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Original Research Article

AN OBSERVATIONAL STUDY TO EVALUATE KNOWLEDGE, ATTITUDE, AND PRACTICE OFPHARMACOVIGILANCE AMONG UNDERGRADUATE MEDICAL STUDENTS OF A TERTIARY CARE TEACHING HOSPITAL OF THE CENTRAL INDIA

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ABSTRACT

Background: Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. Adverse drug reactions (ADRs) are the fourth or the sixth leading cause of death creating a lot of heath care costs. The problems in resource poor developing countries seems to be further grim with ADR related data being scarce, mainly due to underreporting and so the problem being underestimated. **Aim:** Our present study aims to evaluate knowledge, attitude and practice (KAP) of pharmacovigilance among the second year MBBS students. **Materials and Methods:** The present study was carried at BRLSABVM Government Medical College, Rajnandgaon (Chhattisgarh State).A questionnaire based cross sectional observational study was done for assessing the KAP towards ADR reporting. In this study 125 second year MBBS students were assessed regarding their knowledge, attitude and practice of pharmacovigilance. **Data Analyses:** At the end data were collected & tabulated in summary sheets & were analyzed by using computer software SPSS version 20 & Microsoft Excel 2019.**Result:** Out of 65 second year students who participated in our study, were assessed for the knowledge of the pharmacovigilance and 53 (82.8%) knew who can report ADR,57(89.1%) were aware about the specific format in which ADR is reported, 59(92.2%) students knew about the pharmacovigilance programme of India, 36(56.2%)students knew about the location of the international pharmacovigilance centre while 36(46.8%) students were aware of the commonly used scale used for assessing the adverse drug reaction causality. Regarding the attitude of the pharmacovigilance,61(91.3%) thought that reporting of ADR is necessary, while 64(100%) felt that reporting ADR benefits both patients and doctors,61(95.3%) thought that medical students can play a role in the ADR reporting, 60(93.7%) students felt that ADR should be voluntary while 60(93.7%)students felt that ADR reporting should be compulsory. Regarding the practice of the pharmacovigilance, nearly 31(48.4%) reported that they have not seen the pharmacovigilance form while 35(54.6%)students admitted that there are routine discussions on ADR during their ward postings, 40(62.5%) accepted that they have read an article on the ADR prevention, 48(76.2%) admitted that they have been trained in the ADR reporting. **Conclusion**: In our study knowledge and attitude of pharmacovigilance and ADR, among the undergraduate medical students were better than the practice. Pharmacovigilance and ADR reporting should be mandatorily taught to the medical students throughout their medical curriculum. Practice part needs a lot of improvement and should be taught in the practicals of the undergraduate medical students.

INTRODUCTION

Pharmakon is a greek word which means' medicinal substances'and vigilare is a latin word which means'to keep watch',therefore pharmacovigilance is keeping watch on medicinal substances.The main goal of this activity is to promote safe and rational use of medicines hence improving patient care and public health in general.

Medicines and vaccines have transformed the prevention and treatment of diseases. In addition to their benefits, medicinal products may also have side effects, some of which may be undesirable and / or unexpected. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.

All medicines and vaccines undergo rigorous testing for safety and efficacy through clinical trials before they are authorized for use. However, the clinical trial process involves studying these products in a relatively small number of selected individuals for a short period of time. Certain side effects may only emerge once these products have been used by a heterogenous population, including people with other concurrent diseases, and over a long period of time.[1]

Pharmacovigilance Programme of India (PvPI) has been launched by the government with the aim of establishing pharmacovigilance system in our country.The purpose of the PvPI is to collate data, analyze it and use the inferences to recommend informed regulatory interventions,besides communicating risks to healthcare professionals and the public. The broadened patient safety scope of pharmacovigilance includes the detection of medicines of substandard quality as well as prescribing,dispensing and administration errors. Counterfeiting, antimicrobial resistance, and the need for real time surveillance in mass vaccinations are other pharmacovigilance challenges which need to be addressed.

