 35/50	Central Drugs Standard Control Organization 35/50	Central Drug Research Institute 15/50
7. The national centre for monitoring ADRs in India is located at:	Indian Pharmacopeia Commission, Ghaziabad 15/50	Indian Pharmacopeia Commission, Ghaziabad 15/50	AIIMS, New Delhi 35/50
8. Which of the following is the AMC of our region?	GMC Bhopal 45/50	SAIMS Indore 05/50	GMC Bhopal 45/50
9. Rare ADRs can be identified in the following phase of a clinical trial	During phase-4 clinical trials 44/50	During phase-4 clinical trials 44/50	During phase-3 clinical trials 06/50
10. The international centre for adverse drug reaction monitoring is located in	Unites States of America 48/50	Sweden 02/50	Unites States of America 48/50
11. The healthcare professionals responsible for reporting ADR in a hospital is/are	Doctor 45/50	Doctor, nurses and pharmacists 05/50	Doctor 45/50
12. Which one of the following is the 'WHO online database' for reporting ADRs?	Med watch 44/50	Vigibase 06/50	Med watch 44/50
13. Which of the following scales is most commonly used to establish the causality of an ADR?	Schumock and Thornton scale 48/50	Naranjo algorithm 02/50	Schumock and Thornton scale 48/50

There were 03 practice based questions mentioned in Table 3. The percentage based calculation of all the responses were made by taking 50 (the total no. of responders) as the denominator.

98% have not reported any ADR till date [49/50].

84% have not seen an ADR form [42/50].

84% did not know how to report [42/50]. 04% was afraid of legal consequences after reporting [02/50].

Findings show that almost none of the participants have reported any ADR and lack of practice of Pharmacovigilance. Most common reason was they didn't know how to report.

Table 2: Percentage responses to attitude based questions.

Questions	Most frequently answered	Correct answer	Most commonly wrong answered
Do you think Pharmacovigilance should be taught in detail during undergraduate curriculum?	Yes 48/50	Yes 48/50	No 02/50
Do you think reporting of adverse drug reaction is necessary?	Yes 45/50	Yes 45/50	No 05/50
Do you think reporting of ADR should be made mandatory for health care professionals?	Yes 45/50	Yes 45/50	No 05/50
Do you think our hospital should be AMC?	Yes 48/50	Yes 48/50	No 02/50

Table 3: Percentage responses to practice-based questions.

Questions	Most commonly answered	Correct answer
Have you ever seen the ADR reporting form?	No 42/50	Yes 08/50
Have you ever reported an ADR?	No 49/50	Yes 01/50
What practical difficulties you have in reporting ADR at our center?	-Don't know how to report ADR 42/50 -ADRs are already documented in literature 02/50 -Don't know how to fill up ADR form 04 /50 -Fear of legal issues due to reporting ADR 02/50	

DISCUSSION

WHO has defined Pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of the adverse effects (AE), particularly long and short term side effects of medicines or any other drug related problems.^{7,8}

Around 32% and 69% of drug-related problems were reported as definitely or possibly preventable. It clearly indicates the need of proper and prompt reporting of ADRs from healthcare professionals.⁹

As newer drugs keep on coming in market as a new therapeutic intervention, the risk of ADRs are also keep on increasing. It is found that ADRs account for 4.2-30% of hospital admissions in USA and Canada and 3.4% in India.^{10,11}

Dental doctors and physiotherapists are also involved in prescribing many therapeutic interventions, including allopathic medicines like local anaesthetics, antibiotics, analgesic and anti-inflammatory drugs etc. Antibiotics and analgesics are among the leading causes of ADRs.¹² Hence the risk of ADRs cannot be ignored in dentistry and physiotherapy.

Several studies have been done to investigate the cause of underreporting of ADR in Indian medical students.¹³⁻¹⁵ But none such study have been done at our tertiary care centre among post graduate dentist and physiotherapist students. Hence authors planned this study to increase the awareness and practice among Post graduate students at our centre.

Most important thing about KAP studies like these is response of participating candidates. Our study had a very good response rate, 90.90%. It shows most of the candidates were keen towards the subject of pharmacovigilance.

As far as knowledge is concerned, 90% knew ADR while 80% were aware about PvPI.

But only 20% knew its actual purpose to identify unrecognised ADR's. This shows PG students have good approach towards this programme, but they lack the training about it.

70% knew the apex body to monitor ADR is CDSCO and only 30% knew the apex body of PVPI is IPC Ghaziabad. 88% knew about phase 4 trials in which rare ADR's are identified. Above three values indicate that basic theoretical knowledge about ADR and PvPI is average among the participating post graduates.

Advanced knowledge like local AMC was known to only 10% while global centre at Sweden Uppsala was known to only 04%. it shows lack of training in PVPI.

There were 90% thought its only duty of doctors while only 10% actually knew that any healthcare professional can report an ADR which further highlights importance of training in PVPI among budding dentists and physiotherapists.

Overall knowledge was found to be average level among the participant's.

Attitude of the participating doctors was very much positive. 90% said that ADR reporting should be made mandatory to all health care professionals. 96% were of opinion to include pharmacovigilance from undergraduate syllabus itself and also our tertiary care centre should be made a recognised AMC to report ADR.

Practice part was found to be very much poor. 84% had never seen an ADR form ever while 98% never reported any ADR till date. This is a significant observation in this study because this clearly shows total lack of practice and training in PVPI.

The reason behind these findings may be that they are taught about ADR reporting during their under graduation in 2nd year. However, it is not in practice as pharmacovigilance related work has not been included in their undergraduate or post graduate curriculum.

Hence there is strong need to include proper training and practice of pharmacovigilance in undergraduate as well as post graduate curriculum. This will increase the knowledge and practice both in long term.

CONCLUSION

In conclusion, this study strongly suggested that there was a great need to create awareness among the post graduate doctors to improve the reporting of ADRs. Post graduate doctors are the prime candidates to impart the importance of pharmacovigilance because they are the ones who actively are in touch with patients regularly and also they are future specialists.

Lack of knowledge and training about how to report, purpose of PvPI, lack of risk perception of newly marketed drugs, lack of risk perception of ADRs of prescribed drugs are some of the main causes of the study. Proper training and awareness workshops for post graduate students should be designed keeping these findings in focus.

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