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Original Research Article

Comparison of knowledge and perception about adverse drug reaction reporting and pharmacovigilance between pharmacy and medical students

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ABSTRACT

Background: Adverse drug responses are serious public health issues worldwide. Pharmacovigilance (PV) is an important part of the healthcare system since it assesses, monitors, and discovers medication interactions and their consequences in humans. Objective were to assess knowledge and perception about adverse drug reactions (ADR) and PV among pharmacy and medical students.
Methods: A cross-sectional study was conducted for pre-final year and final-year of pharmacy and medical students. Study conducted through semi structured questionnaires and a total 607 participants were recruited in this study.
Results: A total 607 participants of pharmacy (52.5%) and medical (47.4%) from pre final (50.2%), final year (49.9%) students participated in this study. Pharmacy students had a significantly better overall knowledge of ADRs than medical students ($p<0.05$). The perception of pharmacy students regarding ADRs reporting and PV were significantly more than those medical student's ($p<0.05$). In comparison to pharmacy students, a lack of knowledge of where and how to report ADRs was the main barrier that medical students perceived to ADR reporting (0.02).
Conclusions: This study shows that compared to medical students, pharmacy students had better awareness of ADR reporting and shown good perceptions of PV. To enhance the knowledge of PV among healthcare students, an instructional intervention ought to be implemented.

Keywords: KAP questionnaires, PV, ADR reporting

INTRODUCTION

In current world, there is a great need for patient safety and safe use of medications. The first real multinational collaboration on drug monitoring was formed in 1968. The concepts emerged as a result of alleged thalidomide catastrophe. The discovery that thalidomide use results in babies' limb abnormalities may be caused by mothers during pregnancy. Due to fierce rivalry among pharmaceutical producers, medical medicines may be registered and promoted concurrently in several countries, making medication safety an even bigger problem. As result, adverse effects may not always be easily recognized and are not routinely monitored.[1]

The world health organisation defines an ADR as "a noxious and unintended response to a drug that occurs at doses that are not intended generally used in humans for illness prevention, diagnosis, or treatment, or to modify physiological function".[2] In clinical practice, health and safety against adverse medication responses are of the utmost significance. Adverse drug responses are serious public health issues worldwide. It varies in severity; in its most severe form, it can result in morbidity, mortality, hospital admissions, increased risk of readmission, increased length of hospital stay, and other unfavourable consequences. Furthermore, adverse medication responses have an influence on patients' quality of life as well as on the hospital system.[3] Two highly recognized

experts who are essential to therapeutic management are doctors and pharmacists. They are in a great position to oversee the effectiveness and safety of patient therapy. They have access to patient information in clinical settings, allowing them to keep track of and eventually report ADRs.[4] ADRs to lessen or avoid harm to patients resulting from their medications, to identify ADRs before they become clinically evident, and to learn additional knowledge to ensure the safe usage of drugs.[5] As 5 ideal knowledge and positive perception in students for ensuring safe and effective medication use and minimizing medication overuse in future. Underreporting of ADRs by pharmacists is a major hindrance to successful PV. As future pharmacy practitioners, pharmacy students need to be well-trained in how to recognize, prevent, and report ADRs.

Spontaneous reporting of ADRs is an essential way of PV, which is accomplished in the United Kingdom through the yellow card scheme (YCS), which is administered by the medicines and healthcare products regulatory agency (MHRA). Direct reporting of suspected ADRs by patients, which is widely established in other countries, was asked for by the UK consumer association in 2001, albeit a subsequent study found insufficient evidence to support this. According to recent studies, ADRs were responsible for 3.04-5% of hospital admissions reported. And ADRs occupy a considerable part of the inpatient treatment space.[6-8]

PV is an important part of the healthcare system since it assesses, monitors, and discovers medication interactions and their consequences in humans. As a result, for medication safety, ADR monitoring is essential for each treatment throughout its life cycle, including pre-marketing encompassing early phases of drug discovery, clinical trials, and post-marketing surveillance. PV is concerned with identification, evaluation, comprehension, and prevention of ADRs.[9] ADR monitoring and reporting programs in hospitals seek to detect and quantify dangers associated with the drug usage.

Hence in our study aimed to assess knowledge and perception about ADR and PV among pharmacy and medical. Pharmacy and medical students are future healthcare practitioners, as they play a pivotal role in monitoring, preventing, and reporting ADRs. So, for medical and pharmacy students it's essential to have adequate knowledge and a positive perception of the importance of ADR reporting and the PV.

