

Knowledge and Perception about Pharmacovigilance among Pharmacy Students of Universities in Sana'a Yemen

GAMIL QASEM OTHMAN¹, MOHAMED IZHAM MOHAMED IBRAHIM², MOHAMMED ALSHAKKA³, MUKHTAR ANSARI⁴, FAROUK AL-QADASI⁵, ABDULSALAM M. HALBOUP⁶

ABSTRACT

Introduction: Pharmacists in community or hospital setting play a key role in reporting Adverse Drug Reaction (ADRs) during practice. Under reporting is considered as a profession malpractice worldwide.

Aim: To determine the level of knowledge and perception about pharmacovigilance and ADRs reporting among final year pharmacy students of Universities in Sana'a Yemen.

Materials and Methods: A cross-sectional study design was conducted among 385 final year pharmacy students. One public and four private universities were selected randomly using a validated self-administered questionnaire. The questionnaire contained data about student demographic data, knowledge and perception about the ADRs. The data was analysed by SPSS program and Chi-square tests were used to assess the significance of association.

Results: The male students were more knowledgeable than female ($p=0.035$), as well as private university students had better ideas on how to report ADRs than public university students ($p=0.009$). Private university students reported that pharmacovigilance topic is well covered in their curriculum compared to public university

students ($p\leq 0.001$). A significant difference was seen amongst the students of public and private universities when asked about reporting ADRs in future, former found more confident ($p\leq 0.001$). Furthermore, the private university students also had more command on the concept of post-marketing surveillance than public university students ($p\leq 0.001$). The private university students in Yemen were more known to causality assessment of ADRs as compared to the students of public universities ($p\leq 0.001$). The results of perception revealed regarding perception toward ADRs and pharmacovigilance. Female students ($p\leq 0.018$) and private universities students ($p\leq 0.001$) had positive perception than male and public university students respectively.

Conclusion: The findings showed poor knowledge among students in Sana'a Universities and positive perception towards pharmacovigilance and ADRs reporting. A poor knowledge among the future pharmacists suggests need for educational interventions and improvement of strategies to ease the reporting mechanisms. Steps can be taken to improve pharmacovigilance tools and methods in Yemen as well as incorporating subjects of pharmacovigilance in the health faculty's curriculum in Yemen.

Keywords: Adverse drug reactions, Pharmacists, Quality of life

INTRODUCTION

Drugs are used to treat illnesses, decrease symptoms, and improve patient health and quality of life. Conversely, taking a drug is not always free of hazards. The administration of drug is also associated with many undesirable or unintended responses referred as Adverse Drug Reaction (ADRs) [1]. There was an increased public awareness pertaining to drug associated ADRs after the US senates passed a bill which aimed at supplying the ADRs information to common public [2]. Therefore, medical practitioners have been advised by several policy makers and highly publicized reports to dedicate more effort to eliminate the ADRs problem [3,4]. Drug use is generally associated with injury that may range from mild to fatal ADRs. Many studies were conducted to determine the incidence of ADR responsible for patient admission, about 5% to 20% of admissions were related to such reaction [5,6]. ADRs are considered one of the major causes of patient related morbidity and mortality [7]. ADRs require special consideration; and they involve academic scientists, pharmaceutical industries, patients, medical professionals and drug regulatory agencies [7].

Pharmacists are one of the healthcare professionals who work in hospitals or communities, and they play important roles in ADRs reporting and pharmacovigilance activities [8]. In this modern era, the pharmacist roles have been motivated from traditional aspects

of preparing, prescribing and dispensing drugs to more vital roles which involve many pharmaceutical care aspects, such as avoiding medication errors and ADRs, improving Quality of Life (QoL), economic outcomes and patient satisfaction [9,10]. Pharmacist is drug expert either in the community setting or in the hospital, and is the one who is more likely to detect ADR during practice than other healthcare providers [10,11]. Therefore, pharmacist should be equipped with good skills and knowledge to identify and resolve drug related problem and educate the patients about the appropriate use of medication [12].

