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Knowledge and attitude of adverse drug reaction reporting process among Indian medical undergraduates in a tertiary care teaching hospital - A questionnaire based study

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Abstract
Introduction: The primary objective of this study is to assess the knowledge, attitude and awareness of adverse drug reaction reporting process among Indian medical undergraduates in a tertiary care teaching hospital.
Material and Methods: This is a cross sectional questionnaire based study on 250 Indian medical graduates. Phase III – Part 1 and Part 2 Medical Undergraduates at Trichy SRM Medical College Hospital & Research Centre for next 3 months were included. The students were informed in person with participant information sheet during PHASE 3 clinical posting. Those students who did not gave informed consent for participation in the study were excluded.
Results: The mean age of the study participants was 20.12±1.3 years. There was male preponderance with 52% male medical graduates and 48% female medical graduates. Majority of the included subjects were in Phase III Part 1. Table 1 describe the distribution of knowledge related questions. Around 70% correctly answered the definition of pharmacovigilance, 40% answered about important purpose of pharmacovigilance, 48% on healthcare professionals are responsible for reporting ADRs, 61% on organization conducting National Pharmacovigilance Program in India, 40% on regulatory body responsible for monitoring pharmaceuticals and medical devices, 42% answered correctly on location of international centre for adverse drug reaction monitoring.
Conclusion: There is requirement for continuous medical education in these students on regulations of Pharmacovigilance. This study provides baseline data of the knowledge and attitude for providing educational intervention.

Keywords: Pharmacovigilance, knowledge, practice, undergraduates, under-reporting

Introduction
According to the World Health Organization (WHO), an adverse drug reaction (ADR) is any response to a drug that is harmful and unwanted and occurs at dosages utilized in man for prevention, diagnosis, and therapy. This definition applies to any response to a substance that is noxious and unintended. On its website, the Indian Pharmacopoeia Commission (IPC) has made version 1.4 of the ADR Reporting form available for use by Indian healthcare professionals. Similar research on pharmacovigilance have revealed that the underreporting of adverse drug reactions (ADR) may be connected to deficiencies in the knowledge and attitude of healthcare workers. The ADR reporting procedure can be made more efficient by increasing the number of Indian medical undergraduates who are aware of the operations of the Pharmacovigilance Program of India [1].
The need for post-authorization that has been requested. The need for pharmacovigilance comes at this juncture, when such drugs are required to be monitored for their efficacy and safety in conditions similar to those found in everyday life [2]. The safe use of medicines, the early detection of adverse drug reactions (ADRs), the promotion of the rational use of medicines, the reduction in cost of drug-related morbidity and mortality, and the ensuring of public confidence and ethical concern are all reasons why pharmacovigilance is necessary [3]. The process of pharmacovigilance contributes to the evaluation and communication of data on the advantages or hazards associated with the use of medicines, as well as the education and information of patients. A knowledge of the pharmacovigilance system not only prevents the undetected use of inefficient, inferior, or counterfeit drugs but also reduces the likelihood that resources would be wasted [4].

The Indian Pharmacopeia Commission in Ghaziabad, Uttar Pradesh, is home to the country's National Coordination Center for the Pharmacovigilance Programme of India (PvPI), which was launched on July 14, 2010, in response to the realisation that adverse drug reaction (ADR) monitoring was necessary in India [4]. The fundamental purpose of the National Comprehensive Center for Pharmacovigilance and Informatics (NCC-PvPI) is to advance the safest possible use of medical treatments by means of adequate education in pharmacovigilance training activities conducted all across the country. There are currently 444 Adverse Drug Reaction Monitoring Centers (AMCs) that fall within the purview of the PvPI [5]. An international database of ADR reports from around the world may be found at the Uppsala Monitoring Centre (UMC), which is headquartered in Sweden. According to the findings of several studies, adverse drug reactions account for around 6.2 percent of hospital admissions, and approximately 3.2 percent of these reactions take place while the patient is still in the hospital. [6] The possibility of ADRs results in a significant strain being placed on the economy of the nation as well as a decline in people's quality of life [6]. Our nation's people are genetically and culturally very different from one another, which has resulted in a vast demographic diversity.

The primary objective of this study is to assess the knowledge, attitude and awareness of adverse drug reaction reporting process among Indian medical undergraduates in a tertiary care teaching hospital.

Material and Methods

This is a cross sectional questionnaire based study on 250 Indian medical graduates. Phase III – Part 1 and Part 2 Medical Undergraduates at Trichy SRM Medical College Hospital & Research Centre for next 3 months were included. The students were informed in person with participant information sheet during PHASE 3 clinical posting. Those students who did not gave informed consent for participation in the study were excluded.