METHODS

Ethical consideration

After approved by Institution ethical committee of Adichuchanagiri hospital and research centre, this prospective cross-sectional study conducted on pre final and final students of pharmacy and medical studying at Adichuchanagiri university B. G. Nagara, Nagamangala taluk, and Mandya district. The minimum sample of 607 samples was calculated using formula $n=4pq/d^2$, p is 48, q (100-p) 52, $d^2=5.76$ which is 433.3. The study was carried out for over a period of 6 months (June 2023-November 2023). After considering inclusion criteria and exclusion criteria.

Inclusion criteria

Pharmacy students including pre-final year and final year students of B. pharm and medical students and also pharm D students. Students studying in Adichunchanagiri college of pharmacy AIMS at (ACU) university B. G. Nagara were included in study.

Exclusion criteria

M. Pharm students are excluded from study because they are studying in their curriculum design.

Questionnaires design and data collection technique

A questionnaire was developed based on previously published studies.[10-13] The students were enrolled in the study by using suitable data collection form. A standardised semi structured questionnaires was used to assess knowledge and perception about adverse drug reaction and PV among pharmacy medical students based on extensive literature search. The questionnaire consists of 3 sections. The first section includes demographic details such as name, gender, age, marital status, study course. The second section knowledge consists of 16 questionnaires. The 3rd section perception consists of 14 questionnaires.

Data analysis

Data collected through Google form, after data collection and data entry. Data analysis was done using SPSS (Statistical package for social sciences) version 25.

RESULTS

Socio demographics, showed in Table 1 that among 607 study participants, were females (316) and 291 were males. Age distribution among participants, as 21-23 (527), 24-26 (60), 27-30 (19), 31-34 (0). Academic year distribution, as 304 are pre-final year students, and 303 are Final year students. Marital status distribution among participants, as 591 are single and 16 were married. Distribution of study course, as pharmacy students were (321), medical students were (286).

Table 2 shows knowledge about adverse reaction reporting and PV. Our results showed that pharmacy students exhibited more knowledge regarding every aspect of ADRs and their reporting than medical students. However, the discrepancy between pharmacy and medical students varied from question to question. When

asked if aware of ADRs 92.8% pharmacy, 92.6% medical students. Among pharmacy students 75.3% answered correctly, 41.5% medical students answered correctly were aware of PV, definition of PV answered correctly (74.4% Pharmacy and 41.5% medical students), 5.9% were reported ADR from pharmacy students but no medical students reported ADRs and they were reported to an ADR reporting centre, 80.3% pharmacy and 47.2% medical students answered correctly as aware of drug has been due to ADR, 88.7% pharmacy and 78.6% medical students were answered as all serious ADR are known before a medicine is marketed. Conversely, the knowledge level of pharmacy and medical students was almost the same regarding pharmacist is the right person to assist physicians in ADR reporting (99.6% and 91.6%). The 98.1% pharmacy and 89.1% medical were answered correctly as ADR reporting and monitoring system would benefit the patient. The 79.4% pharmacy and 38.4% medical were aware where to get the ADR reporting forms, 95% pharmacy and 54.1% medical were correctly as no ADR reporting is a time-consuming activity with no outcome, (79.4% pharmacy and 73.4% medical) almost same level of knowledge as answered as not all drugs available in market are safe. Factors important while reporting of an ADR, majority of participants (45.7% pharmacy and 35.6% medical) answered as unusualness of the reaction. The 92.8% pharmacy and 85.6% medical were answered as patient can report ADRs independent of HCP. Factors discourage from reporting ADRs majority of 43.3% pharmacy and 50% medical were answered as not knowing where to report.

Table 1: Socio demographics.

Variables		N	Percentage (%)
Gender	Female	316	52
	Male	219	48
Age (in years)	21-23	527	86.8
	24-26	60	9.8
	27-30	19	3.1
	31-34	0	0
Academic year	Pre final	304	50.2
	Final	303	49.9
Marital status	Single	591	97.3
	Married	16	2.6
Study course	Pharmacy	321	52.8
	Medical	286	47.1

Table 2: Knowledge about ADR reporting and PV.

Questions	Variables	Correct answer (%)		P value
		Pharmacy students	Medical students	
Are you aware of the aware of the ADRs?	Yes	92.8	92.6	0.0005
	No			
From which sources do you gather information about ADRs to new drugs?	Textbooks	4.3	6.6	-
	Journals	29.2	37.4	
	Drug advertisements and product catalogues	9.3	10.8	
	Medical representatives	2.8	6.6	
	Seminars/ conference	0	5.2	
	Direct mail brochures	1.8	5.2	
	Google	52.6	27.9	
Are you aware of PV?	Yes	75.3	44.7	0.03
	No			
PV is study that relates to detection, assessment, understanding, and prevention of ADRs?	Yes	74.4	38.4	0.001
	No			
Have you ever reported an ADR?	Yes	5.9	0	0.02
	No			
If yes, how many till date? And where?	An ADR reporting centre	5.9	0	-
	The concerned pharmaceutical company	0	0	
	Others	0	0	

Continued.

