Original Article

Knowledge and Attitude towards Pharmacovigilance and Adverse Drug Reaction Reporting among Dental Students in a Private University, Malaysia

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ABSTRACT

Objective: This study was conducted among the dental students to evaluate the knowledge and attitude towards pharmacovigilance and adverse drug reactions reporting among the dental students in a private university, Malaysia. **Methods:** The survey was carried out among the pre-final and final year dental students using a pre-validated questionnaire that included the demographics details and survey items related to knowledge and perception aspects towards adverse drug reactions and pharmacovigilance. The questionnaire was distributed to the participants (n=100). A total of 61 questionnaires were duly filled out, giving a response rate of 76.25%. The survey data was analyzed using SPSS version 20. **Results:** The overall mean score on knowledge among the dental students was found to be 15.84. The study also observed that mean score on attitude in pre-final year and final year dental students were 11.03 and 20.44 respectively. The overall mean score for attitude on ADRs reporting and pharmacovigilance was found to be 22.65. **Conclusion:** The results show that knowledge of dental students who participated in the study towards pharmacovigilance and adverse drug reaction reporting was low. However, 15.6% of pre-final year students and 27.6% of final year students expressed positive attitude towards pharmacovigilance and ADRs reporting. As part of future health care professionals, they are expected to have sound knowledge and positive attitude towards pharmacovigilance activities.

Key words: Adverse Drug Reactions, Attitude, Dental Students, Knowledge, Pharmacovigilance.

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INTRODUCTION

Adverse drug reactions (ADRs) are one of the major problems associated with medicines and are recognized hazards of drug therapy. In simple definition, an ADR is any undesirable effect of a drug beyond its anticipated therapeutics occurring during clinical use.[1] World Health Organization (WHO) defined Adverse Drug Reaction (ADR) as "any noxious, unintended and undesired effect of a drug which occurs at doses

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used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiologic function.[2] The two most common types of ADR are type A: augmented, which is dose related effects and type B: bizarre, in which effects related to abnormal interaction between patient and drug.[3] Adverse drug reactions (ADRs) are an important cause of morbidity and mortality[4] and are responsible for a significant number of hospital admissions ranging from 0.3% to 11%.[5,6] Adverse reaction monitoring and reporting are very important in identifying the adverse reaction trends and to minimize or prevent harm to patients arising from their drugs.[7] The etymological roots for the word "pharmacovigilance" are: *Pharmakon* (Greek word for 'drug') and *vigilare* (Latin word for 'to keep watch').[8] According to the World Health Organization, Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problem, particularly long term and short term adverse effects of medicines.[9]

It has been recommended for every country to set up their own pharmacovigilance programs and in the recent past several countries have initiated pharmacovigilance programs to identify the drugs causing ADRs. Under-reporting of ADRs is a common problem in pharmacovigilance program.[10,11] Other reasons for under-reporting would be due to inadequate funds, lack of trained staff and lack of awareness about detection, communication and spontaneous monitoring of ADRs.[12,13] The effectiveness and success of any pharmacovigilance system depends highly on the participation of all health care professionals and thus, dentists are also important healthcare professionals responsible for the pharmacovigilance activities and ADR reporting during their practice. National Adverse Drug Reaction Monitoring Centre is the Malaysian national centre for pharmacovigilance which was initiated in 1987.[14] All ADR reports that have been received and screened by the Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) are submitted to the Uppsala Monitoring Centre in Sweden for inclusion in the WHO database.[15] Several hospitals and pharmaceutical companies operate ADR monitoring systems, however all reports are consolidated by the national centre.[16] Under-reporting of ADR is a global issue of major concern. Malaysian pharmacovigilance also experiences the problem of ADR under-reporting[17] where the major limitation of the programme is lack of awareness among health professionals regarding pharmacovigilance.