Meher *et al.* [7] conducted a similar questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance among undergraduate medical students in a Tertiary Care Teaching Hospital of South India. The questionnaire was sent to the participants only after explaining the purpose of the study using participant information sheet and obtaining informed consent. A pre-validated semi-structured questionnaire were distributed to the Gmail Id of participants using Google Forms. Appropriate instruction for filling were also given in the form along with fields for filling demographic characteristics.

Statistical analysis: Data from the submitted questionnaire were coded and entered into Statistical Package for Social Sciences (SPSS) version 16 software for analysis. Information were expresses as counts, percentages and mean. Unpaired T-test to compare phase III part 1 and part 2 students in the tertiary care teaching hospital.

Results

About 250 Indian medical graduates from Phase III – Part 1 and Part 2 Medical Undergraduates at Trichy SRM Medical College Hospital & Research Centre were included. The mean age of the study participants was 20.12±1.3 years. There was male preponderance with 52% male medical graduates and 48% female medical graduates (Figure 1). Majority of the included subjects were in Phase III Part 1. Table 1 describe the distribution of knowledge related questions.

Around 70% correctly answered the definition of pharmacovigilance, 40% answered about important purpose of pharmacovigilance, 48% on healthcare professionals are responsible for reporting ADRs, 61% on organization conducting National Pharmacovigilance Program in India, 40% on regulatory body responsible for monitoring pharmaceuticals and medical devices, 42% answered correctly on location of international centre for adverse drug reaction monitoring.

In this study only 28% knew ADR to be reported in HCP form version 1.4, 68% knew where Adverse Drug Events were related to, 47% had knew in how many days serious adverse drug reaction should be reported and 75% know that ADR Monitoring Centre was located at their Institute (Table 2). The distribution of knowledge and attitude for comparison between phase 3 Part I and part 2 students in Figure 2 and Figure 3.

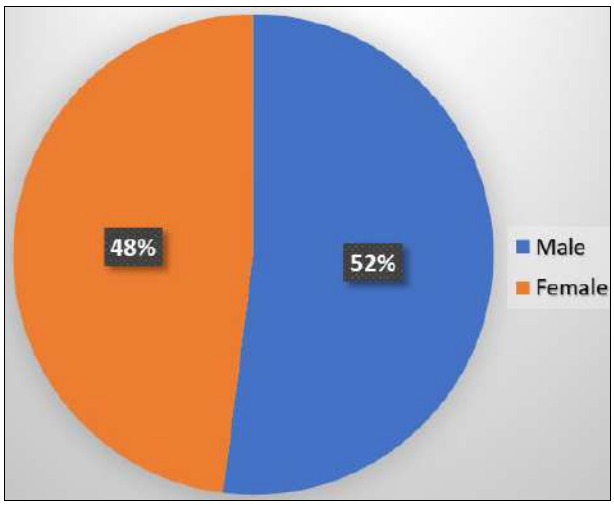

Fig 1: Distribution of gender among the study participants (N=250)

Table 1: Distribution of knowledge related questions on pharmacovigilance (N=250)

S. No	Variable	Correct response N (%)	Incorrect response N (%)
1	Definition of pharmacovigilance	175 (70)	75 (30)
2	The most important purpose of pharmacovigilance	100 (40)	150 (60)
3	The healthcare professionals are responsible for reporting ADRs	120 (48)	130 (52)
4	Organization conducting National Pharmacovigilance Program in India	153 (61)	97 (39)
5	Regulatory body responsible for monitoring pharmaceuticals and medical devices	100 (40)	150 (60)
6	Location of international centre for adverse drug reaction monitoring	105 (42)	145 (58)
7	ADR reported in HCP form version 1.4	70 (28)	180 (72)

8	Adverse Drug Event related to	163 (68)	87 (32)
9	Serious adverse drug reaction reported in how many days	118 (47)	132 (53)
10	ADR Monitoring Centre located in your Institute	188 (75)	62 (25)

Among the study participants 70% had ADR reporting benefited patients and Health Care Professionals, 63% agreed to ADR reporting to be included under 2nd year MBBS practical examination, 54% agreed to professional obligation of all HCP, 47% agreed to Phase 3 MBBS students can play a role in creating ADR reporting awareness, 62% agreed to ADR management during clinical posting has relevance to medical students, 57% agreed to drug history being significant part in clinical history, 60% agreed to treatment of ADR increases the financial burden of the patients in health system, 46% agreed to ADR can be reduced by medication error audit by Pharmacology Department, 45% agreed to ADR monitoring centre being necessary in every medical college and 69% agreed to Pharmacovigilance should be taught to all Healthcare Professionals.

