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A Questionnaire-Based Study to Evaluate the Basic Understanding of Pharmacovigilance of the Under Graduate Medical Students of a Rural Teaching Hospital

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Abstract

Introduction: Adverse Drug Reactions (ADRs) have presently been greatly contributing to the hospital admissions, prolongation of the hospital stays, visits to the emergency departments, in turn, contributing to the economic burden of healthcare management. Pharmacovigilance is predominantly concerned with ADRs, and drug safety. The basic understanding about pharmacovigilance is essential for future medical professionals as they will come in contact with the patients and can efficiently report the ADRs.

Aim: To evaluate the basic understanding about pharmacovigilance and create awareness in medical students of a rural teaching hospital.

Materials & Methods: This was a non-interventional questionnaire-based study, where medical students from a rural teaching hospital were included in the study. They were distributed a simple questionnaire related to pharmacovigilance basic knowledge, through google form link, which they had submitted. The data was analysed.

Results: Total 92 participants were included in the study. It was found that, 57.8% of these were female and 42.2% were males. Moreover, regarding assessing the basic pharmacovigilance knowledge it was reported that 98.9% were aware about healthcare professionals who can report ADR. Nearly 83.5% were aware about pharmacovigilance. Nearly 70% of the participants had not heard about pharmacovigilance before joining pharmacology lectures. Majority of the participants had never attended any seminar/workshops and agreed to attend in future.

Conclusion: The results indicate that the basic understanding about pharmacovigilance is improving and medical student shows interest about creating awareness related to pharmacovigilance, as it is an important aspect of drug safety. However, to further improve their understanding awareness programs for medical student can be conducted.

***Keywords**: Adverse Drug Reactions, CDSCO, MBBS students, Medical under graduates, Pharmacovigilance, WHO*

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Introduction

Paracelsus stated that, all substances (drugs) are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy[1].The safety and efficacy of the drugs used in the treatment of various clinical conditions in any individual remains complex and multifactorial and difficult to analyse or identify the suspected drug that causes the Adverse Drug Reaction

(ADR). Adverse effects usually predict hazard from future administration and warrant prevention, or specific treatment, or alteration of the dosage regimen, or withdrawal of the product[2]. Continuous monitoring of drug effects, side effects, contraindications and outright harmful effects which could result in a high degree of morbidity, and in some cases, even mortality, are essential to maximize benefits and minimize risks[2,3]. As mentioned by WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden WHO promotes pharmacovigilance at the country level[4]. The Central Drugs Standard Control Organisation (CDSCO), New Delhi, has started a National Pharmacovigilance Programme[5].

Therefore, looking to the above facts, it is important to safeguard patient safety and must be applied at all healthcare establishments. However, deficiency of awareness, training, and underreporting of Adverse Drug Reactions (ADRs) are the major difficulties in the successful application of Pharmacovigilance (PV) programmes[6,7].

Adverse drug reactions (ADRs) have presently been greatly contributing to the hospital admissions, prolongation of the hospital stay, visits to the emergency departments, in turn, contributing to the economic burden of healthcare management. Studies have shown that 4.2% - 30 % of the hospital admissions, in U.S.A.; occur due to the ADRs[8]. The ADRs that occur, affect the individuals irrespective of their age, gender, weight, race, or ethnicity. This is evident with several epidemiological studies conducted across the world which show that 2.1% - 5.2% of the ADRs have been observed to occur in children contributing to their hospital admissions, of which 39% of the ADRs were considered to be life-threatening or fatal while 10-20 % of the ADRs occurred among the geriatric patients, while 11.4% - 35.5% of the visit to emergency department have been related to the ADRs[9-12]. It has also been observed that 32%-65% of the ADRs were found occurred in geriatric cases admitted to the nursing homes[13]. Thus, the ADRs greatly contribute to the economic burden in healthcare management as the treatment of ADRs is more costly then treatment of the diseased condition. Although, the investigation of the expenditures on the adverse drug events (ADEs) is less, the implications of research makes it clear that the ADRs cause injury to the patients with a disproportionate increase in the expenses to treat these injuries[14]. Moreover, for certain conditions or disease either for the prevention nor for the treatment, there have been no drugs or vaccines proven to be effective and molecules are being investigated and developed as potential therapies or as adjuvant therapies[15] therefore there is need for pharmacovigilance.

