ORIGINAL ARTICLE

Knowledge of Pharmacovigilance and Adverse Drug Reaction reporting of Pharmacy and Medical Students

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ABSTRACT

Background: Pharmacovigilance and ADRs reporting is practiced in developed countries regularly but its application in the developing countries is not appropriate due to lack of knowledge, understanding of ADR and its reporting and less positive attitude. Studies have shown that health centers and tertiary hospitals including regulatory authorities or hospital administration are not promoting or efficiently forcing to health professionals for reporting of ADRs timely.

Methodology: A descriptive cross-sectional survey was conducted. The questionnaire was distributed in fourth year and final year classes of MBBS and pharmacy professions. Wrong answer coded with "0" and correct answer coded with "1".

Results: 133 students of MBBS fourth year, 77 students of MBBS final year, 66 pharmacy students from fourth year class and 57 pharmacy students from final year class. Most of the p-values are significant which represents that students of each class have their own perception may be different from others. Low percentage was seen towards pharmacovigilance and ADRs reporting and attitude.

Conclusion: Overall poor knowledge towards pharmacovigilance and ADRs reporting was noticed but fourth year students and final year students of MBBS have poor knowledge and awareness comparatively to fourth year pharmacy and final year pharmacy students respectively.

Key words: Pharmacovigilance, Adverse Drug Reactions Reporting, comparison, pharmacy, medical

INTRODUCTION

Pharmacovigilance and ADRs reporting are practiced regularly in developed countries as compared to developing countries. Pharmacy students as compared to medical students generally have better knowledge of pharmacovigilance and awareness of its practices in medicine in terms of reporting the adverse drug reaction. As all healthcare professionals are responsible to report ADRs for reinforcing the pharmacovigilance systems. Recently pharmacy and medical students were compared regarding the reporting of adverse drug reaction (ADR) and found that there are conflicting results about medical and pharmacy student's knowledge of pharmacovigilance and practicing of adverse drug reporting in daily practice. As Sivadasan et al found that both specialties have better knowledge, attitude and awareness level towards pharmacovigilance and ADR reporting[1], but other group found that pharmacist have good knowledge of ADRs reporting as compared to physicians, nurses and pharma technicians[2] .

The attitude towards learning of pharmacovigilance and adverse drug reporting among the students of both pharmacy and medicine have been found encouraging and they felt the need for improvement in the syllabus and continuous educational strategies for learning of pharmacovigilance and adverse drug reporting[3,4]

Many health professionals do not know where to report the ADRs this is due to lack of knowledge, awareness and attitude of ADRs reporting and pharmacovigilance[5].

We planned to conduct a survey to assess the knowledge and attitude about pharmacovigilance and ADR and ADR reporting among both pharmacy and medical students in our setting so that we can improve its application in our country.

The objective of the were to compare knowledge regarding Pharmacovigilance and Adverse Drug Reaction Reporting between Pharmacy and Medical students and to assess which group of students, have better knowledge regarding Pharmacovigilance and Adverse Drug Reaction Reporting

METHODOLOGY

A descriptive survey study based on cross-sectional survey using well-structured questionnaire was conducted. This study information was collected from fourth and final year pharmacy students from Lahore College of Pharmaceutical Sciences and medical students of Avicenna Medical College Lahore respectively. Ethical aspects in questionnaire were investigated by Institutional Review Board (IRB) before collection of data. Pre-validated questionnaire was filled by students after signing the informed consent and the language of questionnaire was English.200 medical students filled the questionnaire, out of these, there were 133 fourth year medical students and 77 fifth year medical students. From pharmacy133 students filled the validated questionnaire, out of these, there were 66 from fourth year and 57 were from fifth year. Questionnaires were distributed in all said classes by lottery method. The questionnaire variables include demographic characteristics like age, residential status, parental education, usage of internet along with questions involving attitude, awareness and knowledge of ADR reporting and pharmacovigilance. There were 16 multiple

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questions and each question have almost four option, out of this one option is correct. Incorrect answer was coded with "0", correct were coded with "1" for calculating mean score and comparison among fourth year medical to fourth year pharmacy and fifth year medical to fifth year pharmacy. Simple information was compared by frequency (percentage). Percentage of responses within the class calculated by the total number responses of whole relevant class. Overall percentage calculated by considering total number of responses of each profession. P-value was calculated by chi square tests. Data was entered in SPSS version 24.0

RESULTS

Among the participated medical students 36.7% were male and 63.3% were female while in pharmacy40.6% were male and 59.3% were female students in the study. Percentage of medical and pharmacy students in rural area as compared to urban were (27.14% vs 72.86%) and (34.15% vs 65.85%) respectively (Table-1).