The vision of PvPI is to improve patient safety and welfare in Indian population by monitoring drug safety and thereby reducing the risk associated with use of medicines.The ultimate safety decisions on medicines may need considerations of comparative benefit/risk evaluations between products for similar indications, so the complexity is great.[2]

Adverse drug reactions(ADRs) are the fourth or the sixth leading cause of death creating a lot of heath care costs.ADRs are the most common cause of hospital admissions.Thus ADRs cause a significant mortality & morbidity.

1.34%of total documented ADRs amount to fatal ADRs.[3]

The problems in resource poor developing countries seems to be further grim with ADR related data being scarce,mainly due to underreporting and so the problem being underestimated.[4]

A healthcare system that includes pharmacovigilance promotes the safety of medications by minimising ADRs' occurrence & provides a warning network of various healthcare providers,regulators, manufacturers and consumers to take remedial actions in a timely and orderly manner.[5]

The key stakeholders involved in pharmacovigilance are patients, healthcare professionals,governments and pharmaceutical companies.[6] Among these stakeholders, healthcare professionals play the most significant role.

Pharmacovigilance is a multidisciplinary approach that includes the collaboration of multiple disciplines such as clinicians, pharmacists, nurses and dentists. A clinician's role in handling ADRs is essential not only for patients' safety but also for drug safety monitoring at the population level.[7]

Pharmacists monitor the ongoing safety of medicines and are the most responsible members of the multidisciplinary team to establish and maintain an effective pharmacovigilance programme in a practice setting. Pharmacists provide information related to medication safety after critical evaluation.[5] The exclusive role of nurses in pharmacovigilance is identifying ADRs, which is difficult for other healthcare providers.[8] Dentists may help build a better pharmacovigilance system by adopting pharmacovigilance practices and reporting ADRs that are useful for dentistry as a whole.[9]

MATERIALS AND METHODS

Study design: This is a prospective cross sectional observational, questionnaire-based study was conducted during the period of December to February 2023-24 in Department of Pharmacology, BRLSABVM Medical College and Hospital, Rajnandgaon Chhattisgarh India.

Study population: The study population was of either gender, above the age of 18 years who were second year MBBS students attending lectures.

Sampling/sample size: A non – probability sampling techniques (convenience method) was used to achieve representative sample from the whole batch. Data collection was done after institutional ethics committee approved this study. A total of 125 participants were recruited for the study and goggle form was distributed via email. Before filling out the questionnaire,the study participants were explained the study importance & purpose.

After the informed consent was obtained from the target population, the semi structured questionnaire were distributed & sufficient time was given to the participants to complete the questionnaire,out of which 65 participants gave consent & their response were considered. The questionnaire comprises three parts;in which part I includes demographic details of study participants such as name,email & knowledge of pharmacovigilance. The inquiries related to

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awareness & attitude of participants would come under part II & practices of pharmacovigilance were included in part III. The data were represented as percentage &analyzed through the Microsoft office package.

Data Analyses: At the end data were collected & tabulated in summary sheets & were analyzed by using computer software SPSS version 20 & Microsoft Excel 2019.

RESULTS

Evaluation of knowledge about pharmacovigilance

Majority of the students knew about who can report adverse drug reaction,53(82.8%).Around 57(89.1%) students were aware of the specific format in which adverse drug reaction has to be reported.Majority of students knew about the existence of the pharmacovigilance programme of India,59(92.2%),36(56.2%) students knew that international pharmacovigilance centre is located at Uppsala(Sweden).While 30(46.8%) students were aware of the most commonly used scale used for assessing the adverse drug reaction causality. [Table 1]

Evaluation of attitude about pharmacovigilance

Majority of students thought that reporting of adverse drug reaction is necessary,61(95.3%). All the students 64(100%)felt that reporting adverse drug reaction benefits both patients and doctors.61(95.3%) students thought that medical students can play a role in the adverse drug reaction reporting.Around 60(93.7%) students felt that adverse drug reaction reporting should be voluntary.60(93.7%)students felt that adverse drug reaction reporting should be compulsory. [Table2]

Evaluation of practice about pharmacovigilance

About 31(48.4%)students admitted that they had not seen the adverse drug reaction reporting form.35(54.6%)students accepted that there is routine discussions on adverse drug reaction during their ward postings.Around 40(62.5%)students accepted that they had read an article on prevention of adverse drug reactions.48(76.2%)admitted that they have been trained on how to report adverse drug reaction.Around29 (45.3%)accepted that they have come across with an adverse drug reaction in their patients during their training or ward postings. [Table3]

