

An evaluation of knowledge, attitude and practice of pharmacovigilance among interns in a tertiary care teaching hospital of North Maharashtra

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ABSTRACT

Background: Adverse Drug Reactions (ADRs) are considered as one of the leading cause throughout the world resulting in significant increase in mortality and morbidity, therefore its monitoring is very essential in today's practice of medicine. Spontaneous reporting of ADRs have played a major role in the detection of unsuspected, serious and unusual ADRs previously undetected during the phases of clinical trials. Under-reporting of ADRs is considered as one of the major hurdle for the success of pharmacovigilance. Aims and objectives were to assess the knowledge, attitude and practice of pharmacovigilance among interns in a tertiary care teaching hospital.

Methods: A cross sectional, observational, questionnaire based study was carried out using a predesigned Knowledge Attitude Practice (KAP) questionnaire. Study was conducted after the permission of Institutional Ethical Committee (IEC). The study included 100 interns who had completed at least ten months of their internship. The KAP questionnaire was assessed and analyzed and data was presented as percentages.

Results: On an average only 31.17% interns answered correctly related with knowledge about pharmacovigilance. 88.63% interns agreed that ADRs reporting is necessary. According to 85.22% interns, pharmacovigilance must be taught in details to healthcare professionals. Only 34.09% had ever seen the ADR reporting form. Only 17.04% interns had knowledge about how to report ADR?

Conclusions: Our study revealed that there was lack of awareness related with knowledge, attitude and practice of pharmacovigilance among the interns. There is need of implementation of pharmacovigilance awareness programs for undergraduates.

Keywords: Adverse drug reaction, Pharmacovigilance, Spontaneous reporting

INTRODUCTION

Adverse drug reactions (ADRs) are considered as one of the important cause of morbidity and mortality.¹ According to World Health Organization (WHO), ADR is defined as 'any noxious, unintended and undesired effect of the drug that occurs at doses used for prophylaxis, diagnosis or cure of a disease.'²

Pharmacovigilance is defined as 'science and activities relating to the detection, assessment, understanding and

prevention of adverse effects or any other drug related problems.'² Spontaneous reporting system is considered as backbone of pharmacovigilance. It plays major role in the detection of unsuspected, serious and unusual ADRs which could not be detected during the clinical trial phases.³ However major hurdle in the complete success of pharmacovigilance programme is underreporting of the ADRs.⁴

In a country like India, with a large population and vast diversity, implementation of standard pharmacovigilance

programme is very necessary. Under reporting of ADRs is very common in India as compare to other countries.⁵ This underreporting may delay the detection of serious ADRs and definitely have major negative impact on the public health. Various studies have shown that inadequate knowledge about pharmacovigilance among healthcare professionals as well as their attitude towards pharmacovigilance mainly responsible for underreporting of ADRs.⁶⁻¹¹

Due to under reporting of ADRs, assessment of awareness of pharmacovigilance is very important.

METHODS

It was a cross sectional, observational, questionnaire based study. The study was conducted at a tertiary care hospital of North Maharashtra after the permission from Institutional Ethical Committee (IEC). The study was conducted among 100 interns who had completed at least 10 months of their internship programme.

The questionnaire was made to evaluate the Knowledge Attitude Practice (KAP) of pharmacovigilance among the interns. The KAP questionnaire was obtained from the previous studies.¹²⁻¹⁶ The KAP questionnaires consisted of total 28 questions. Out of which 13 related with the knowledge, 9 related with the attitude and 6 related with the practice of pharmacovigilance.

The questionnaires were distributed among the interns to fill up the answers and 30 min of time duration was given for fill up the answer.

After the completion of the study, analysis of the data was done by using Microsoft excels and the results were formulated in the form of percentage.

RESULTS

Only 88 out of 100 interns filled and returned the questionnaire within the stipulated time frame. Response rate of the interns was found to be 88%.

The KAP questionnaire consisted of total 28 questions. Out of which 13 related with knowledge, 9 related with attitude and 6 related with practice of pharmacovigilance.

Analysis of knowledge related questions

Only 34.09% interns answered correctly for the definition of pharmacovigilance while 44.31% interns were aware of the purpose of pharmacovigilance. 26.13% interns were aware of the location of international ADR monitoring center while 51.13% interns had knowledge about the regulatory body involved in the regulating ADR in India. Only 26.13% interns were aware about the phase of clinical trial in which rare adverse effects commonly found. Only 39.77% interns found to have knowledge

related with the ‘WHO online database’ for reporting ADR. 32.95% interns had knowledge about the order of ADR report submission. 36.36% interns answered correctly about the chairman of pharmacovigilance program in India.

Table 1: Questions related with knowledge of pharmacovigilance.

No.	Questions related with knowledge of pharmacovigilance	% of correct response
1	Definition of pharmacovigilance	34.09
2	Purpose of pharmacovigilance	44.31
3	What pharmacovigilance incudes?	32.50
4	Where the international centre for ADR monitoring is located?	26.13
5	Which regulatory body responsible for monitoring ADRs in India?	51.13
6	A serious adverse event in India should be reported to the regulatory body within how many days?	32.95
7	Rare ADR usually identified in which phase of clinical trial?	26.13
8	Which is the ‘WHO online database’ used for reporting ADRs?	39.77
9	According to Wills and Brown, ADRs are classified into how many types?	4.54
10	Which type of ADR is common?	23.86
11	What is the order of ADR submission?	32.95
12	Who is the chairman of pharmacovigilance programme in India?	36.36
13	ADR reporting forms are periodically reviewed by whom?	20.45

From Table 1, on an average only 31.17% interns correctly answered the questions related with knowledge about pharmacovigilance.