Therefore, it is known that pharmacovigilance is predominantly concerned with ADRs, and drug safety. The basic understanding about pharmacovigilance is essential for future medical professionals as they will come in contact with the patients and can efficiently report the ADRs. Hence, the present study was aimed to evaluate the basic understanding about pharmacovigilance and create awareness in medical students of a rural teaching hospital.

Materials & Methods

The present observational (non-interventional) questionnaire-based study was conducted over a period of one month at S. B. K. S. Med. Inst. & Res. Centre, Sumandeep Vidyapeeth An institution deemed-to be University; the study was conducted amongst MBBS students. The required permission was obtained. The required consent for participation for the study was obtained from the under graduate students of MBBS. The participants were 92 undergraduate medical students of S. B. K. S. Med. Inst. & Res. Centre, Sumandeep Vidyapeeth An institution deemed-to be University; they were enrolled in the study. A total of 92 questionnaires were shared through google form link (total *n=92*) which included total 20 questions based on earlier study and other sources[2,5,6,7]. The questionnaires were based on answering from options or as short answers related to the pharmacovigilance basic understanding amongst undergraduate medical (MBBS) students. Data collected was further entered in Microsoft excel sheet and were further analysed.

Inclusion criteria: Medical undergraduates from S. B. K. S. Med. Inst. & Res. Centre were included in the study.

Those participants who gave consent.

Exclusion criteria: Students not willing to participate in the study or not willing to give consent.

Results and Discussion

The results were evaluated based on the detail questionnaire and its analysis done. The results were grouped as medical students' knowledge, and basic understanding on pharmacovigilance as shown in **Table no 1.**

Among the total of 92 participants (n=92) who participated in this present research study; 57.8% of these were female and 42.2% were males. The significant outcome was, 98.9% were aware about healthcare professionals who can report ADR. 83.5% were aware about pharmacovigilance. Majority of them, 96.7% had heard about clinical trials earlier, however only 69% knew about pharmacovigilance is in which phase of clinical trial. Almost all, 98.9% knew about suspected ADR reporting form. 94.5 % have heard about PvPI. Nearly 70% of the participants had not heard about pharmacovigilance before joining pharmacology lectures. Majority of the participants had never attended any seminar/workshops and agreed to attend in future. Also, nearly all MBBS students 96.7% were aware about the terminology ADR. The details are listed in **table no 1.**

Table no. 1: Questionnaire to access UG students' knowledge regarding pharmacovigilance basic understanding (n=92):

Q. no.	Questionnaire2,5,6,7 (in brief)	Response (Yes/No) from participants n=92 (%)
Q. 1	Healthcare professional includes dentists, physicians & pharmacists.	98.9 (Yes)
Q. 2	Pharmacovigilance is about drug safety.	83.5 (Yes)
Q. 3	Heard about "clinical trials" earlier.	96.7 (Yes)
Q. 4	Pharmacovigilance comes under Fourth phase of clinical trials.	69 (Yes)
Q. 5	Aware about Suspected ADR reporting form/white form.	98.9 (Yes)
Q. 6	Knows about of pharmacovigilance programme in India.	94.5 (Yes)
Q. 7	Agree that ADRs might result in hospital admission, prolonged hospitalization or might lead to permanent disability or even death.	91.1 (Yes)
Q. 8	Knows the terminology ADR.	96.7 (Yes)
Q. 9	Know about which kind of ADR/s need to be reported.	89 (Yes)
Q. 10	Had NOT heard about terminology "Pharmacovigilance" before joining Pharmacology Lectures.	70 (Reply No)
Q. 11	Knows the full form of ADR.	89 (Yes)
Q. 12	Knows that adverse event and adverse effect are different and knows the difference.	69 (Yes)
Q. 13	Agreed that they have ever filled any ADR form. During Pharmacology practical.	86 (Yes)
Q. 14	Will motivate any of the healthcare providers to fill ADR form.	79 (Yes)
Q. 15	Aware of any ADR monitoring centre in our institution where you can submit the filled ADR form and its location.	76 (Yes)
Q. 16	Gave any suggestions to improve ADR reporting.	55 (Yes)
Q. 17	They had NEVER attended any workshop/seminar/training programme related to pharmacovigilance.	77.3 (Reply No)
Q. 18	Interested in attending any seminar/training programme related to pharmacovigilance	31.1 (Yes)
Q. 19	Knows different Types of ADR.	72 (Yes)
Q. 20	Knows about PvPI.	70 (Yes)