Questions	Variables	Correct answer (%)		P value
		Pharmacy students	Medical students	
Are you aware of any drug that has been banned due to ADRs?	Yes	80.3	47.2	0.02
	No			
All serious ADRs are known before a medicine is marketed?	Yes	88.7	78.6	0.004
	No			
Do you think that pharmacists should be the right person to assist physicians in ADR reporting?	Yes	99.6	91.6	0.012
	No			
Do you think that ADR reporting and monitoring system would benefit patient?	Yes	98.1	89.1	0.01
	No			
Do you know where can you get the ADR reporting form?	Yes	79.4	38.4	<0.001
	No			
Do you think ADR reporting is a time-consuming activity with no outcome?	Yes	95	54.1	<0.001
	No			
Do you believe all the drugs available in market are safe?	Yes	79.4	73.4	0.02
	No			
What factors do you think are important while deciding to report an ADR? Seriousness of ADR?	Unusualness of reaction	45.7	35.6	-
	Involvement of a new drug	39.5	52.7	
	Confidence in diagnosis of an ADR	14.6	11.5	
Patients can report ADRs Independent of HCP?	Yes	92.8	85.6	0.01
	No			
Which are the factors that discourage you from reporting ADRs?	Did not how to report	32.08	32.5	-
	Not knowing where to report	43.3	50	
	Did not think it would be important	15.5	16	
	Managing patience was more important than ADR reporting	9.03	1.3	

ADR: Adverse drug reaction, PV: Pharmacovigilance, HCP: healthcare professionals.

Table 3: Perception about adverse drug reactions reporting and PV.

Questions	Variables	Correct answer (%)		P value
		Pharmacy students	Medical students	
Do you think ADR reporting is necessary?	Yes	88.7	82.1	0.01
	No			
Do you think reporting adverse drug reactions is a professional obligation?	Yes	79.4	43.7	0.005
	No			
PV should be taught to all healthcare students during their curriculum?	Yes	95.9	59	0.005
	No			
Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it?	Yes	99	61.1	0.005
	No			
At present ADR reporting is voluntary; do you feel it should be made mandatory?	Yes	89	57.6	0.04
	No			
Purpose of the ADR spontaneous reporting system is to measure the incidence of ADR?	Yes	59.1	52	0.02
	No			
Female patients should be asked if she is pregnant when dispensing medication to them.	Yes	82.5	73.4	0.004
	No			
Do you think that it is necessary to report only serious and unexpected?	Yes	75.3	68.1	0.002
	No			
Serious and unexpected reactions that are not fatal are life-threatening during clinical trials must not be reported?	Yes	95	62.2	0.05
	No			

Continued.

Questions	Variables	Correct answer (%)		P value
		Pharmacy students	Medical students	
Do you know how to manage ADRs in an emergency, from progressing to mortality of patients?	Yes	56.3	50.6	0.01
	No			
Have you ever come across an educational session specifically about PV?	Yes	100	62.5	0.05
	No			
Are you aware of the PVPI of CDSCO, ministry of health, and govt. of India?	Yes	90.9	47.2	0.004
	No			
Non-medical person can report ADR to a nearby healthcare professional?	Yes	65.4	66.7	0.001
	No			
Do you worry about legal problems while you think of ADR reporting?	Yes	50.1	50.3	0.009
	No			
Do you support Direct ADR reporting by patients instead of physicians?	Yes	89.7	54.1	0.03
	No			

PVPI: Pharmacovigilance programme of India.

