

Impact of educational intervention on awareness of pharmacovigilance among medical undergraduates in Karnataka, India: a cross-sectional study

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ABSTRACT

Background: India being a part of national pharmacovigilance program (NPP), its contribution to UMC (Uppsala monitoring centre) is very little and pharmacovigilance program of India (PvPI) is still in its infancy. Lack of vibrant reporting culture necessitates bringing the awareness and importance of it. Objective of this study was to assess the level of knowledge, awareness, and the method of application of pharmacovigilance (PV) and to evaluate the impact of an educational intervention among second year medical students for improving awareness of pharmacovigilance.

Methods: This was a cross-sectional questionnaire based study conducted among 146 students in a tertiary care teaching hospital in B.G. Nagara, Mandya, Karnataka, India. Purpose of the study was explained to all the participants. Pretest questionnaires were distributed and filled questionnaires were collected following the educational intervention through continued medical education (CME), same questionnaire was given as post-test questionnaire. Both the test results were analysed to know the educational impact.

Results: Out of 146, a total 130 medical students were involved in pre and post-test questionnaire. The overall response rates between pre and post intervention had improved in majority of the medical undergraduates which brings out the effectiveness of intervention for improving the reporting system.

Conclusions: Educational intervention was more effective in improving student's knowledge, awareness and applications of pharmacovigilance. Early sensitization through educational interventions in II phase of MBBS itself enhances the reporting frequency in future through their active participation & emphasizing the need to design the suitable strategies to develop vibrant as well as voluntary reporting culture.

Keywords: Pharmacovigilance, Educational intervention, Impact, Awareness

INTRODUCTION

WHO defines Pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem”.¹

The world health organization (WHO) defines an ADR as “a response to a drug which is harmful and unintended, and which occurs at doses normally used in man for the

prophylaxis, diagnosis, or therapy of disease or for the modification of body functions”.²

Adverse drug reactions (ADRs) are one of the leading causes of morbidity and mortality. Previous studies have revealed that around 2.9-5.6% of all hospital admissions are due to ADRs and as many as 35% of hospitalized individuals experience an ADR during their period of hospitalization.³

It is as well a financial burden on health care system due to prolonging the hospital stay and augments the expenditure of the cure.⁴

The pharmacovigilance programme in India (PvPI) started in the year 2010 with a mission to safeguard the health of the Indian population by ensuring that the benefit of using medicine outweighs the risks associated with its use. In spite of the best efforts, still the reporting of serious ADRs rarely exceeds 10%.^{5,6}

Although, India is one of participating in national pharmacovigilance program, but its contribution to UMC database is very little. Now a days, participation is increased but not up to mark, due to the absence of a vibrant ADR monitoring system and also lack of a reporting culture among health care professional in India.⁶

In spite of the limitations spontaneous reporting is the backbone of pharmacovigilance and provides valuable information regarding safety of a drug.

The backbone of pharmacovigilance programme lies in active and voluntary participation in spontaneous adverse drug reaction reporting. The existence of under reporting system necessitates the bringing of awareness among the young generation.

Therefore, the study was planned to evaluate the awareness towards pharmacovigilance and ADRs reporting system through educational intervention because undergraduate students are the future doctors where they can observe and cultivate the reporting behaviour so that they can contribute to the patient safety across the world.

The objective of this study was to assess the awareness, method of applications related to pharmacovigilance among MBBS students before and after educational interventions and to know the impact of educational intervention in enhancing pharmacovigilance knowledge.

METHODS

This study was conducted at Adichunchanagiri institute of medical sciences (AIMS) B.G. Nagara, Mandya, Karnataka, India

Study design

The study was a cross-sectional, questionnaire based study.

Study population

146 second year medical undergraduates were involved in the study. Participants involved were in IIIrd term.

Ethical clearance was taken from the Institutional Ethics Committee (IEC) of AIMS, B.G. Nagara, Karnataka, India

Data collection

A closed ended validated questionnaire containing 15 questions with two to four options was given to all the participants. The questionnaire consisted of information about knowledge, attitude and application aspects of ADR reporting system. All underwent an educational intervention on pharmacovigilance, continued medical education by department of pharmacology during December 2015. The participants were given the same questionnaire as post-test. The impact of effectiveness of it among students was evaluated by analysing the results obtained from pre and post-test.

Statistical analysis

Fully completed data were analysed expressed in percentages (%) using Microsoft Excel software.

RESULTS

Out of 146 students 3rd term students, 130 students voluntarily participated and gave completed answers to the pre and post intervention questionnaire. Response rate was 89.04 %.

Table 1: Awareness.

Awareness (n=130)	Correct pre educational intervention response (%)	Correct post educational intervention response (%)	% of response improved by intervention.
Definition	64.62	80	15.38
Mandatory	93.08	93.85	0.77
Most common ADR	54.62	72.31	17.69
Related products for reporting	54.62	59.23	4.61
Disaster which led to modern PV	24.64	63.85	39.21

Table 2: Knowledge.

Knowledge (n=130)	Correct pre educational intervention response (%)	Correct post educational intervention response (%)	% of response improved by intervention.
Reporting centers	21.54	39.23	17.69
Inauguration year	29.23	41.54	12.31
Responsibility in clinical trial	58.46	75.38	16.92
National pharmacovigilance program centre	32.31	51.54	19.23
CDSCO South sub zonal located at	51.54	57.69	6.15
Uppsala located at	27.69	85.38	57.69

Table 3: Method of applications.