Out of total 92 participants, 90 number of participants had responded which is depicted in below mentioned **Table no. 2**. Gender ration was calculated, which shows the percentage distribution of male and female participants in **Table no. 2.**

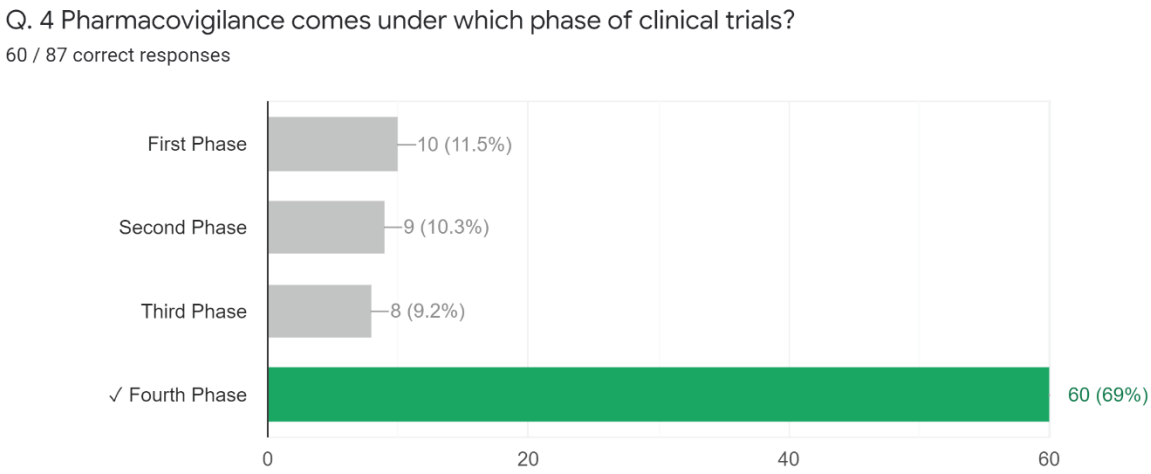
Table no. 2: Assessment of gender ratio of the participants:

Gender Ratio (n= 90)		**%**
Female Participants =	52	57.8
Male Participants =	38	42.2
Total MBBS UG students who responded	90	100%

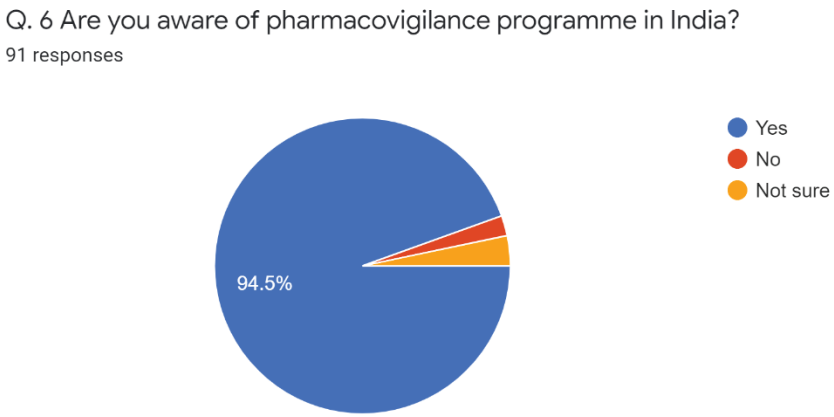
The detailed distribution of each question is depicted in **Table no. 1** and some significant distribution is depicted in **Figure no. 1 (a -d)** as mentioned below.