Several studies have been conducted to evaluate the knowledge, attitude and practice (KAP) towards pharmacovigilance activity among doctors, pharmacists or nurses in various countries.[18-21] Concluded in their study that resident doctors and nurses had good knowledge and awareness on ADR reporting; however there is need of improvement in their practices.[19] Concluded in their study that the rate of reporting to ADR monitoring centres (AMC) by doctors was low despite having good observation and knowledge of ADR.[20] Conferred in their study that majority of the health care professionals felt ADR monitoring to be important, but only a few had ever reported an ADR to the pharmacovigilance centre. The authors have reported that, the reasons for under-reporting were either they did not come across an ADR or a few were unaware of the existence of a pharmacovigilance centre at the hospital.[21] Concluded that, it is necessary to offer continuous ADR related educational programs until reach the point that voluntary reporting of adverse drug reactions become conventional and habitual among nursing staff. Educational intervention among the dental students is also essential.

Similar studies have been also conducted among medical or pharmacy students in different countries.[22-25] The pharmacy students had strong intentions and favourable attitudes toward ADE reporting but they had inadequate knowledge of how to report serious ADEs. Upadhyaya, concluded that the knowledge of first-year doctors regarding ADR reporting is quite poor. Hence there is a need to incorporate adverse drug reaction (ADR) reporting into undergraduate teaching. concluded in their study that the majority of final-year pharmacy students in Malaysian public universities have insufficient knowledge about pharmacovigilance and ADR reporting. Evaluated the knowledge and attitude among the medical and pharmacy students in a private university in Malaysia and reported that pharmacy students have better knowledge, awareness and understanding towards pharmacovigilance and ADR reporting compared to medicine students.

In spite of studies conducted among different health care professionals and students, there is a lack of information among dental students and dentists in Malaysia on KAP towards pharmacovigilance and ADR reporting. So there is a need to study the awareness among the dental students and dentists as they are also part of the health care team who are responsible to report ADR during their practice if any. Hence this study was designed to examine the knowledge among dental students at a private university in Malaysia. The study also evaluated the knowledge and attitude among pre-final and final year dental students towards pharmacovigilance and ADR reporting.

METHODS

This study was carried out using a pre-validated survey questionnaire among the pre-final and final year dental students in a private university, Malaysia after getting the prior permission from the dean of the faculty. This study was approved by the faculty ethical committee. The questionnaire was adapted from the previously published article[25] and modified according to the need of the present study. The questionnaire was evaluated by the experts from faculty of pharmacy and medicine, AIMST University who have sound knowledge on the topic and their suggestions regarding the relevance, clarity, and appropriateness of the items was considered for inclusion in the questionnaire. In order to test the validity and reliability of the survey form, the revised questionnaire was tested by administering it to a sample of 20 pharmacy students who were taught about the topic. The overall Cronbach's alpha value was 0.73.

The questionnaire was distributed to the pre-final and final year dental students after briefing them on the study objective in their respective classrooms and the participants' informed consent was obtained. The confidentiality of their response was ensured.

The pre-validated questionnaire included the demographics and a total of 29 survey items organized into two sections. The first section included 15 questions to evaluate the participants' knowledge and the second section included 14 elements to study the attitude and attitude of the participants. Knowledge on pharmacovigilance and adverse drug reactions reporting aspects were mainly focused among the students. From the students' response, a score of 1 and 0 was given for each correct and wrong answer respectively. From the participants' response, the mean score was calculated. Five levels likert scaling (1=strongly agree, 2=agree, 3=neutral, 4=disagree, and 5=strongly disagree) was used to analyze the attitude and perception of the respondents.

The data was analyzed using SPSS version 20 program. Descriptive statistical analyses such as frequencies and percentages were used to represent the respondents' demographic information. The relationship between the categorical data was examined with the chi-square test. The mean knowledge score on pharmacovigilance and ADR reporting of pre-final and final year dental students was analyzed using Mann-Whitney U test.

RESULTS

The questionnaire was administered to 100 participants and 61 responses were received back of whom 32 were from pre-final year and 29 were from final year. The response rate was 76.25%. The average time taken to complete the questionnaire was 15 min.