Analysis of attitude related questions

About 88.63% interns agreed that ADR reporting is necessary. According to 85.22% interns, pharmacovigilance must be taught in detail to healthcare professionals. 45.45% interns came across the article related with adverse drug reaction during their internship programme while only 38.64% interns agreed that reporting of adverse drug reaction is an obligation to them. 34.09% interns were aware about the existence of pharmacovigilance programme in India. According to 34.09% interns, ‘A single unreported case may not affect ADR database’ is the factor which discourage them from reporting ADR while according to 27.27% , ‘lack of time’ is the factor which discourage them from reporting ADR.

Table 2: Questions related with attitude towards pharmacovigilance.

No	Questions related with attitude towards pharmacovigilance	% of correct response
1	Is it necessary to report adverse drug reaction?	88.63
2	Should pharmacovigilance be taught in detail to healthcare professionals?	85.22
3	Have you read any article about adverse drug reaction?	45.45
4	Is it necessary to establish ADR monitoring center in every hospital?	46.59
5	Can a nonmedical person report to a nearby Healthcare Professional?	60.23
6	Do you think reporting of adverse reaction is an obligation to you?	38.64
7	Do you know regarding the existence of a National Pharmacovigilance Programme in India?	34.09
8	Are you aware of the term of pharmacovigilance?	84.09
	Most important factor which discourages you from reporting ADR?	
	A. Non – remuneration for reporting	22.73
9	B. Lack of time to report ADR	27.27
	C. A single unreported case may not affect ADR database	34.09
	D. Difficult to decide whether ADR has occurred or not	15.91

Table 3: Questions related with practice of pharmacovigilance.

No	Questions related with practice of pharmacovigilance	% of correct response
1	Have you ever experienced adverse drug reaction in the patient during your internship training programme?	50 % Yes
2	Have you ever reported ADR to pharmacovigilance centre?	2.27% Yes
3	Have you ever seen the ADR reporting form?	34.09%
4	Have you got the training on ‘how to report Adverse Drug Reaction?’	17.04%
5	Which of the following methods is commonly employed by the healthcare professional to monitor adverse drug reactions of new drugs once they are launched in the market	30.68
6	Is there any pharmacovigilance committee in your Institute?	21.59

Analysis of practice related questions

50% interns experienced adverse drug reaction in the patients during their internship training programme but only 2.27% interns reported to pharmacovigilance centre. 34.09% interns were aware about ADR reporting form. Only 17.04% interns got the training on ‘how to report ADR?’ Only 21.59% interns were aware about the pharmacovigilance committee in their institute.

DISCUSSION

Pharmacovigilance is considered as one of the important post-marketing tools to provide the safety of pharmaceutical, herbals and related health products. Due to detection of ADRs in the post marketing studies, many drugs like cisapride, valdecoxib, sibutrabine, benoxaprofen, cerivastatin have been withdrawn from the market.¹⁷⁻¹⁹

The spontaneous reporting system is considered as backbone of pharmacovigilance, however under-reporting of ADRs is considered as most important hurdle for the success of pharmacovigilance.²⁰ According to Hema NG et al, lack of proper knowledge and awareness

about pharmacovigilance is considered as most important reason for the underreporting of adverse drug reactions.⁵

We conducted the study to find out awareness about knowledge, attitude and practice of pharmacovigilance among interns of tertiary care hospital of North Maharashtra. In our study we found inadequate awareness about pharmacovigilance among interns. Only 31.17% interns answered correctly about knowledge related questions of pharmacovigilance. Good pharmacovigilance knowledge is very important for practicing pharmacovigilance. Though 88.63% interns agreed about necessity of reporting ADR, only 17.04% interns had knowledge about ‘how to report ADR?’

Study conducted by Rehan HS et al at a tertiary care hospital, New Delhi showed that the students and prescribers needed further improvement in their knowledge, attitude and practices.²¹ A similar study conducted by Desai CK et al at a tertiary care hospital, Ahmedabad, found under reporting and lack of knowledge about the reporting system among the prescribers.²²

A cross sectional, questionnaire based, multi-centric study conducted by Vora MB et al at six different

colleges in Gujarat found overall low awareness about pharmacovigilance among undergraduate medical students.²³ Also an awareness on the reporting systems was found very low amongst the resident doctors in a study conducted by Gupta P et al at two government teaching hospitals of Maharashtra.²⁴ Inadequate knowledge on pharmacovigilance among resident doctors have been found in similar studies conducted in Nigeria and France.^{25,26}

A study which was conducted at a tertiary care hospital of Nepal have also found low KAP scores among prescribers and it suggested the need for educational interventions.²⁷ Study conducted by Muraraiah S et al have demonstrated that educational interventions can increase the awareness of pharmacovigilance among the health care professionals.²⁸

Limitations of the study

One of the limitations of our study was small number size. It is recommended that similar kind of studies must be conducted in other health professionals.

CONCLUSION

In our study we found inadequate knowledge about pharmacovigilance, so it is recommended to implement educational intervention programme to improve knowledge of future students, as well as pharmacovigilance should be included in the curriculum of medical students.

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