Figure no. 1: Distribution of percentage to access UG students' knowledge based on questionnaire regarding pharmacovigilance basic understanding:

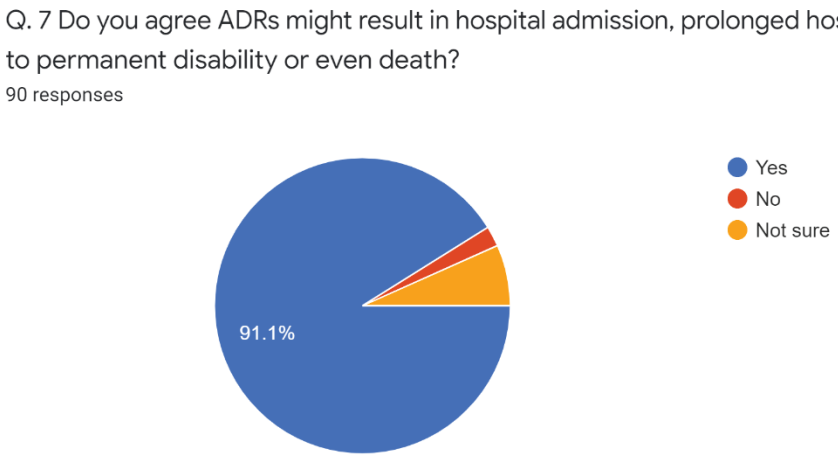
(a) Pharmacovigilance comes under Fourth phase of clinical trials.



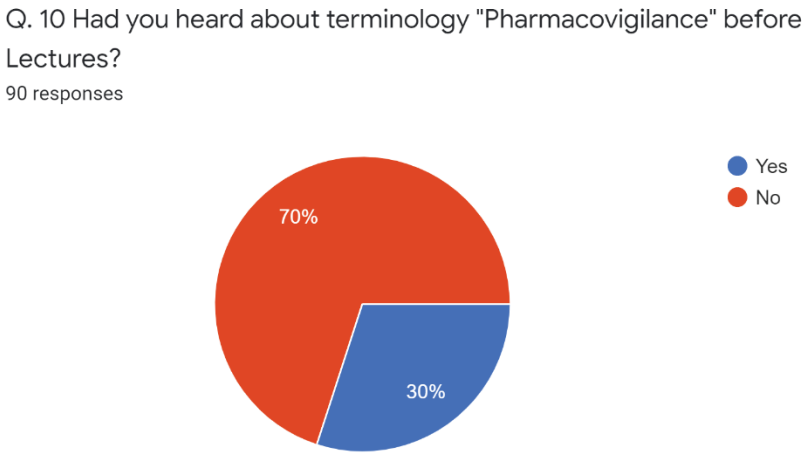
(b) Knows about of pharmacovigilance programme in India.



(c) Agree that ADRs might result in hospital admission, prolonged hospitalization or might lead to permanent disability or even death.



(d) Had heard about terminology "Pharmacovigilance" before joining Pharmacology Lectures.



The present study provides an important insight regarding the knowledge, about basic understanding on pharmacovigilance undergraduate future clinicians. Almost all the MBBS students has the basic knowledge, however, it is very essential to sensitize the undergraduate students on the importance of Pharmacovigilance program of India, and also regarding Post marketing surveillance Phase.

Hence, this will help us to learn the design and will help us to narrow down the distance between academic knowledge among future clinicians and clinical practice. Majority of the students have given suggestions so as to improve ADR reporting and though majority of them have not attended and seminar/workshop, they are interested in attending such programs.

Conclusion

The results indicate that the basic understanding about pharmacovigilance is improving amongst MBBS students. Also, medical students show interest about creating awareness related to pharmacovigilance, as it is an important aspect of drug safety. However, to further improve their understanding and to sensitize them, awareness programs for medical student can be conducted.

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Competing interests: NIL.

Ethical clearance: As the present study is based on google form link questionnaire online method and does not involve any risk to humans, the consent from the participants is taken and their identity is not disclosed.

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