Knowledge analysis and comparison on knowledge of pre-final and final year dental students

The results for knowledge on pharmacovigilance and ADRs reporting based questions are presented in Table 1. Out of the 61 participants, about 24.6% of participants answered correctly for the definition of pharmacovigilance. About 51.7% of students among final year students answered correctly and there were none among the pre-final year students who answered correctly. It was found that 34.4% of participants answered correctly for the question on the important purpose of pharmacovigilance. Among the pre-final year and final year students, 15.6% and 55.2% respectively answered correctly. For the definition of adverse drug reaction, 57.4% of participants answered correctly. It was found that 50.0% of participants among the pre-final year and 65.5% of participants among the pre-final year answered correctly. Only 6.6% of participants answered correctly for the question on which of the phase in clinical trial, the rare ADRs can be identified. It was found that that only 3.1% of the participants answered correctly among the pre-final year and 10.3% of participants answered correctly among the final year. Overall only 1.6% of participants answered correctly for the question on the location of the international centre for adverse drug reaction monitoring. None of the participants from final year answered correctly for this question. However, 3.1% of participants answered correctly among the pre-final year.

It was found that only 3.3% of participants answered correctly on the 'WHO online database' for reporting ADR. Among those who answered correctly, it was observed that 3.1% of participants were among pre-final year and 3.4% of participants were among final year students. About 11.5% of the participants answered correctly for the method employed by pharmaceutical companies to monitor ADR of new drugs after launching them into the market. Among the pre-final and final year students, 9.4% and 13.8% respectively answered correctly.

For the most commonly used scales to establish the causality of an ADR, only 1.6% of participants answered correctly and it was found that none of the participants among final year answered correctly for the this question. However, 3.1% of participants answered correctly among the pre-final year. Similarly for the question on the factor

Table 1: Knowledge assessment on pharmacovigilance and ADRs reporting among pre-final and final year dental students

Questions	Correct response			P-Value
	Pre-final year N=32	Final year N=29	Overall N=61	
Pharmacovigilance is	0 (0%)	15 (51.7%)	15 (24.6%)	<0.05
The important purpose of Pharmacovigilance is	5 (15.6%)	16 (55.2%)	21 (34.4%)	<0.05
Which one of the following best describes the 'Adverse drug reaction'?	16 (50.0%)	19 (65.5%)	35 (57.4%)	<0.05
Rare ADRs can be identified during which of the following phase of a clinical trial	1 (3.1%)	3 (10.3%)	4 (6.6%)	<0.05
The international centre for adverse drug reaction monitoring is located in	1 (3.1%)	0 (0%)	1 (1.6%)	0.252
Which one of the following is the "WHO online database" for reporting adverse drug reaction?	1 (3.1%)	1 (3.4%)	2 (3.3%)	<0.05
Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched into the market?	3 (9.4%)	4 (13.8%)	7 (11.5%)	<0.05
Which of the following scales is most commonly used to establish the causality of an ADR?	1 (3.1%)	0 (0%)	1 (1.6%)	0.252
Which factor will be the cause of ADR under-reporting?	0 (0%)	1 (3.4%)	1 (1.6%)	0.252
Which of the following regulatory body in Malaysia regulates ADR reporting?	0 (0%)	0 (0%)	0 (0.0%)	-
Pharmacovigilance centre in Malaysia was established under	1 (3.1%)	7 (24.1%)	8 (13.1%)	<0.05
Which of the following ADR reporting system is used in Malaysia?	1 (3.1%)	1 (3.4%)	2 (3.3%)	1.000
A serious adverse event is	14 (43.8%)	14 (48.3%)	28 (45.9%)	1.000
A serious adverse event in Malaysia should be reported to the Regulatory body within	0 (0%)	0 (0%)	0 (0%)	-
The most important healthcare professional(s) responsible for reporting ADR in a hospital is/are (Can choose more than one option)	9 (28.1%)	8 (27.6%)	17 (27.9%)	0.266

which will be the of cause ADR under-reporting, it was found that only 1.6% answered correctly. None of the participants among pre-final year answered correctly for this question. However, 3.4% of participants answered correctly among the final year. The next question was on the regulatory body in Malaysia regulating ADR reporting, it was found that none of the participants answered correctly. However, 13.1% knew that the pharmacovigilance centre in Malaysia was established under Drug Control Authority (DCA). It was found that among the pre-final year and final year students, 3.1% and 24.1% respectively answered correctly. For the ADR reporting system used in Malaysia only 3.3% of students answered correctly and among the pre-final year and final year students, it was found that 3.1% of participants among the pre-final year and 3.4% of participants answered correctly among final year.