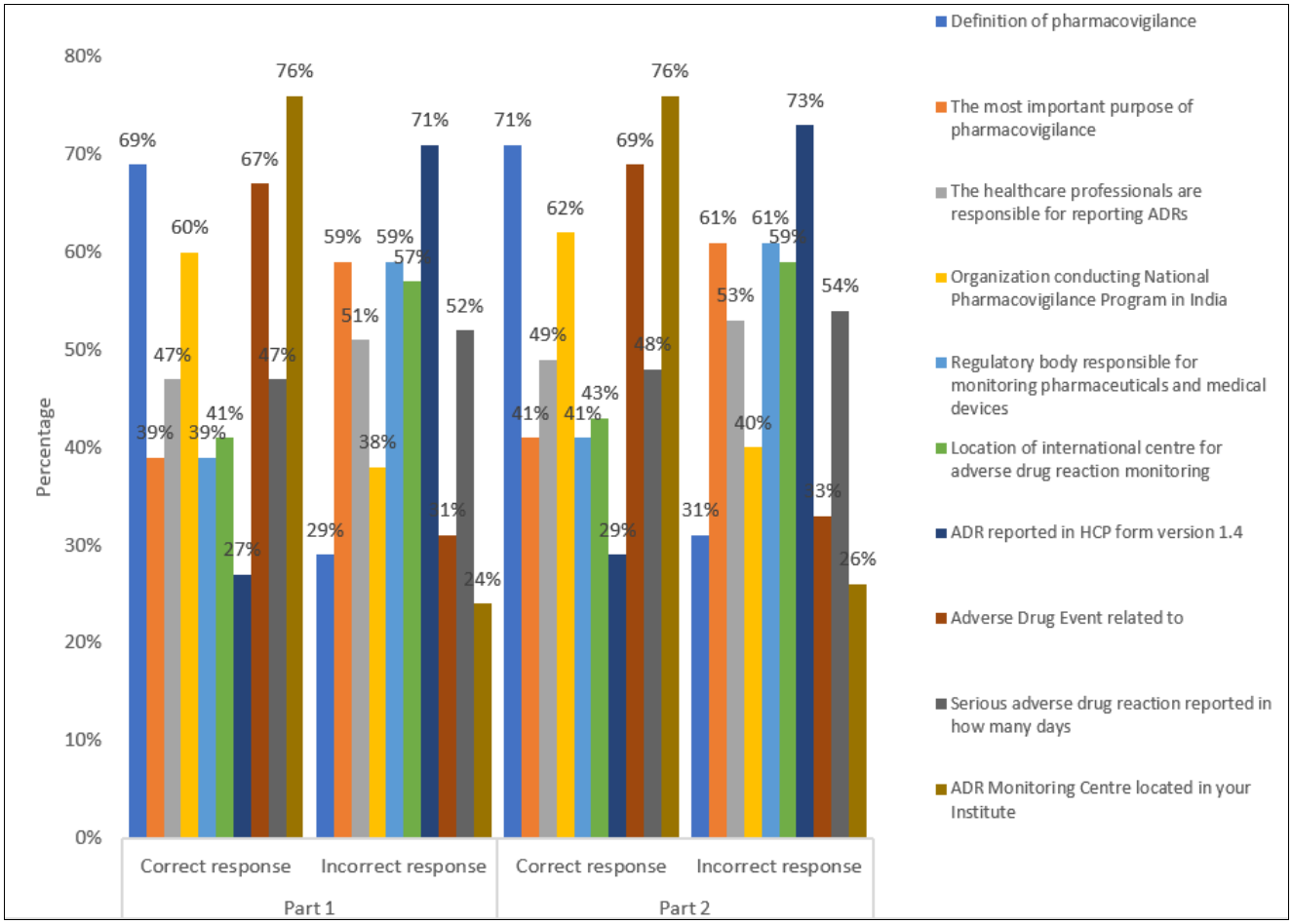

Fig 2: Distribution of knowledge related questions between part 1 and part 2 students (N=250)

Table 2: Distribution of perception related questions on pharmacovigilance (N=250)