DISCUSSION

Table 4 shows comparision of knowledge based questions of our study with that of other studies. In our study 82.8% students knew about who can report ADR, similar result was obtained by Kumar S,[12] et al who reported it to be 81% while Verma S,[13] et al got different result which was as low as 50%. In our study 89.1% students knew that ADR reporting has a specific format, while it was 87.1% in the study conducted by Gupta R et al,[10] which was comparable to our study. In our study 92.2% students knew about the Pharmacovigilance programme of India, similar result of 95% was obtained in a study by Verma S et al while different result was obtained in a study done by Gupta R et al et al who got 77.5% and it came out to be as low as 47% in a study conducted by Kumar S et al. Nearly 56.2% students knew the location of the international ADR monitoring centre in our study, results were similar in a study conducted by Kumar S et al who got a result of 59%,but in a study done by Verma S et al a high percentage of the students nearly 94% knew of the international ADR monitoring centre. In our study 46.8% students were aware of the scale most commonly used to establish the ADR causality, but a low percentage around 20% of students knew about the ADR causality scale in a study conducted by Gupta R et al this was similar to 21.51% found in a study carried out by T.A.Acharya et al.[11]

Table 5 shows comparision of attitude based questions of our study with that of other studies. In our study 95.3% students thought that reporting of ADR is necessary, similar results were obtained from a study by Verma S et al who got 98% and Gupta R et al who got 98.75% while it was somewhat low in a study conducted by Kumar S et al who got 85%.100% students of our study thought that ADR reporting benefits both patients and doctors. Similar results were obtained in a study conducted by Gupta R et al who got 95% and Acharya T.A. et al who got 96.77%.In our study 95.3% students thought that medical students could play a role in reporting the ADR, similar result was obtained by Gupta R et al who got 92.5% while a low 61.29% result was reported by Acharya T.A. et al. In our study 93.7% students felt that ADR reporting should be voluntary. In our study 93.7% students felt that ADR reporting should be compulsory and similar result of 92.47% was reported by Acharya T.A.et al.

Table 6 shows comparision of practice based questions of our study with that of other studies. In our study 48.4% students committed that they have seen ADR reporting form by CDSCO, which seems to be lower than that of other studies, viz 98% by Verma S et al and 73.75% by Gupta R et al. In our study 54.6% students reported that there are routine discussions on ADR, during their ward postings while a low result of 30% was obtained by Gupta R et al and 23.66% result was obtained in a study by Acharya T.A. et al. In our study 62.5% students admitted that they have read an article on the prevention of ADR, a low result of 42% was obtained in a study by Verma S et al,36.25% result was obtained by Gupta R et al and 36.56% by a study carried out by Acharya T.A. et al. In our study 76.2% students admitted that they have been trained on how to report an ADR, it was somewhat low to the findings obtained in other studies as Verma S et al which found it to be 95% and 82% in a study by

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Kumar S et al. In our study 45.3% students admitted that they have come across an ADR during their training /ward postings and in a study carried out by Verma S et al the result came out to be as low as 25%.

Table 1: Response to Knowledge Based Questions

KNOWLEDGE BASED QUESTIONS	NO.(%) OF STUDENTS RESPONDED CORRECTLY
1.WHO CAN REPORT ADVERSE DRUG REACTION	53(82.8%)
2.DOES ADVERSE DRUG REACTION REPORTING HAS SPECIFIC FORMAT?	57(89.1%)
3.DO YOU KNOW REGARDING THE EXISTENCE OF PHARMACOVIGILANCE PROGRAMME OF INDIA?	59(92.2%)
4.WHERE IS INTERNATIONAL CENTRE FOR ADVERSE DRUG REACTION LOCATED?	35(55.6%)
5.WHICH SCALE IS MOST COMMONLY USED TO ESTABLISH ADVERSE DRUG REACTION CAUSALITY?	29(46%)