ADRs are also commonly serious enough to result in hospital admissions. They place a significant burden on the services of healthcare. Several studies conducted to quantify ADRs have revealed that these reactions account 6.5% of patient admission [6,13] and 6.7% either inpatient ADRs or causing patient admission to hospital [5]. According to another study, more than 2% of patients admitted with an ADR died. It is evident that the patients' QoL is adversely affected by ADRs resulting in patient's loss of confidence in the healthcare system. It also increases the patient care cost and may lead to lengthening of hospital stay. ADRs may also mimic diseases, leading to delays in treatment and unimportant investigations [6].

Various studies have been performed to evaluate the attitude and knowledge towards ADRs reporting and pharmacovigilance. These studies found that the students have insufficient knowledge about ADRs reporting and pharmacovigilance [14-19]. In Yemen, pharmacovigilance initiatives have been established, but pharmacovigilance related studies among future pharmacists are lacking. This is one of the first studies in Yemen among pharmacy students of private and public universities. There are several important implications of the current study towards pharmacy education in Yemen.

This study was aimed to assess the level of knowledge and perception of the final year pharmacy students about pharmacovigilance activities and ADRs reporting in Sana'a universities.

MATERIALS AND METHODS

A cross-sectional study was conducted between February 2016 and April 2016 among final year undergraduate pharmacy students of the five universities in Sana'a. One university was public and the others four were private universities. Ethical approval was obtained from the Ethical Committee of the University of Science and Technology. Every student was informed about the objectives of the study and consented before participating in the study.

Study Population and Sample

The study was done among all the final year pharmacy students in five universities of Sana'a. There are fourteen pharmacy colleges in Sana'a, one is a public and the others are privates. This study was done in the public university (Sana'a University) and four private universities that were selected randomly by simple random sampling. The students were recruited according to the proportions of students in each university. Students not willing to participate in the study were excluded from the study. Sample size was calculated by using the equation of one proportion formula; {with P: proportion of Internet addiction from previous study in Malaysia (0.556) [14]}. Sample size was calculated as 380 students.

We added 10% to the calculated sample size to overcome the probability of non respondent students, which is 38, so the total sample size needed was 418 students. Of them, 33 students refused to fill the questionnaires and 385 students completed them.

Study Tools Development

The data was collected using a validated self-administered questionnaire. The questionnaire was designed after a detailed review of relevant literatures [16,20]. The questionnaire was written in English and Arabic. The questionnaire was used to assess final year pharmacy students' knowledge and perceptions about pharmacovigilance and ADRs reporting. The questionnaire comprised of 23 questions and it was divided into three portions: the first portion was concerned with students' demographic data. The 10 questions of second portion were related to the pharmacy students' knowledge about pharmacovigilance and ADR reporting. The answer of each question consisted of yes and no answers. Yes answer was considered the correct knowledge for all questions. The third portion of the questionnaire was designed to determine pharmacy students' perception about the ADR reporting. It consisted of 10 questions that based on Likert scale from 1 (strongly disagree) to strongly agree [5]. Strongly agree and agree answers for each questions were considered the positive perception about ADRs reporting except for one question (Serious and unexpected reactions that are not fatal or life threatening during clinical trials must not be reported), strongly disagree and disagree answers were the negative perception.

The questionnaire was tested for its face and content validity. Four independent faculty members from the college of pharmacy evaluated the questionnaire with reference to the relevance, clarity, conciseness of the items and ease of understanding of the questions.

Expert's comments were taken into consideration in the final draft of the questionnaire. Prior to the survey, the questionnaire was piloted among 20 students. Those 20 students were not included in the final analysis.

Data Collection

The questionnaire was handed to the students after explaining to them the purpose of the study. A total of 418 final year pharmacy students were requested to complete the questionnaire and submit it back immediately after they finish answering the questionnaire.

STATISTICAL ANALYSIS

Data were analysed using the Statistical Package for Social Science (SPSS, Version 23.0) for windows version. The level of the statistical significance was set at p-value of <0.05 for all analyses. Descriptive analysis was performed to present the demographic characteristics and dependent variables. Chi-square and Chi-square with Yate correction tests were used to test the significance of association for categorical variables.