Table 3 shows perception of ADR, reporting and PV, 88.7% pharmacy and 82.1% medical students answered as ADR reporting is necessary, 79.4% pharmacy and 43.7% medical students were answered as reporting ADR is not a professional obligation. 95.9% pharmacy and 59% medical participants perception as PV should be taught to all health care students during their curriculum, 99% pharmacy and 61.1% medical students answered correctly as it is necessary to confirm that an ADR is related to a particular drug before reporting it, 89% pharmacy and 57.6% medical were answered as ADR reporting should be made mandatory, 59.1% pharmacy and 52% medical students perception as purpose of the ADR spontaneous reporting system is to measure the incidence of ADR. The 82.5 % pharmacy and 73.4% medical students' perception as female patient should be asked if she is pregnant when dispensing medication to them. The 75.3% pharmacy and 68.1% medical students' perception as not only serious and unexpected reactions necessary to report were answered as it is no necessary to report only serious and unexpected. The 95% pharmacy and 62.2% medical were answered correctly for serious and unexpected reactions that are not fatal or life threatening during clinical trial must not be reported. The 56.3% pharmacy and 50.6% medical students answered as they know to manage ADRs in an emergency, from progressing to mortality of patients. The 100% pharmacy and 62.5% medical students were coming across educational session specifically about PV. The 90.9% pharmacy and 47.2% medical students were aware of PVPI of CDSCO, ministry of health, and govt. of India. 65.4% pharmacy and 66.7% medical student perception as non-medical person can report ADR to nearby Health care professional. The 50.1% pharmacy and 50.3% medical student perception as they worried about legal problems while ADR reporting. The 89.7% pharmacy and 54.1% medical student's perception as they support direct ADR reporting by patients instead of physician.

DISCUSSION

We included 607 students from pharmacy and medical, among them 304 students are from the pre-final year, and 303 are from the final year, the total participants were categorized based on gender, age, study course, academic year, and marital status. In the present study, the number of students belonging to the age group of 21-23, 24-26, 27-30, and 31-34 were 527 (86.8%), 60 (9.8%), 19 (3.1%) and 0 (0%) respectively. A study done by Rajiah et distributed participants based on gender as male (25%), female (75%), age to 22 (39.8%), 23 (49.1%), 24 (2.8%), 25 (3.7%), and 26 (2.8%), 27 and 28 (0.9).[14] In the present study, the distribution of students based on gender was female 291 (47.9%), and male 316 (52%) respectively. In the present study, distribution is based on study course Pharmacy 321 (52.8%) and Medical 286 (47.1%) respectively. A study done by Khan et al also distributed participants based on gender male (84), female (115), study course pharmacy (98) and medical (108).[15] The average knowledge score of the respondents was 32%, indicating that there is still much to be done to educate the prescribers regarding ADR reporting.[16]

Are you aware of the term ADRs? Most of the students aware of term ADR pharmacy and medical (92.8% and 92.6%). Sources of the term ADR heard majority of pharmacy and medical students' sources journals (29.2% and 37.4%) and google (52.6% and 27.9%). A study done by Khan et al showed the majority from the internet (60% pharmacy and 30% medical).[15] The term PV, most of pharmacy heard about PV (75.3%), due to lack of curriculum about PV in medical (44.7%) and definition of PV were known correctly (74.4%) pharmacy and (38.4%) medical. A study done by Suyagh et al (27.7%) community pharmacist and (44.9%) hospital pharmacist heard about PV and definition of PV answered correctly (19.2%) community pharmacist and (35.9%) hospital pharmacist.[13] In our study 5.9% pharmacy students reported ADR, no medical student reported ADR and

they reported to an ADR reporting centre. Study done by Sharrad et al how to report of ADR (8.3%) were known to report ADR.[16] We found that perception regarding ADR and PV is moderate due to the lack of education intervention. In present study at present ADR reporting is voluntary, it should be made mandatory perception of pharmacy and medical students (89% and 57.6%), worry about legal problems while think of ADR reporting perception of pharmacy and medical students (50.1% and 50.3%). Likewise, a study done by Binu et al, shows ADR reporting is voluntary, it should be made mandatory (84%) were answered yes, worry about legal problems while think of ADR reporting (80%) answered yes.[12] However, the results must be interpreted with caution, as the results of a single-centre study may not be generalizable to the entire population. Despite this limitation, we believe that our results are a valuable contribution to the existing literature in light of the scarcity of relevant data. Furthermore, our results encourage researchers to investigate this issue by assessing the situation in different pharmacy and medical students in India.

Limitations

This study was conducted for a set number of time-6 months. It was conducted with pharmacy and medical pre- and final-year college students. It was exclusively done in the campus of Adichuchanagiri.

CONCLUSION

This study shows that compared to medical students, pharmacy students had better awareness of ADR reporting and shown good perceptions of PV. All healthcare professionals are responsible for reporting ADRs to reinforce the PV systems. To enhance the knowledge of PV among healthcare students, an instructional intervention ought to be implemented for this gaining knowledge of PV into their everyday clinical practice. This will act as a pre-emptive step to ensure that every healthcare student understands every facet of PV and can minimise or avoid ADR reporting. All healthcare students should view PV and ADR reporting favourably as they prepare to become healthcare professionals.

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