The next question was on what a serious event is, for which 45.9% students answered correctly. It was found that 43.8% and 48.3% of participants among the pre-final year and final year respectively answered correctly. However, none of the students answered correctly for the question on within how many days a serious adverse event should be reported to the regulatory body in Malaysia. For the last question on the most important health care professions for reporting ADR, about 27.9% of participants answered correctly for which 28.1% of participants among the pre-final year and 27.6% of participants among the final year

answered correctly. The overall mean score for knowledge based questions was found to be 15.84. The mean score for knowledge based questions among pre-final year and final year students was 11.03 and 20.44 respectively.

Attitude analysis towards pharmacovigilance and adverse drug reaction reporting

The results on the attitude towards pharmacovigilance and adverse drug reaction reporting among the pre-final and final year dental students are presented in Table 2. About 96.9% of participants among the pre-final year and 99.6% of participants among the final year participants either strongly agreed or agreed that ADR reporting is necessary. For the attitude towards reporting adverse drug reaction as a professional obligation, 84.4% and 79.3% of participants among the pre-final and final year either strongly agreed or agreed respectively. For the necessity of confirming ADR is related to a particular drug before reporting it, about 81.3% and 79.3% of participants among the pre-final and final year either strongly agreed or agreed respectively.

The participants were asked whether they think ADR reporting should be voluntary for which only 31.2% of participants among the pre-final year either agreed or agreed. However, 48.3% of participants among the final year either agreed or agreed. Similarly the participants were asked whether they think ADR reporting should be compulsory for which, 53.1% and 48.3% participants among the pre-final and final year either strongly agreed or agreed respectively.

For the question on whether it is necessary to report serious and unexpected reactions, 34.4% of participants among the pre-final year and final year either strongly agreed or agreed. About 59.4% of students from pre-final year either strongly agreed or agreed that pharmacovigilance should be taught to all health care students during their curriculum. Among final year students, 79.3% had the same perception. About 18.8% of pre-final year and 10.3% of final year participants either strongly agreed or agreed that the topic on pharmacovigilance is well covered in their curriculum.

The results found that 50% of pre-final students either agreed or agreed that do not have idea on how to report ADRs to the relevant authorities in Malaysia. Among the final year students, about 69% of participants had the same perception. Only 50% of pre-final year participants either agreed or strongly agreed that information on reporting of ADRs should be taught to all health care students during their curriculum. Whereas, 69% of final year participants had the same perception.

About 68.7% of pre-final students have agreed that the information on ADR reporting shall be better learnt during internships. Among the final year, 55.1% of participants agreed to the same. It was found that only 59.4% of pre-final students admitted that pharmacist is one of the most important health care personnel to report ADR whereas, among the final 41.3% of the participants have the same perception. For the students' perception on whether reporting of known ADRs will make any significant contribution to the reporting system, about 18.7% and 20.6% of participants from pre-final and final year respectively either agreed or strongly agreed. Only 21.9% and 24.1% of pre-final and final year students respectively either strongly agreed or agreed that with their present knowledge, they are very well prepared to report any ADRs in their future practice.

The study also found that mean score on attitude and perception in pre-final year and final year students were 32.35 and 25.40 respectively. The overall mean score for attitude and perception on ADRs and pharmacovigilance was found to be 22.65.

