Pharmacovigilance awareness among the teaching staffs of a medical college in Karnataka: a cross sectional study

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Abstract

Background: Pharmacovigilance deals with adverse drug reactions and required for early detection and prevention of drug-related morbidity and mortality. The objective of the present is to evaluate the Pharmacovigilance awareness among the teaching staffs of a private medical college in Karnataka.

Methodology: A cross sectional, questionnaire based study was conducted in a private medical college of Karnataka. A total of 219 (n=219) medical staffs were participated in this study. Participation in this study was purely on voluntary basis. The questionnaire form was validated by two subject experts prior to the study. A preformed questionnaire form was distributed to all the teaching staffs of medical college and requested them to fill accordingly. All the participants filled the forms completely.

Results: The results were analyzed by using SPS software. Statistical analysis was done by chi square test. Most of the teaching staffs (55.3%) heard about Pharmacovigilance, 69% of teaching staff wants to report adverse reactions, 55% teaching staffs undergone training on reporting of ADR, 40% staff wants to report ADR to pharmaceutical company, 31% of staff knows about Pharmacovigilance work structure in India and 48% of teaching staff knows about classification of ADR. But, only 22% of teaching staff attended Pharmacovigilance training programme and the rest 78% of teaching staff willing to undergo training for Pharmacovigilance.

Conclusion: This study revealed that majority of the teaching staff knows about Pharmacovigilance and wants to know more about the functioning and structure of Pharmacovigilance in India, in order to prevent adverse drug reactions in patients.

Key words: Pharmacovigilance, Adverse drug reactions, Questionnaire form, Cross sectional study, Teaching staff.

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Introduction

Pharmacotherapy is an integral part of treating a disease. Drugs interact with specific enzymes or receptors to promote healthy functioning of body system and cure the illness. Drugs are extensively studied and tested before marketing. However, drugs may cause unexpected and undesirable effects during pharmacotherapy. World Health Organization (WHO) defines an adverse drug reaction (ADR) as "one which is noxious and unintended and which occurs in doses normally used in human for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological functions.[1] In United States, more than 50% of the approved drugs are associated with some type of adverse effects which are not detected prior to approval.[2]

Pharmacovigilance is a branch of pharmacology deals with the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.[3] Pharmacovigilance was launched by WHO in the 1960's after the thalidomide disaster. Many countries including India have established drug monitoring systems for early detection and prevention of drug-related morbidity and mortality.

Incidence of ADR in India was found to be 1.82%.[4] Around 5%-20% of total hospital admissions are due to ADR.[5,6] ADR monitoring and reporting activity in India is still in its infancy stage. Lack of well structured monitoring system and awareness of Pharmacovigilance are the major problems for under reporting of ADR in India. The clinicians are best suited person to detect adverse reactions based on the information collected from their patients or from their own clinical observations. However, due to the lack of interest and time constraint, many untoward adverse drug reactions go unnoticed. Moreover, many physicians are unaware of the procedure to report ADRs. These issues can be addressed by establishing or setting up more number of hospital-based reporting and monitoring and awareness programs that can motivate healthcare professionals. Hence, it is mandatory to create awareness and motivate clinicians about detection, reporting and management of ADR.[4] Previous studies also shown that inadequate knowledge about pharmacovigilance among healthcare professionals is the reason for underreporting of ADR.[7] Therefore, the present was under taken to evaluate the Pharmacovigilance awareness among the teaching staffs of our institution in Karnataka.

Objectives

To evaluate the Pharmacovigilance awareness among the teaching staffs of a private medical college in Karnataka.

Methodology

A cross sectional, questionnaire based study was conducted in Yenepoya Medical College, Mangalore, Karnataka. A total of 219 (n=219) medical staffs were participated in this study. Participation in this study was purely on voluntary basis. The questionnaire form was validated by two subject experts prior to the study. The study was conducted during February-March 2014. The questionnaire had eight questions with Yes or No option. The questionnaire forms were distributed department wise to all the medical teaching staffs and requested them to fill accordingly. Participants were instructed not to reveal their identity in the questionnaire form. Sufficient time of thirty minutes was given to the participants for filling the questionnaire. The questionnaire form was based on previous studies done and slight modification was done to meet the objective of our study. All the participants filled the forms completely. The questionnaire forms were collected and data were entered in Microsoft excel sheet.

Results

All the participants (n=219) completely filled the questionnaire form. Table 1 shows the distribution of study participants according to their specialty, year of experience and gender. Total 94 non-surgical, 47 non-clinical and 78 surgical medical staffs were participated and completely filled the form.

Among the 219 participants, 158 participants were male and remaining 61 were female. Most of the teaching staffs (55.3%) heard about Pharmacovigilance, 69% of teaching staff wants to report adverse reactions, 55% of staff undergone training on reporting of ADR, 40% staff wants to report ADR to pharmaceutical company, 31% of staff knows about Pharmacovigilance work structure in India and 48% of teaching staff knows about classification of ADR. But, only 22% of teaching staff attended Pharmacovigilance training programme and the rest 78% of teaching staff willing to undergo training for Pharmacovigilance (Table 2).

