ORIGINAL ARTICLE

Fourth and Final Year Pharmacy Students' Knowledge about Adverse Drug Reaction Reporting and Pharmacovigilance in A Pharmacy College of Lahore

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ABSTRACT

Background: There is very poor knowledge and awareness regarding Adverse Drug Reaction (ADR) reporting and Pharmacovigilance. This is evident from the literature that the mean score and the percentage towards the knowledge about adverse drug reaction reporting and pharmacovigilance is very low. Majority of the students are of the opinion that the pharmacy syllabus should be improved and these subjects should be taught more thoroughly. In the meantime awareness programs should be launched for ADR reporting and better detection, assessment and monitoring for prevention of adverse drug reactions.

Aim: To assess the knowledge about adverse drug reaction reporting and pharmacovigilance amongst 4th and final year pharmacy students.

Methods: A cross sectional descriptive survey was conducted and 122 students were enrolled randomly in this study to get the feedback regarding knowledge and awareness of adverse drug reaction reporting and pharmacovigilance. Out of them 66 students were studying in 4th year and 56 students were in 5th year of pharmacy degree program.

Results: Correct reply of fifth year student's means score 8.57 ± 1.57 was higher than fourth year student's mean score 6.53±2.21. The p-value being 0.00. Overall mean score of knowledge and awareness towards ADRs and pharmacovigilance was 7.46 ± 2.19. There was a significant difference in the mean score between the two groups of classes for knowledge.

Conclusion: The fifth year students have better knowledge and awareness towards ADR reporting and pharmacovigilance.

Key words: Pharmacovigilance, Adverse Drug Reactions Reporting, Undergrad Pharmacy Students,

INTRODUCTION

Although great care and vigilance is undertaken regarding the safety, efficacy and quality of a drug before marketing when the products undergo phase II and III trials assessing their safety and efficacy, some adverse effects remain undetected, only to be seen after prolonged use and after the drug is marketed and are seen in the post-marketing surveillance (Phase IV studies).

The concept of Adverse Drug Reaction reporting and Pharmacovigilance had started after the thalidomide tragedy in the late 60s. After which the health regulatory authorities started asking for more studies on the safety and efficacy of the products. "The science relating to the detection, assessment, understanding, and prevention of adverse effects" was defined as Pharmacovigilance by the World Health Organization[1]. This is now being practiced by the developed world. Uppsala Monitoring Center in Sweden was established and is the center where reports from all over the world are collected and assessed.

Among healthcare professionals pharmacists are at the top of the list regarding dispensing of medicines and their related products. Professionally, they are the first ones to be contacted if any undesired drug reaction occurs[2,3].

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This makes them responsible for reporting the matter/complaint of an adverse drug reaction to the concerned authority. But in a study conducted by Elkkalmi et al., the results demonstrated that the majority of final-year pharmacy students in Malaysian public universities have insufficient knowledge about pharmacovigilance and ADR reporting[4].

A study in Quetta, Pakistan indicated that the respondents, the majority of who were hospital pharmacists had inadequate knowledge and positive attitude toward ADR reporting and pharmacovigilance and poor ADR reporting practices. It was concluded that efforts were required to enhance knowledge and attitude toward pharmacovigilance and ADR reporting[5].

ADR is known to be a leading cause of mortality as well as morbidity around the globe. Most of the studies in Asia showed that Pharmacists had lack of knowledge, had less practice and good (or poor) attitude towards adverse drug reaction (ADR). They also concluded that intervention in this regard would be helpful to improve the reporting of ADR. They also noted that a few number of professional pharmacist's counseled the patients towards ADRs [6,7].

Most ADRs present as minor symptoms but others can lead to serious consequences requiring hospital admissions and even cause death[8 9].

This poses a public health problem and also upsets the fiscal balance of the healthcare system of the society[10]. Pharmacy graduates leaving college, having studied pharmaceutical medicine must have the expertise to adapt to this new role of pharmacovigilance and detection of rare ADRs once they are in the field[11].

This study was conducted with the view to assess the knowledge of pharmacy students about ADR reporting and pharmacovigilance.

The objective of the study was to assess the knowledge about adverse drug reaction reporting and pharmacovigilance amongst 4th and final year pharmacy students.