The paternal education of medical students as compared to pharmacy students was(22.38% vs21.14%)at matric to under graduate level and (44.28% vs30.89%) at qualified graduation degree level. Whereas the maternal education level of medical students as compared to pharmacy students was (30.95% vs 46.34%) at matric to under graduate level and (40.48% vs 30.89%) at qualified graduation degree level (Table 1).

About reporting of ADR 42.9% 4th year medical students and 48.1% 5th year medical students while 25.8% 4th year pharma students and 68.4% 5th year pharma students had the knowledge that all (nurses, doctors and pharmacist) are responsible of reporting ADR at hospitals but overall 44.76% medical students and 42.10% pharma students knew that all (nurses, doctors and pharmacist) are responsible of reporting ADR(p value 0.0001).In this study 40.6% 4th year medical students and 59.7% 5th year medical students while 54.5% 4th year pharma students and 77.2% 5th year pharma students correctly defined the term of pharmacovigilance but overall 47.62% medical students and 60.15% pharma students correctly defined the termof pharmacovigilance(p value 0.000).The knowledge about objectives of pharmacovigilance to identify the safety of drug correctly was around 50% in 4th and 5th year medical students while among the pharma students this percentage was70.9% in5th year and40.2% in 4th year students thoughOverall46.67% medical students and 50.38% pharma students correctly defined the objective of pharmacovigilance to identify the safety of drug. (P-value 0.007). The overall information about the exact location of international center of monitoring ADRs among both specialties was just over 9%. Overall54.13%of pharmacy students and 21.90% of medical students had the knowledge of names of commonly used scale for assessment of causality of ADRs (p- value 0.003) and this percentage was highest in 5thyearspharma students.
Commonly used scale for assessment of causality of an ADR did not reach the statistical significance (p-value 0.209). The overall correct information about rare ADR that may be identified in phase 4 clinical trial was given by14.28% of pharma students and15.24% of medical students whereas overall 39.52% medical students and 50.44% pharma students knew about the drugs causing rare ADR. Overall 78.94% of pharmacy students and 60.95% medical students had the accurate knowledge of ADRs classification (p value 0.000). The understanding of ADRs leading to hospitalization, congenital abnormality and death of patient was 72.18%and 60.95% among the medical and pharma students respectively (P-value 0.244). The information about Regulatory body which is responsible for monitoring ADRs in Pakistan was nearly same in pharmacy and medical students respectively (49.62% vs 46.67% P-value 0.010) but the 43.80% of medical and 35.33% of pharmacy students had the knowledge about common method to monitor ADRs of new drugs once they are launched (p-value 0.180). The results regarding the reading of article on prevention of ADRs among medical and pharma students were28.57% and 20.3% respectively(p -value 0.030). Overall 78.95% pharma students as compared to 59.05% medical students knew that each type of ADR should be reported (P-value0.000). Knowledge about professional obligation of ADR reporting among pharma students and medical students was 66.19% and64.7%respectively (P-value 0.165). Knowledge regarding measures to be taken when ADR is suspected between pharma students and medical students was77.44% and 57.14% respectively (p- value 0.000) (Table 2).