Table 3 shows awareness of study participants according to their specialty. There was significant difference ($p<0.01$) among surgical (79%), medical (47%) and non-clinical teaching staff (27%) with respect to training on reporting of ADR. There was also significant difference ($p<0.01$) among surgical (65%), medical (34%) and non-clinical teaching staff (12%) with respect to reporting ADR to pharmaceutical company. Similarly, statistical significant difference ($p<0.01$) was found among surgical (34%), medical (22%) and non-clinical teaching staff (4%) with respect to pharmacovigilance training. Study also revealed that more of medical staff (84%) willing to undergo training for pharmacovigilance when compared to surgical (80%) and non-clinical teaching staff (61%).

Table 1: Distribution of study participants according to their specialty, experience and sex

Specialty	Experience	Sex		Total
		F	M	
Non-surgical	< 5years	13	49	62
	5-15years	2	19	21
	15-25years	0	7	7
	>25years	1	3	4
	Total	16	78	94
Non-Clinical	< 5years	16	6	22
	5-15years	6	4	10
	15-25years	0	4	4
	>25years	4	7	11
	Total	26	21	47
Surgical	< 5years	13	38	51
	5-15years	1	5	6
	15-25years	2	3	5
	>25years	3	13	16
	Total	19	59	78

Table 2: Awareness of study participants about various aspects of Pharmacovigilance according their gender

Awareness about Pharmacovigilance	Male (N=158)		Female (N=61)		Total (N=219)		'p' value
	No	%	No	%	No.	%	
Heard about Pharmacovigilance	91	57.6	30	49.2	121	55.3	0.262
Report adverse event in patients	118	74.7	33	54.1	151	68.9	0.03
Staff trained on reporting of adverse event	89	56.3	31	50.8	120	54.8	0.463
Report adverse event to pharmaceutical company	74	46.8	15	24.6	89	40.6	0.03
Aware of Pharmacovigilance structure in India	57	36.1	11	18	68	31.1	0.01
Aware of classification of adverse events	79	50	26	42.6	105	47.9	0.327
Undergone training for Pharmacovigilance	46	29.1	4	6.6	50	22.8	< 0.01
Willing to undergo training for Pharmacovigilance	125	79.1	46	75.4	171	78.1	0.553

Table 3: Awareness of study participants about various aspects of Pharmacovigilance according their specialty

Awareness about Pharmacovigilance	Surgical (N=78)		Medical (N=94)		Non-clinical (N=47)		Total (N=219)		'p' value
	No.	%	No.	%	No.	%	No.	%	
Heard about Pharmacovigilance	28	35.9	43	45.7	27	57.4	98	55.3	0.062
Report adverse event in patients	62	79.5	74	78.7	15	31.9	151	68.9	0.058
Staff trained on reporting of adverse event	62	79.5	45	47.9	13	27.7	120	54.8	< 0.01
Report adverse events to pharmaceutical company	51	65.4	32	34	06	12.8	89	40.6	< 0.01
Aware of pharmacovigilance structure in India	27	34.6	31	33	10	21.3	68	31.1	0.256
Aware of classification of adverse events	37	47.4	52	55.3	16	34	105	47.9	0.058
Undergone training for Pharmacovigilance	27	34.6	21	22.3	2	4.3	50	22.8	< 0.01
Willing to undergo training for Pharmacovigilance	63	80.8	79	84	29	61.7	171	78.1	0.008

Discussion

Adverse drug reactions (ADRs) are one of the major causes for morbidity and mortality in general population.[8] The only goal of pharmacovigilance programme is to prevent the negative consequences of pharmacotherapy on the patients. But, lack of awareness about the Pharmacovigilance among physicians may lead to failure to identify the ADR which ultimately cause high morbidity and mortality rates among patients as well as increase in patient care costs.[9]

Main reason for under reporting of ADRs by health care professionals in India is lack of awareness. However, this problem can be addressed by delivering them short and frequent hands on a training session on Pharmacovigilance and also how to fill a standard ADR reporting form in available in PvPI. This may probably improve the quantity as well as the quality of ADR reporting. There are many lot misconceptions about ADR reporting which can also be cleared by conducting training.

Spontaneous reporting by the clinicians can prevent severity of ADR. The paramedical staffs like nurses and pharmacists should be motivated for ADRs reporting, as they are in contact with the patients for long time and can make the pharmacovigilance programs more successful. In India, Central Drugs Standard Control Organization (CDSCO) maintains the ADR database which will be shared with Uppsala Monitoring Centre (UMC, WHO) in Sweden.[10]

In this study most of the medical teaching faculty (55.3%) heard about Pharmacovigilance and wants to report ADRs (69%). These findings are similar to the previous studies conducted by Khan SA et al.[11] Majority of our teaching staff (78%) suggested for Pharmacovigilance training programme for spontaneous reporting of ADR, this finding is similar to the previous study done by Manuela Tabali et al.[12] The best way to reinforce Pharmacovigilance knowledge in health professionals is by conducting regular seminars/ workshops, etc in teaching hospitals. In our study, less proportion of teaching staff had ever been trained on reporting ADRs which is similar to the low percentage of training imparted to healthcare professionals in previously reported study by Remesh A.[13] The major limitation of our study was that we did not include paramedical staffs like pharmacists and nurses who are also in involved in patient care. However, we are planning to include them in the next study.

Conclusion

In conclusion, this study has shown that majority of our teaching staff had good knowledge about Pharmacovigilance and understand the need for reporting. Spontaneity of ADR reporting can be increased by conducting workshops and seminars.

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