MATERIALS AND METHODS

This descriptive cross-sectional questionnaire based study was conducted at Lahore College of Pharmaceutical Sciences Lahore. A well designed and structured questionnaire was distributed to fourth year and final year students. The response rate for filled questionnaires was ninety-seven percent. Overall sample size was 122 students of both classes, 56 belonging to fifth year and 66 to forth year. Some questions consisted the demographic information and the rest were directed towards knowledge and understanding of pharmacovigilance and adverse drug reporting. All questions except age were categorical and each category in each question was coded with some numeric characteristics. The lowest code being 0 and the highest was 6. The results and the data were entered inSPSS version 24 for analysis purpose. Frequency and percentages were calculated with chi square. Overall comparison was explored by applying student t test to observe the significance difference between knowledge and awareness of fourth year and final year students. Only fourth and final year students were enrolled and first to third year students were excluded. There was no ethical issue seen and all the data was given by the student willingly after signing an informed consent. IRB approval was taken from the institution. This study was conducted using own funding and interest.

RESULTS

Mean age of fourth year students was 21.21±1.13 (mean ± SD) while mean age of fifth year student was 22.73±1.018 (mean ± SD). Overall 42.2% male students and 59.8% female students gave their feedback. Highest percentage of mother and father of respondents had a graduate degree (Table-1).

13.9% fourth year students and 31.1% fifth year students said that all (doctors, nurses and pharmacists) are responsible to report ADRs. 29.9% fourth year students and 35.2% fifth year students correctly defined pharmacovigilance. 22.1% fourth year students and 32.8% fifth year students correctly defined the main objective of pharmacovigilance. Only 9.8% fourth year students correctly responded to the location of international ADR reporting being Sweden. 18% fourth year students and 41% fifth year student correctly rated common algorithm used to assess the ADR was Naranjo algorithm. 16.4% fourth year students and 6.6% fifth year students answered that Vigibase is the WHO online database of ADR reporting. Only 4.1% fourth year students and 11.5% fifth year students correctly stated that rare ADR is identified in phase 4 clinical trial. 19.7% fourth year students and 27% fifth year students correctly picked up the ADR of causative drug. Correct classification of ADRs was identified by 45.1% fourth year students and 40.2% fifth year students. 42.6% fourth year students and 38.5% fifth year students knew the importance of reporting the ADRs leading to hospitalization, congenital abnormality and death. 29.5% fourth year students and 24.6% fifth year student gave the correct answer that drug regulatory authority is responsible to monitor the ADRs in Pakistan. The common method for monitoring ADRs of new drug is spontaneous reporting system which was marked by 15.6% fourth year students and 23% fifth year students. 10.7% fourth students and 11.5% fifth year students had read any article on prevention of ADR. 44.3% fourth year students and 41% fifth year students gave the correct answer for the type of ADR to be reported. 36.1% fourth year and 35.2% fifth year students knew that ADR reporting is a professional obligation. 42.6% fourth year and 41% fifth year students agreed for reporting the ADR, stopping the drug and starting treating the reaction is the measure to be taken when ADR is suspected. (Table-2). Fifth year student's mean score of correct reply was higher than fourth year students but the overall mean score of knowledge and awareness towards ADRs and pharmacovigilance is 7.46 and p-value showed a significant difference between knowledge level of fifth year and fourth year students (Table-3).

Table -1: Demographics

Characteristics		**Frequency(%) of 4th year**	**Frequency(%) of 5th year**	**Total (%)**
Gender	Male	29(23.8)	20(16.4)	49(40.2)
	Female	37(30.3)	36(29.5)	73(59.8)
Residence	Rural	21(17.2)	21(17.2)	42(34.4)
	Urban	45(36.9)	35((28.7)	80(65.6)
Father's Education	PG	11(9)	2(1.6)	13(10.7)
	Primary	11(9)	1(0.8)	12(9.8)
	Matric	14(11.5)	18(14.8)	32(26.2)
	Secondary	6(4.9)	2(1.6)	8(6.6)
	Undergraduate	5(4.1)	15(12.3)	20(16.4)
	Graduate	19(15.6)	18(14.8)	37(30.3)
Mother's Education	PG	8(6.6)	1(0.8)	9(7.4)
	Primary	12(9.8)	6(4.9)	18(14.8)
	Matric	16(13.1)	12(9.8)	28(23)
	Secondary	4(3.3)	7(5.7)	11(9)
	Undergraduate	8(6.6)	11(9)	19(15.6)
	Graduate	18(14.8)	19(15.6)	37(30.3)