Method of applications (n=130)	Correct pre educational intervention response (%)	Correct post educational intervention response (%)	% of response improved by intervention.
Who can report	61.54	76.92	15.38
Reporting centre sequence	36.92	43.08	6.16
Causality assessment	30.77	50	19.23
Red card system	20.77	53.85	33.08
Mandatory elements	61.54	78.46	16.92
Dechallenge	31.54	43.08	11.54
Reporting common ADR	73.85	76.92	3.07
Online reporting system	30	57.69	27.69
ADR synonymous to adverse event (AE)	47.70	73.85	26.15

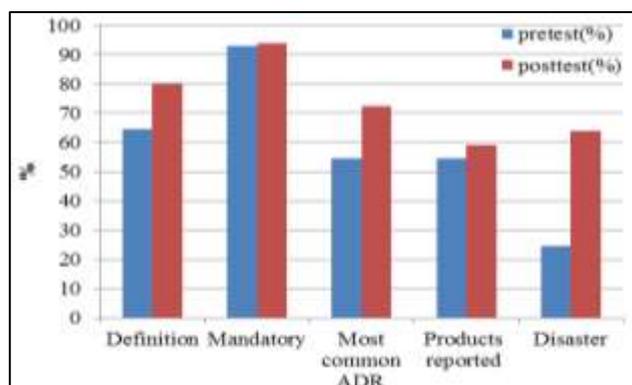


Figure 1: Awareness.

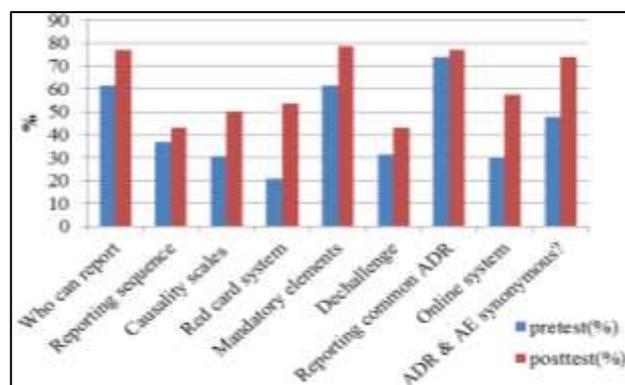


Figure 3: Methods of applications.

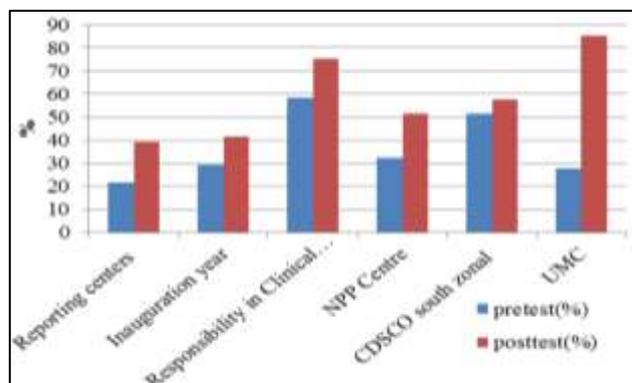


Figure 2: Knowledge.

There was an overall improvement in all the three aspects i.e. Awareness, knowledge and its applications.

Results were significant with respect to, Uppsala monitoring centre (57.69% improvement) disaster which led to modern PV (39.21% improvement), red card system (33.08% improvement), system for online reporting (27.69% improvement), difference between ADR and adverse event (26.15% improvement). Apart from this they also showed improvement towards definition (15.38%), most common ADR (17.69%), trial responsibilities (16.92), NPP centre (19.23%). Reporting nature i.e. regarding the personals who can report (15.38%), scales for assessment (19.23%) and mandatory elements to be filled (16.92%).

DISCUSSION

MCI (medical council of India) recommends including pharmacovigilance and ADR reporting curriculum to second year medical undergraduate, so that they acquire basic structural and functional concepts.⁷

Our study result shows that, overall knowledge after the educational intervention was fairly good and improved a lot when compared to pre interventional results. Our undergraduates were aware of national and international pharmacovigilance centre for reporting ADRs, its causality assessment, reporting system involved from peripheral monitoring centre until it reaches the Uppsala monitoring centre. Professionals involved and the adverse reaction from various products that needs to be reported in creating a very active and vibrant voluntary reporting culture through continuous everlasting encouragement to the all health care professionals, so that we can have our nations own data base for the safety of mankind and for their welfare.

Pharmacovigilance programme plays a very vital role in detection of ADRs and banning of several drugs which otherwise may prove fatal consequences in future.⁸

The present study results were in par with the study done by Joseph et al in which there was improvement in terms of knowledge and awareness of pharmacovigilance among medical undergraduate students.⁹

Our study goes hand in hand with the results of the study done by Sanghavi et al, Hardeep et al, Manuela Tabali et al in which intervention improved knowledge of the participants about ADR reporting system.¹⁰⁻¹² All these study demonstrated that an educational intervention could increase the awareness on ADRs among practitioners and they could incorporate the knowledge gained from training into their everyday clinical practice for the success of PvPI.

Response of students in our study group regarding ADR monitoring showed that educational intervention has improved their knowledge towards practice of reporting ADRs.

The limitations of this study was small sample size and study results cannot be generalized as it was conducted in single centre; hence there is a need to conduct more multi-centric studies among undergraduate medical students including all the allied health care personals.

CONCLUSION

Our study strongly suggests that there is a urgency of creating awareness among the medical students to improve the reporting culture of ADRs. Time to time continued medical education (CME) programs, symposium regarding spontaneous reporting of adverse drug reactions and training sessions, must clarify the roles

various healthcare professionals including medical undergraduate, a future budding doctors in pharmacovigilance. Pharmacovigilance programme of India (PvPI) should be made an integral part of medical education in order to improve ADR monitoring and patient care. Thus, it forms a basis for solid foundation about pharmacovigilance programme among students.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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