Mean score of 4th year pharmacy students were 6.92±1.826 (mean ± SD) and medical students was 6.31± 2.250 (mean±SD)P- value 0.04. Mean score of final year Pharmacy students was 8.28±1.509 (mean±SD) and medicinal students was 5.83±1.915 (mean± SD) P-value 0.000).Overall mean score of pharmacy students was7.55 and medical students was 6.13 (P-value 0.000) (Table-3)

Table-1: Descriptive of Demographical characteristics

Characteristics		M13-4th Year	M12-5th Year	Total	PH-4th Year	PH-5th Year	Total
Gender	Male	48(36.1%)	29(37.7%	77(36.67%)	29(43.9%)	21(36.8%)	50(40.65%)
	Female	85(63.9%)	48(62.3%)	133(63.33%)	37(62.3%)	36(63.2%)	73(59.35%)
Area	Rural	36(27.1%)	21(27.3%)	57(27.14%)	21(31.8%)	21(36.8%)	42(34.15%)
	Urban	97(72.9%)	56(72.7%)	153(72.86%)	45(68.2%)	36(63.2%)	81(65.85%)
Father's Education	Under Matric	42(31.58%)	27(35.06%)	69(32.86%)	22(33.33%)	4(7.02%)	26(21.14%)
	Matric-	33(25.56%)	14(18.18%)	47(22.38%)	25(37.88%)	34(59.65%)	59(47.97%)
	Graduate	57(42.9%)	36(46.8%)	93(44.28%)	19(28.8%)	19(33.3%)	38(30.89%)
Mother's Education	Under matric	26(19.55%)	16(20.78%)	42(20%)	20(30.30%)	8(14.03%)	28(22.76%)
	Matric-Undergraduate	36(27.1%)	29(37.66%)	65(30.95%)	28(42.42%)	29(50.88%)	57(46.34%)
	Graduate	53(39.85%)	32(41.56%)	85(40.48%)	18(27.3%)	20(35.1%)	38(30.89%)