Table-2: Knowledge and awareness of ADRs and Pharmacovigilance

Characteristics		Frequency(%) of 4th yr	Frequency(%) of 5th year	Total (%)	P-Value
Responsibility healthcare professionals to report ADRs in a hospital are	Nurses	1(0.8)	3(2.5)	4(3.3)	0.000*
	Pharmacist	47(38.5)	15(12.3)	62(50.8)	
	Doctor	1(0.8)	0	1(0.8)	
	All of above	17(13.9)	38(31.1)	55(45.1)	
Define Pharmacovigilance	**Detection, assessment, understandir**	36(29.5)	43(35.2)	79(64.8)	0.016*
	Science of detecting	13(10.7)	10(8.2)	23(18.9)	
	Science of monitoring ADRs	15(12.3)	3(2.5)	18(14.8)	
	Process of improving safety	2(1.6)	0	2(1.6)	
Important objective of Pharmacovigilance	To calculate incidence of ADRs	18(14.8)	12(9.8)	30(24.6)	0.002*
	To identify ADRs occurring at high dose	12(9.8)	1(0.8)	13(10.7)	
	To identify safety of drugs	27(22.1)	40(32.8)	67(54.9)	
	To identify predisposing factors to ADR	9(7.4)	3(2.5)	12(9.8)	
Location of International center for ADRs monitoring	USA	41(33.6)	55(45.1)	96(78.7)	0.000*
	Canada	6(4.9)	0	6(4.9)	
	Australia	7(5.7)	1(0.8)	8(6.6)	
	Sweden	12(9.8)	0	12(9.8)	
Scales commonly used to assess the causality of an ADR	Hartwig scale	16(13.1)	2(1.6)	18(14.8)	0.000*
	Karch& Lasagna scale	3(2.5)	0	3(2.5)	
	Naranjo algorithm	22(18)	50(41)	72(59)	
	Schumock& Thornton scale	25(20.5)	4(3.3)	29(23.8)	
"WHO" online database for reporting ADRs?	ADRs advisory committee	24(19.7)	21(17.2)	45(36.9)	0.164
	Med Safe	20(16.4)	25(20.5)	45(36.9)	
	Med Watch	2(1.6)	2(1.6)	4(3.3)	
	Vigibase	20(16.4)	8(6.6)	28(23)	
Rare ADRs can be identified in the phase of clinical trial	Phase -1 clinical trials	28(23)	13(10.7)	41(33.6)	0.02*
	Phase -2 clinical trials	14(11.5)	15(12.3)	29(23.8)	
	Phase -3 clinical trials	19(15.6)	14(11.5)	33(27)	
	Phase -4 clinical trials	5(4.1)	14(11.5)	19(15.6)	
ADR and its causative drug	**Cleft lip - Phenytoin**	24(19.7)	33(27)	57(46.7)	0.056
	Hemolytic anemia - Thalidomide	19(15.6)	14(11.5)	33(27)	
	I PA axis suppression - Oflaxacin	11(9)	4(3.3)	15(12.3)	
	Phocomelia - Streptomycin	12(9.8)	5(4.1)	17(13.9)	
Classification of ADRs	Type A is predictable, dose related	5(4.1)	4(3.3)	9(7.4)	0.277
	Type B is unpredictable, dose unrelated	4(3.3)	0	4(3.3)	
	Both a) and b) are correct	55(45.1)	49(40.2)	104(85.2)	
	None of the above	2(1.6)	3(2.5)	5(4.1)	
ADRs leading to	Hospitalization	6(4.9)	3(2.5)	9(7.4)	0.775
	Congenital abnormality	4(3.3)	2(1.6)	6(4.9)	
	Patient Death	4(3.3)	4(3.3)	8(6.6)	
	All of the above	52(42.6)	47(38.5)	99(81.1)	
Regulatory body is responsible for monitoring ADRs in Pakistan	**Drug Regulatory Authority of Pakistan**	36(29.5)	30(24.6)	66(54.1)	0.452
	Pakistan Health Research council (PI-IRC)	22(18)	23(18.9)	45(36.9)	
	Pakistan Medical and Dental Council	3(2.5)	2(1.6)	5(4.1)	
	Pakistan Medical Association	5(4.1)	1(0.8)	6(4.9)	
Common methods to monitor ADRs of new drugs once it launched in market.	Meta-analysis	8(6.6)	8(6.6)	16(13.1)	0.049
	Population Studies	34(27.9)	19(15.6)	53(43.4)	
	Regression analysis	5(4.1)	1(0.8)	6(4.9)	
	Spontaneous Reporting System	19(15.6)	28(23)	47(38.5)	
Have you read any article on prevention of Adverse Drug Reaction?	No	44(36.1)	28(23)	72(59)	0.256
	Yes	13(10.7)	14(11.5)	27(22.1)	
	May be	5(4.1)	9(7.4)	14(11.5)	
	Cannot say	4(3.3)	5(4.1)	9(7.4)	
What type of ADRs to be reported?	Mild	3(2.5)	2(1.6)	5(4.1)	0.500
	Moderate	2(1.6)	0	2(1.6)	
	Severe	7(5.7)	4(3.3)	11(9)	
	All of above	54(44.3)	50(41)	104(85.2)	
ADR reporting is a Professional obligation?	No	7(5.7)	8(6.6)	15(12.3)	0.117
	Yes	44(36.1)	43(35.2)	87(71.3)	
	Don't Know	15(12.3)	5(4.1)	20(16.4)	
Measures to be taken when ADR is suspected	Stop the drug	5(4.1)	3(2.5)	8(6.6)	0.18
	report ADR	5(4.1)	0	5(4.1)	
	treat the reaction	4(3.3)	3(2.5)	7(5.7)	
	all of the above	52(42.6)	50(41)	102(83.6)	