S. No	Variable	Agree N (%)	Undecided	Disagree N (%)
1	ADR reporting benefited patients and Health Care Professionals	175 (70)	12 (5)	63 (25)
2	ADR reporting to be included under 2nd year MBBS practical examination	158 (63)	40 (16)	52 (21)
3	Professional obligation of all HCP	135 (54)	55 (22)	60 (24)
4	Phase 3 MBBS students can play a role in creating ADR reporting awareness	118 (47)	83 (33)	49 (20)
5	ADR management during clinical posting has relevance to medical students	155 (62)	20 (8)	75 (30)
6	Drug history is a significant part in clinical history	143 (57)	50 (20)	57 (23)
7	Treatment of ADR increases the financial burden of the patients in health system	150 (60)	50 (20)	50 (20)
8	ADR can be reduced by medication error audit by Pharmacology Department	115 (46)	50 (20)	85 (34)
9	ADR monitoring centre is necessary in every medical college	113 (45)	50 (20)	88 (35)
10	Pharmacovigilance should be taught to all Healthcare Professionals	173 (69)	25 (10)	52 (21)

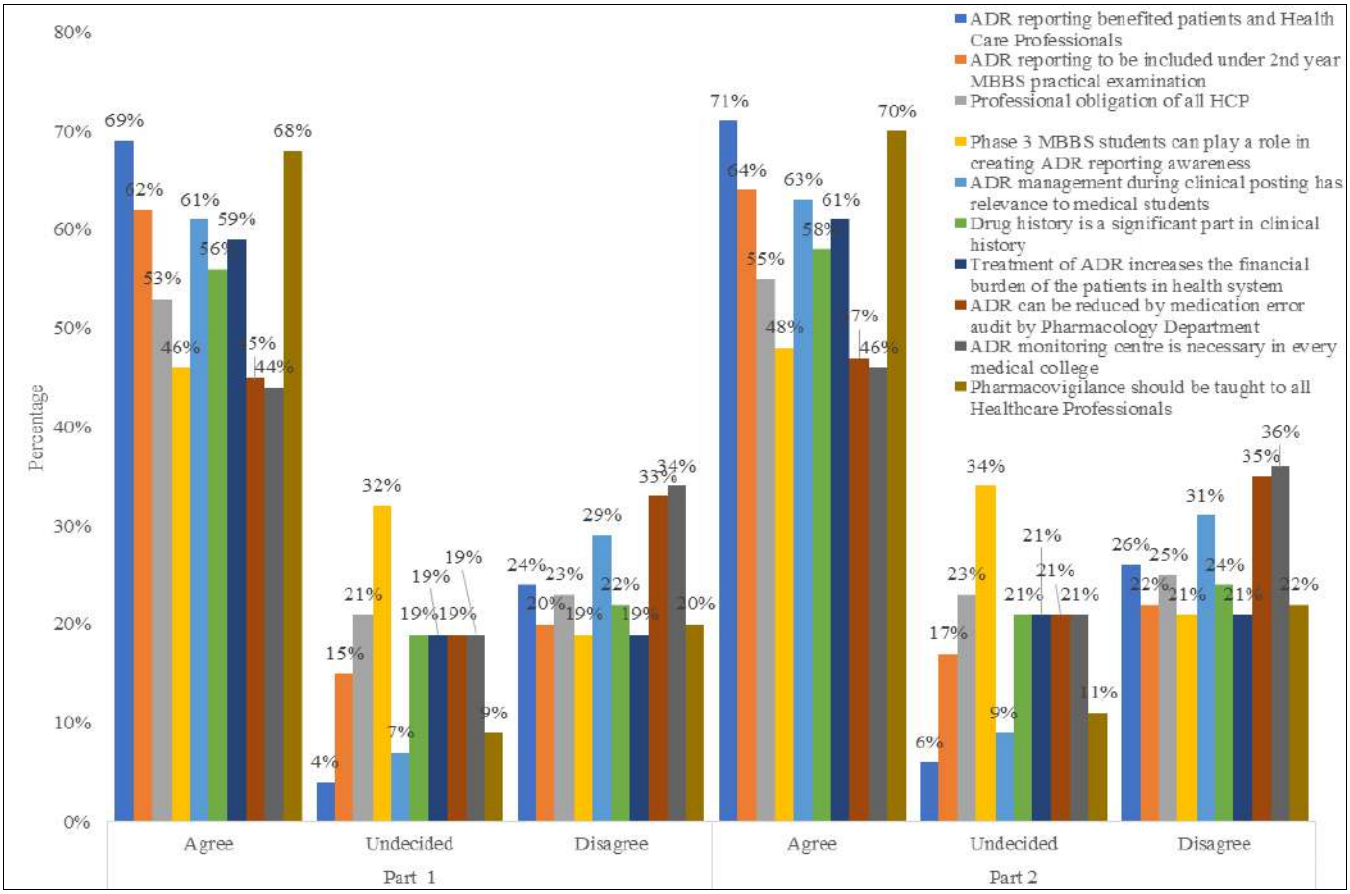

Fig 3: Distribution of perception related questions between part 1 and part 2 students (N=250)

Discussion

This study seeks to evaluate the levels of knowledge and pharmacovigilance practised by Indian medical graduates with regard to adverse drug reactions (ADRs). In India, the primary source of information used for drug safety surveillance is a system that relies on voluntary reporting. There are a variety of studies conducted to evaluate the KAP of pharmacovigilance among health care professionals (HCPs), but there are relatively fewer studies conducted among undergraduates [8].