Table-2: Attitude, awareness and knowledge towards ADRs and Pharmacovigilance

Characteristics		M13-4th Year	M12-5th Year	PH-4th Year	PH-5th Year	P-value
The healthcare professionals responsible for reporting ADRs l	Nurses	10(7.5%)	11(14.3%)	1(1.5%)	3(5.3%)	0.000
	Pharmacist	31(23.3%)	14(18.2%)	47(71.2%)	15(26.3%)	
	Doctor	35(26.3%)	15(19.5%)	1(1.5)	0(0.0%)	
	All of above	57(42.9%)	37(48.1%)	17(25.8%)	39(68.4%)	
Definition of Pharmaco-vigilance	The detection, assessment, understanding, preventions of adverse effects	54(40.6%)	46(59.7%)	36(54.5%)	44(77.2%)	0.000
	The science of detecting	29(21.8%)	15(19.5%)	13(19.7%)	10(17.5%)	
	The science of monitoring ADRs	31(23.3%)	8(10.4%)	15(22.7%)	3(5.3%)	
	The process of improving the safety	19(14.3%)	8(10.4%)	2(3.0%)	0(0.0%)	
Important objective of Pharmacovigilanc e	To calculate incidence of ADRs	27(20.3%)	14(18.2%)	18(27.3%)	11(19.3%)	0.007
	To identify ADRs occurring at high dose	18(13.5%)	6(7.8%)	12(18.2%)	2(3.5%)	
	To identify safety of drugs	61(45.9%)	37(48.1%)	27(40.9%)	40(70.2%)	
	To identify predisposing factors to ADRs	27(20.3%)	20(26.0%)	9(13.6%)	4(7.0%)	
Location of international center for ADRs monitoring	USA	97(72.9%)	57(74.0%)	41(62.1%)	55(96.5%)	0.003
	Canada	11(8.3%)	8(10.4%)	5(7.6%)	0(0.0%)	
	Australia	10(7.5%)	7(9.1%)	8(12.1%)	2(3.5%)	
	Sweden	15(11.3%)	5(6.5%)	12(18.2%)	0(0.0%)	
Commonly used scale for assessment of causality of ADR	Hartwig scale	26(19.5%)	10(13.0%)	16(24.2%)	2(3.5%)	0.000
	Karch& Lasagna scale	17(12.8%)	14(18.2%)	3(4.5%)	0(0.0%)	
	Naranjo algorithm	27(20.3%)	19(24.7%)	22(33.3%)	50(87.7%)	
	Schumock& Thornton scale	63(47.4%)	34(44.2%)	25(37.9%)	5(8.8%)	
WHO online database for ADRs reporting	ADRs advisory committee	56(42.1%)	35(45.5%)	24(36.4%)	23(40.4%)	0.209
	Med Safe	41(30.8%)	22(28.6%)	20(30.3%)	25(43.9%)	
	Med Watch	10(7.5%)	2(2.6%)	2(3.0%)	2(3.5%)	
	Vigibase	26(19.5%)	18(23.4%)	20(30.3%)	7(12.3%)	
Rare ADRs can be identified in the following phase of clinical trial	Phase -1 clinical trials	36(27.1%)	21(27.3%)	28(42.4%)	14(24.6%)	0.118
	Phase -2 clinical trials	41(30.8%)	28(36.4%)	14(21.2%)	15(26.3%)	
	Phase -3 clinical trials	35(26.3%)	17(22.1%)	19(28.8%)	14(24.6%)	
	Phase -4 clinical trials	21(15.8%)	11(14.3%)	5(7.6%)	14(24.6%)	
ADR and its causative drug	**Cleft lip - Phenytoin**	59(44.4%)	24(31.2%)	24(36.4%)	33(57.9%)	0.039
	Hemolytic anemia - Thalidomide	34(25.6%)	32(41.6%)	19(28.8%)	14(24.6%)	
	HPA axis suppression - Oflaxacin	27(20.3%)	12(15.6%)	11(16.7%)	5(8.8%)	
	Phocomelia - Streptomycin	13(9.8%)	9(11.7%)	12(18.2%)	5(8.8%)	
Regarding classification of ADRs the correct option	Type A is predictable, dose related	29(21.8%)	18(23.4%)	5(7.6%)	4(7.0%)	0.000
	Type B is unpredictable, dose unrelated	0(0.0%)	23(29.9%)	4(6.1%)	0(0.0%)	
	Both a) and b) are correct	97(72.9%)	31(40.3%)	55(83.3%)	50(87.7%)	
	None of the above	7(5.3%)	5(6.5%)	2(3.0%)	3(5.3%)	
It is important to report ADRs leading to	Hospitalization	20(15.0%)	9(11.7%)	6(9.1%)	4(7.0%)	0.244
	Congenital abnormality	14(10.5%)	8(10.4%)	5(7.6%)	3(5.3%)	
	Patient Death	20(15.0%)	11(14.3%)	5(7.6%)	4(7.0%)	
	All of the above	79(59.4%)	49(63.6%)	50(75.8%)	46(80.7%)	
Regulatory body is responsible for monitoring ADRs in Pakistan	**Drug Regulatory Authority of Pakistan**	63(47.4%)	35(45.5%)	36(54.5%)	30(52.6%)	0.010
	Pakistan Health Research council	36(27.1%)	21(27.3%)	22(33.3%)	25(43.9%)	
	Pakistan Medical and Dental Council	23(17.3%)	15(19.5%)	3(4.5%)	1(1.8%)	
	Pakistan Medical Association	11(8.3%)	6(7.8%)	5(7.6%)	1(1.8%)	
Common method to monitor ADRs of new drugs once they are launched in market.	Meta-analysis	22(16.5%)	11(14.3%)	8(12.1%)	8(14.0%)	0.180
	Population Studies	44(33.1%)	30(39.0%)	34(51.5%)	20(35.1%)	
	Regression analysis	5(3.8%)	6(7.8%)	5(7.6%)	1(1.8%)	
	Spontaneous Reporting System	62(46.6%)	30(39.0%)	19(28.8%)	28(49.1%)	
Have you read any article on prevention of Adverse Drug Reaction?	No	72(54.1%)	41(53.2%)	44(66.7%)	28(49.1%)	0.030
	Yes	43(32.3%)	17(22.1%)	13(19.7%)	14(24.6%)	
	May be	5(3.8%)	7(9.1%)	5(7.6%)	10(17.5%)	
	Cannot say	13(9.8%)	12(15.6%)	4(6.1%)	5(8.8%)	
What type of ADRs to be reported?	Mild	14(10.5%)	4(5.2%)	3(4.5%)	1(1.8%)	0.000
	Moderate	26(19.5%)	13(16.9%)	2(3.0%)	1(1.8%)	
	Severe	17(12.8%)	12(15.6%)	7(10.6%)	4(7.0%)	
	All of above	76(57.1%)	48(62.3%)	54(81.8%)	51(89.5%)	
ADR reporting is a Professional obligation	No	27(20.3%)	13(16.9%)	7(10.6%)	9(15.8%)	0.165
	Yes	86(64.7%)	53(68.8%)	45(68.2%)	45(78.9%)	
	Don't Know	20(15.0%)	11(14.3%)	14(21.2%)	3(5.3%)	
Measures to be taken when ADR is suspected	Stop the drug	32(24.1%)	10(13.0%)	5(7.6%)	3(5.3%)	0.000
	report ADR	16(12.0%)	12(15.6%)	5(7.6%)	1(1.8%)	
	treat the reaction	15(11.3%)	5(6.5%)	4(6.1%)	2(3.5%)	
	all of the above	70(52.6%)	50(64.9%)	52(78.8%)	51(89.5%)	