Table 2: Response to attitude based questions

ATTITUDE BASED QUESTIONS	No.(%)OF STUDENTS RESPONDED CORRECTLY
1.DO YOU THINK REPORTING OF ADVERSE DRUG REACTION IS NECESSARY?	60(95.2%)
2.DO YOU THINK ADVERSE DRUG REACTION REPORTING BENEFITS BOTH PATIENTS AND DOCTORS?	63(100%)
3.DO YOU THINK THAT MEDICAL STUDENTS COULD PLAY A ROLE IN ADVERSE DRUG REACTION MONITORING?	60(95.2%)
4.DO YOU THINK ADVERSE DRUG REACTION REPORTING SHOULD BE VOLUNTARY?	59(93.7%)
5.DO YOU THINK ADVERSE DRUG REACTION REPORTING SHOULD BE COMPULSORY?	59(93.7%)

Table 3: Response to practice based questions

PRACTICE BASED QUESTIONS	No.(%)OF STUDENTS RESPONDED CORRECTLY
1.HAVE YOU SEEN AN ADVERSE DRUG REACTION FORM BY CDSCO?	30(47.6%)
2.IS THERE ANY ROUTINE DISCUSSION ON ADVERSE DRUG REACTIONS DURING YOUR WARD POSTINGS?	33(53.2%)
3.HAVE YOU ANYTIME READ ANY ARTICLE ON PREVENTION OF ADVERSE DRUG REACTIONS?	39(61.9%)
4.HAVE YOU EVER BEEN TRAINED ON HOW TO REPORT ADVERSE DRUG REACTION?	48(76.2%)
5.HAVE YOU EVER COME ACROSS WITH AN ADVERSE DRUG REACTION IN YOUR PATIENT DURING YOUR TRAINING / WARD POSTINGS?	28(44.4%)

Table 4: Comparison with results of other studies: knowledge based questions

QUESTIONSASKED	OURSTUDY(%)	VERMA S et al [13](%)	KUMAR S et al[12](%)	GUPTA R et al[10](%)	ACHARYA T.A. et al[11](%)
1.Who can report ADR?	82.8	50	81	--	--
2.Does ADR reporting has specific format?	89.1	--	--	87.5	--
3.Do you know regarding the existence of Pharmacovigilance Programme of India?	92.2	95	47	77.5	--
4.Where is international centre for ADR located?	56.2	94	59	--	--
5.Which scale is most commonly used to establish ADR causality?	46.8	--	--	20	21.51

Table 5: Comparison with results of other studies: attitude based questions

QUESTIONSASKED	OURSTUDY(%)	VERMA S[13] et al(%)	KUMAR S et al[12](%)	GUPTA R et al[10](%)	ACHARYA T.A. et al[11](%)
1.Do you think reporting of ADR is necessary?	95.3	98	85	98.75	--
2.Do you think ADR reporting benefits both patients & doctors?	100	--	--	95	96.77
3.Do you think that	95.3	--	--	92.5	61.29

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medical students could play a role in ADR reporting?					
4.Do you think ADR reporting should be voluntary?	93.7	--	--	--	--
5.Do you think ADR reporting should be compulsory?	93.7	--	--	--	92.47

Table 6: Comparison with results of other studies: practice based questions

QUESTIONS ASKED	OUR STUDY(%)	VERMA S[13] et al(%)	KUMAR S et al[12](%)	GUPTA R et al[10](%)	ACHARYA T.A. et al[11](%)
1.Have you seen ADR form by CDSCO?	48.4	98	--	73.75	--
2.Is there any routine discussions on ADR during your ward postings?	54.6	--	--	30	23.66
3.Have you anytime read any article on prevention of ADR's?	62.5	42	--	36.25	36.56
4.Have you ever been trained on how to report ADR?	76.2	95	82	--	--
5.Have you ever come across with an ADR in your patient during your training /ward postings?	45.3	25	--	--	--

CONCLUSION

In our study knowledge and attitude of pharmacovigilance and ADR, among the undergraduate medical students were better than the practice.Thus sensitizing and teaching pharmacovigilance and ADR reporting to the medical students is gradually improving them in their knowledge and attitude.

A lot more has to be done thus pharmacovigilance and ADR reporting should be mandatorily taught to the medical students throughout their medical curriculum.Practice part needs a lot of improvement and should be taught in the practicals of the undergraduate medical students.

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