RESULTS

[Table/Fig-1] describes the demographic information. Out of 418 final year pharmacy students approached, 385 students gave consent to participate in our study with a response rate of 92.1%, of whom 291 (75.6%) were males. Most 235 (61%) of the students were studying in the private universities and only 150 (39%) in public universities [Table/Fig-1].

Knowledge

The results for knowledge on pharmacovigilance and ADRs reporting based on questions are presented in [Table/Fig-2]. Overall, there were significant differences regarding gender, age and universities. The male students were more knowledgeable than female ($p=0.035$), as well as private students had better ideas on how to report ADRs than public university students ($p=0.009$).

An age less than 23 years were more knowledgeable than the age ≥ 23 years ($p=0.003$). As well as private students had agreed that the topic of pharmacovigilance is well covered in their curriculum than the curriculum of public university ($p\leq 0.001$). Public university student knowledge about reporting of known ADRs makes more significant contribution to the reporting system than private universities students ($p\leq 0.001$).

Male and private universities students knew the different classifications of ADRs more than female and public university students ($p\leq 0.001$, $p=0.033$; respectively). The private universities students had knowledge about the difference between ADR and the adverse event more than public university students ($p\leq 0.001$). Furthermore, the private universities students also had more command on the concept of postmarketing surveillance than public students ($p\leq 0.001$). The private universities students had known about how causality assessment of ADR is done in Yemen more than public university students ($p\leq 0.001$).

Perception

The results of perception on pharmacovigilance and ADRs reporting based on questions are presented in [Table/Fig-3]. The data about

Demographics		Frequency	Percentage (%)
Gender	Male	291	75.6
	Female	94	24.4
Age (years)	<23	58	15.1
	≥ 23	327	84.9
University	Public	150	39.0
	Private	235	61.0

[Table/Fig-1]: Demographic details of respondents (N= 385).

Item	Total		Age (year)				p-value	Gender					University				
			<23		≥ 23			Male		Female		p-value	Public		Private		p-value
	No.	%	No.	%	No.	%		No.	%	No.	%		No.	%	No.	%	
I have an idea of how to report ADRs.	133	34.5	23	39.7	110	33.6	0.375	109	37.5	24	25.5	0.035	40	26.7	93	39.6	0.009
Students can perform adverse drug reactions reporting during their clerkship	216	56.1	36	62.1	180	55	0.321	165	56.7	51	54.3	0.678	81	54	135	57.4	0.506
The topic of pharmacovigilance is well covered in my curriculum	94	24.4	23	39.7	71	21.7	0.003	75	25.8	19	20.2	0.275	7	4.7	87	37.0	<0.001
Reporting of known ADRs makes a significant contribution to the reporting system	312	81.0	46	79.3	266	81.3	0.716	231	79.4	81	86.2	0.144	139	92.7	173	73.6	<0.001
I know the different classifications of ADRs	175	45.5	27	46.6	148	45.3	0.856	156	53.6	19	20.2	<0.001	58	38.7	117	49.8	0.033
Hypersensitivity reactions are related to ADRs	306	79.5	44	75.9	262	80.1	0.459	237	81.4	69	73.4	0.093	124	82.7	182	77.4	0.216
There is a difference between ADRs and the adverse event	258	67.0	41	70.7	217	66.4	0.518	191	65.6	67	71.3	0.312	81	54	177	75.3	<0.001
I know the different types of hypersensitivity reactions	218	56.6	36	62.1	182	55.7	0.364	171	58.8	47	50	0.136	84	56	134	57	0.844
I know what postmarketing surveillance is	224	58.2	31	53.4	193	59	0.428	177	60.8	47	50	0.064	61	40.7	163	69.4	<0.001
I know how causality assessment of ADR is done in Yemen	78	20.3	16	27.6	62	19	0.132	62	21.3	16	17	0.369	11	7.3	67	28.5	<0.001

[Table/Fig-2]: Respondents' knowledge on ADRs reporting and pharmacovigilance.