Table-3: Mean score of knowledge and awareness towards ADR reporting and Pharmacovigilance

Class Year	Mean	Std. Deviation	P-Value
Forth Year	6.5303	2.21338	0.000
Fifth Year	8.5714	1.57084	
Overall	7.46	2.19	

DISCUSSION

Although majority of the pharmacists believe that reporting of ADR is their professional responsibility and obligation but very few fulfill this during practice. Among the pharmacy student, final year students had more knowledge and awareness as compared to the 4th year students, which is similar to the studies conducted on pharmacy and medical students[12-14].

In some countries in Asia there is more understanding as compared to the other countries like China[15].

Our study showed that only one third of 4th and 5th year students correctly defined pharmacovigilance. Main objective of pharmacovigilance was defined by one fifth of the students in our study. Very less percentage knew regarding international ADR reporting center, WHO online database, type of clinical trial for rare ADR and had read articles to get knowledge regarding prevention of ADRs. There is no difference among senior and junior students regarding assessment algorithm of ADRs but knowledge regarding classification of ADR was good. Very little percentage of students in both classes knew about the regulatory body that monitors the ADRs in Pakistan. This was also similar to the study done in Jordan[13].

In our study one fifth of students knew correctly about the ADR of a causative drug. This is the same like other studies in Pakistan[12].

Prakasam, Nidamanuri, & Kumar[16], in their study in South India in 2012 found that 61.9% of community pharmacists had poor knowledge about Pharmacovigilance. They also found that 64.3% of respondents thought that the ADRs being very simple and non-serious and hence did not warrant reporting. In our study 42.6% fourth year students and 38.5% fifth year students only correctly told that it was important to report ADRs leading to hospitalization, congenital abnormality and death. There is strong evidence that pharmacy students have wrong concepts and poor knowledge as well regarding the ADR reporting and pharmacovigilance.

In our study, fifth year student's mean score (8.57) of correct replies was higher than fourth year student's mean score (6.54) and overall mean score of knowledge and awareness towards ADRs and pharmacovigilance is 7.46. In a study by Ibrahim et al.[17], very low mean score (6.9) of pharmacovigilance knowledge was seen in the final year pharmacy students. Elkalmi, et al.[4], in their study on knowledge and perception of pharmacovigilance and ADR reporting found mean score of only 6.9. The mean score (4.0) of pharmacovigilance knowledge and ADR reporting was very low in the study by Farha et al.[13]. The overall mean score of fourth year students was 6.09 and final year students was 6.40 which was noted amongst medical students as noted by Khan, et al.[12], in the study on medical students. In our study cohort, overall mean score of knowledge and awareness towards ADRs and pharmacovigilance was seen to be higher as compared to other studies[4, 13,16].

Increased knowledge of Pharmacovigilance and ADR reporting awareness should be given to the pharmacy students and also a comprehensive coursework that consists of rich knowledge of pharmacovigilance and ADRs reporting should be included in the syllabus of pharmacy education for effective awareness so the pharmacy students are able to incorporate pharmacovigilance and ADRs reporting in their clinical practices[18].

CONCLUSION

Although the knowledge of final year students was better than the fourth year students, but it still remains poor. More is to be done to improve proper training to pharmacy students to achieve the required level of this very important system and improve it to be at par with other countries particularly the developed world. The pharmacy syllabus should be improved incorporating the subject thoroughly. This should be coupled with continuous education of the subject through seminars and workshops as a constant reminder.

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