In our study the mean age of the study participants was 20.12±1.3 years. There was male preponderance with 52% male medical graduates and 48% female medical graduates. In a study

by Meher *et al.* [7] the results of the survey showed that among the respondents, 61.67 percent of second-year students got the definition of ADR right, whereas 80 percent of final-year students and pre-final-year students got it right (P <0.05). 56.67 percent of students in their second year were aware of the location of the National Pharmacovigilance Center, compared to 41.67 percent of students in their final year and 55 percent of students in their prefinal year. Forty percent, forty-four percent, and thirty-eight percent of final, prefinal, and second-year students, respectively, were aware of who can report ADR.

The understanding of pharmacovigilance among undergraduates is highly important given that they are in personal touch with all occurrences that occur after the administration of medications. Almost one hundred percent of postgraduate students were aware of the existence of the Pv branch, ADR, and the significance of their roles. In our study around 70% correctly answered the definition of pharmacovigilance, 40% answered about important purpose of pharmacovigilance, 48% on healthcare professionals are responsible for reporting ADRs, 61% on organization conducting National Pharmacovigilance Program in India, 40% on regulatory body responsible for monitoring pharmaceuticals and medical devices, 42% answered correctly on location of international centre for adverse drug reaction monitoring.

In this study only 28% knew ADR to be reported in HCP form version 1.4, 68% knew where Adverse Drug Events were related to, 47% had knew in how many days serious adverse drug reaction should be reported and 75% know that ADR Monitoring Centre was located at their Institute.

In a study by Meher *et al.* [7] there was statistically significant difference in the mean score between the three groups when it comes to knowledge and attitude, but not when it comes to practise. They have a more positive attitude, however their understanding and practise in regards to pharmacovigilance are lacking. In a study by Rani *et al*, seventy percent of people who responded were aware of the precise meaning of the term "adverse incident." Approximately 52 percent of post-graduates were aware of what had to be disclosed in the ADR reporting form and took the necessary precautions. A total of 49 percent of respondents were aware that there is a regulatory body that monitors ADRs. Post-graduates made up only 12–20 percent of the population that was aware of post-marketing surveillance.[9] Knowledge of pharmacovigilance among undergraduates has been shown to be lower than expected, which indicates a relative fall. Respondents' attitudes were positive, as evidenced by the fact that one hundred percent of graduates believe that reporting adverse drug reactions is necessary in order to lessen the impact of ADRs on society for a variety of reasons. When it comes to undergraduate students, the practise of pharmacovigilance activities is hampered primarily by a lack of comprehensive knowledge

of ADR reporting, which is followed by the difficulty of deciding whether or not an ADR has happened. Lack of understanding and indifference to reporting are the primary factors contributing to the problem of under-reporting. [10] The minor causes of underreporting include things like a shortage of time and inadequate compensation. It is possible to reduce the amount of information that is not reported by establishing additional adverse event monitoring centres (AMCs), facilitating communication between registrars and pharmacovigilance centres, simplifying documents, providing assistance via a toll-free number, simplifying registration forms, and providing financial incentives [11, 12]. The notification rates of problems related to medicine would all improve if all of these measures were carried out. In order to raise people's levels of knowledge regarding the reporting of ADRs, there is a need for educational and training efforts. The health care workers who are employed at tertiary care hospitals should periodically participate in educational and interventional programmes, as well as sensitization programmes, in order to reduce the number of barriers that contribute to under-reporting [13-16].

Limitations

The sensitization activities did not achieve the level of success that was anticipated. It's possible that this is one of the reasons why undergraduate students have less knowledge. Only a few of the undergraduates did not respond to the questionnaire with the proper level of detail. These were the most significant challenges that arose throughout the course of the investigation.

Conclusion

These students are required to participate in ongoing medical education that focuses on the requirements associated with pharmacovigilance. The results of this study provide baseline information on the knowledge and attitude necessary for providing educational intervention.

Conflict of Interest

Not available

Financial Support

Not available

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