Note: The answers are for correct ones

Item	Total		Age (year)				p-value	Sex					University				
			<23		≥ 23			Male		Female		p-value	Public		Private		p-value
	No.	%	No.	%	No.	%		No.	%	No.	%		No.	%	No.	%	
ADR reporting should be made compulsory for healthcare professionals	369	95.8	56	96.6	313	95.7	1.000	275	94.5	94	100.0	0.043	147	98.0	222	94.5	0.090
Information on how to report ADRs should be taught to students	374	97.1	55	94.8	319	97.6	0.471	284	97.6	90	95.7	0.562	148	98.7	226	96.2	0.263
With my present knowledge, I am very well prepared to report any ADRs noticeable in my future practice	322	83.6	52	89.7	270	82.6	0.179	236	81.1	86	91.5	0.018	113	75.3	209	88.9	<0.001
Healthcare is one of the most important professions to report adverse drug reactions	360	93.5	52	89.7	308	94.2	0.316	275	94.5	85	90.4	0.163	137	91.3	223	94.9	0.167
Serious and unexpected reactions that are not fatal or life threatening during clinical trials must not be reported	234	60.8	31	53.4	203	62.1	0.274	172	59.1	62	66.0	0.237	98	65.3	136	57.9	0.144
The purpose of ADRs spontaneous reporting system is to measure the incidence of ADRs	327	84.9	49	84.5	278	85.0	0.917	251	86.3	76	80.9	0.203	130	86.7	197	83.8	0.448
Any ADR (serious or non-serious) should be reported spontaneously	350	90.9	52	89.7	298	91.1	0.719	266	91.4	84	89.4	0.548	138	92.0	212	90.2	0.552
Reason for not reporting a suspected ADR is due to the uncertainty of its association with drugs	278	72.2	37	63.8	241	73.7	0.121	212	72.9	66	70.2	0.619	113	75.3	165	70.2	0.274
Patients should be counselled about ADRs every time their medications are dispensed	346	89.9	49	84.5	297	90.8	0.140	259	89.0	87	92.6	0.321	145	96.7	201	85.5	<0.001
Female patient should be asked about pregnancy status during medication dispensing	375	97.4	57	98.3	318	97.2	0.995	284	97.6	91	96.8	0.677	148	98.7	227	96.6	0.359

[Table/Fig-3]: Respondents' perception on ADRs reporting and pharmacovigilance.

Note: The answers are for positive perception

perception revealed that there was positive perception towards ADRs and pharmacovigilance reporting. Female students ($p=0.018$) and private universities students ($p=0.001$) in the question with my present knowledge, "I am very well prepared to report any ADRs noticeable in my future practice" had positive perception than male and public university students respectively. The male students in the public university preferred that patients should be counselled

about ADRs every time their medications are dispensed ($p=0.001$). Additionally, male students also advocated that ADRs reporting should be compulsory for all healthcare professions ($p=0.043$).

DISCUSSION

This is the first study reporting Knowledge, Attitude, and Perception (KAP) of ADR and pharmacovigilance of the final year pharmacy

students of universities in Yemen. The response rate was high (92.1%), high response rate in our study attributed to the help of course coordinators during data administration collection. This result was similar to two different studies conducted in Malaysia and Oakwood which showed response rate as 84% and 91%, respectively [16,21]. The low response rate in the other studies might attributed to that students were off campus for experiential rotations [10], the method of questionnaires distribution was through E-mail [22], or the questionnaires were distributed after the beginning of different classes then collected thereafter as indicated by [18].

After analysis each demographic factor separately, the study found that majority of student were the male (75.6%), our finding were in opposite with previous studies [16,18,21,22].

The present study revealed that more than 65% of the students did not have any idea about how to report ADRs. This finding is in contrast to the report of previous studies conducted among healthcare professionals in Malaysia by Rajiah K et al., Nigeria by Oshikoya KA et al., and in Saudi Arabia by Al-Arifi MN [20,23,24]. The present study revealed that also more than 75% of the students reported that the topic of pharmacovigilance not covered in curriculum, the student feedback on the pharmacovigilance topic opposed to another study from the private universities in Malaysia by Rajiah K et al., [20] and is consistent with study conducted in Malaysia by Elkalmi RM [16].