Table-3: Mean score table with decision value

Class Year	N	Mean	Std. Deviation	P-Value
MBBS-4th Year	133	6.31	2.250	0.04
PHARMACY-4th Year	66	6.92	1.826	
MBBS-5th Year	77	5.83	1.915	0.000
PHARMACY-5th Year	57	8.28	1.509	
OVERALL MBBS	210	6.13	2.141	0.000

DISCUSSION

This study had quite balanced proportion of both medical and pharmacy students. Overall pharmacy students had better knowledge of pharmacovigilance, ADR and ADR reporting. A great number of pharmacy students were in their final year as compared to medical students.

This study showed thatreasonable number of medical students and good number of pharmacy students knew about the definition of and about half of the students of both groups knew about objectives of pharmacovigilance to identify the safety of drugs. Recently study among the pharmacists showed they are eager to get experience to enhance their Pharmacovigilance information[6,7].

As ADR and ADR reporting is the most important aspect of clinical medicine only less than half of the students of pharmacy and medicine knew that ADR should be reported by all the health care staff including nurses, doctors and pharmacists. Twice the number of Pharmacy students as compared to medical students were aware of the International center of monitoring ADRs and the scale used for the assessment of causality of ADRs. This study showed that pharmacy students had very poor information about the online data base used for ADR reporting which should be included in the curriculum. Both medical and pharmacy students had poor knowledge about the reporting of rare ADRs in different phases of clinical trials and similarly only one third students of both specialties had read articles about prevention of ADR, which should be encouraged to improve their knowledge. Medical students were slightly more efficient in reading about the prevention of ADRs than pharmacy students. The information about the drugs which most commonly caused ADR was more among pharmacy students as compared to medical students and needs to be improved for their clinical knowledge. The information regarding ADR classification and AD Reporting for the ones leading to hospitalization, congenital abnormality and occurrence of patient death was good and found more in our cohort of medical and pharmacy students which is clinically very significant.

Both groups were a lot more aware of the reporting of all types of ADR and their obligation of reporting ADRs. Recent studies in other centers showed that pharmacists working in the hospitals have good knowledge of ADR reporting but most of them are not reporting the ADRs and practicing pharmacovigilance which needs improvement. They recommended for well-defined syllabus and intervention in academic courses and workshops, which may increase the knowledge about pharmacovigilance an ADRs reporting[7].

Generally, information on the subject differs significantly between pharmacy and medicine education and use of ADR forms and unfavorable medication responses (ADRs). Pharmacy students believed workshops on ADR reporting and clinical hands on training may play significant role for increase in ADR reporting in the future[8]

CONCLUSION

Medical students have greater percentage of giving correct response in very few characteristics, but pharmacy students have greater percentage in many characteristics when we looked partially and comparatively on each class. It is also seen that overall poor knowledge towards pharmacovigilance and ADRs reporting was noticed but fourth year students and final year students of MBBS have poor knowledge and awareness comparatively to fourth year pharmacy and final year pharmacy students respectively.

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Aknowledgement: MUA plan the study, checked the termnology and review the final draft. SK worte the intial draft and made the changes as required. KMA coded and entered the data. Analyzed, interpret the the data, review the final copy and formatted the article. AAM searched the literature and provide the help in data collection.

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