Eighty percent of the students did not know about how causality assessment of ADRs is done. This finding is similar to the study conducted by Rajiah K et al., which reflects that the students were not fully prepared to contribute towards ADRs reporting in future practice, and the study showed that the private universities students were more knowledgeable than public university students on the causality assessment ($p=0.001$) [20].

Educational training programs can clarify and enhance the knowledge of ADR reporting and how causality assessment of ADRs is done [25-27].

Private universities students and those more than 23-year-old indicated that the topic of pharmacovigilance was well covered in the curriculum ($p=0.001$ and $p=0.003$), respectively.

Male students had an idea about ADRs reporting ($p=0.035$). Additionally, male students and the students of private universities were able to differentiate between different classes of ADRs in better way ($p<0.001$ and $p=0.033$, respectively).

There was significant difference in knowledge among the students belonging to different universities. Understanding the procedure of reporting an ADR reflects the knowledge and attitudes towards the ADR reporting. The results revealed that the students were less knowledgeable regarding ADRs reporting. This result contradicts with the results of the previous study in Malaysia by Rajiah K et al., [20]. It showed that the private universities students were more knowledgeable than public university students and this attributed to the curriculum updating in the private university.

The perception toward ADRs reporting and pharmacovigilance was positive. The finding of this study showed that fifth year pharmacy students were willing to report ADR voluntarily. In addition, majority of the students reported that ADRs reporting should be made necessarily for healthcare professions. The previous findings are in the same line with a study conducted in a private university in Kuala Lumpur, Malaysia [20]. The finding of current study revealed that the majority of the students strongly agreed that pharmacovigilance should be taught to them as they were not sure about their preparedness to report an ADR in the future.

The majority of the students agreed that patients should be counseled about ADRs during dispensing of medications. This is necessary to ensure that the patients are well informed of the adverse reactions caused by the drugs taken. Pharmacovigilance should be taught to undergraduate medical, nursing, pharmacy

curriculum and other healthcare related to ensure a well prepared graduates in future practice. In Yemen, at the time being, there is a very limited educational program for the undergraduate students in the area of pharmacovigilance.

LIMITATION

Limitations of the study are the number of students who participated in this study was relatively small considering the number of students currently enrolled in various universities in Yemen. Additionally, this study was conducted in universities located in Sana'a city only. Knowledge and perception may vary based on the other localities. Hence, this study may not generalize the preception for all pharmacy students in Yemen. Another limitation to this study is that it only surveyed pharmacy students instead the data from other health professional may add more credibility to the study.

CONCLUSION

The findings showed poor knowledge among students in Sana'a Universities and positive perception towards pharmacovigilance and ADRs reporting. This survey strongly suggests that there is a great need of increasing knowledge and creating awareness among pharmacy students so that they can be able to identify the type of ADRs to be reported. Besides, they may need more information on the local pharmacovigilance systems and the ADRs reporting processes.

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PARTICULARS OF CONTRIBUTORS:

1. Associate Professor, College of Pharmacy, University of Science and Technology, Sana'a, Yemen.
2. Professor, College of Pharmacy, Qatar University, Doha, Qatar.
3. Assistant Professor, Section of Clinical Pharmacy, Faculty of Pharmacy, Aden University, Yemen.
4. Associate Professor, Department of Clinical Pharmacy, College of Pharmacy, University of Hail, and Saudi Arabia.
5. Faculty, Department of Community Medicine, University of Science and Technology, Sana'a, Yemen.
6. Faculty, Department of Clinical Pharmacy and Pharmacy Practice, University of Science and Technology, Sana'a, Yemen.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Abdulsalam M. H alboup,
M.Sc. Clinical Pharmacy, College of Pharmacy, University of Science and Technology, Sana'a, Yemen.
E-mail: a_halboob@yahoo.com

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