DISCUSSION

Adverse drug reactions results in unnecessary health care expenditures through augmented patient morbidity and mortality. Awareness about ADRs among the health care professionals can minimize the factor contributing to adverse drug reaction reporting. Knowledge is a very important factor that influences attitude and practice. Various studies had been carried out in different countries to assess the knowledge of pharmacovigilance among the medical, pharmacy, dental students and practitioners.[21,23-25] The present study was conducted among the pre-final and final year dental students and an overall response rate was 76.25%. From the results, it was noticed that the overall knowledge on the definition of pharmacovigilance was poor among these students. On comparison, final year dental students had better knowledge that pre-final year students. However, a higher percentage of students knew the purpose of pharmacovigilance. The definition of adverse drug reaction was known better by the final year students. The student's knowledge was poor for the question on the phase which rare ADRs can be identified, the location of the international centre for ADR monitoring, 'WHO online database' for reporting ADR, the most commonly used scales to establish the causality of an ADR, cause of ADR under-reporting, regulatory body that regulates reporting in Malaysia. The result were similar to the studies which also revealed that little information on ADRs reporting systems and hence underreporting were

Table 2: Attitude towards pharmacovigilance and adverse drug reaction reporting among pre-final and final year dental students

Questions	Pre Final Year					Final Year				
	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
Do you think adverse drug reaction reporting is necessary?	17 (53.1%)	14 (43.8%)	1 (3.1%)	0 (0%)	0 0%)	16 (55.2%)	12 (41.4%)	1 (3.4%)	0 (0%)	0 (0%)
Do you think reporting adverse drug reaction is a professional obligation?	15 (46.9%)	12 (37.5%)	2 (6.3%)	3 (9.4%)	0 (0%)	14 (48.3%)	9 (31.0%)	4 (13.8%)	2 (6.9%)	0 (0%)
Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it?	10 (31.3%)	16 (50.0%)	5 (15.6%)	1 (3.1%)	0 (0%)	9 (31.0%)	14 (48.3%)	6 (20.7%)	0 (0%)	0 (0%)
Do you think pharmacovigilance reporting should be voluntary?	1 (3.1%)	9 (28.1%)	20 (62.5%)	2 (6.3%)	0 (0%)	6 (20.7%)	8 (27.6%)	10 (34.5%)	5 (17.2%)	0 (0%)
Do you think pharmacovigilance reporting should be compulsory?	5 (15.6%)	12 (37.5%)	15 (46.9%)	0 (0%)	0 (0%)	5 (17.2%)	13 (44.8%)	8 (27.6%)	1 (3.4%)	2 (6.9%)
Do you think that it is necessary to report only serious and unexpected reactions?	3 (9.4%)	8 (25.0%)	11 (34.4%)	10 (31.3%)	0 (0%)	1 (3.4%)	9 (31.0%)	7 (24.1%)	10 (34.5%)	2 (6.9)
Pharmacovigilance should be taught to all health care students during their curriculum.	7 (21.9%)	12 (37.5%)	12 (37.5%)	1 (3.1%)	0 (0%)	7 (24.1%)	16 (55.2%)	6 (20.7%)	0(0%)	0 (0%)
I believe that the topic of pharmacovigilance is well covered in my curriculum.	2 (6.3%)	4 (12.5%)	13 (40.6%)	8 (25.0%)	5 (15.6%)	0 (0%)	3 (10.3%)	7 (24.1%)	11 (37.9%)	8 (27.6%)
I do not have any idea on how to report ADRs to the relevant authorities in Malaysia.	4 (12.5%)	12 (37.5%)	14 (43.8%)	2 (6.3%)	0 (0%)	10 (34.5%)	10 (34.5%)	9 (31.0%)	0(0%)	0 (0%)
Information on reporting ADRs should be taught to all health care students in their curriculum.	8 (25.0%)	16 (50.0%)	8 (25.0%)	0 (0%)	0 (0%)	7 (24.1%)	16 (55.2%)	6 (20.7%)	0 (0%)	0 (0%)
Information on reporting ADRs shall be better learnt during the internship /training/ clinical posting	5 (15.6%)	17 (53.1%)	8 (25.0%)	2 (6.3%)	0 (0%)	6 (20.6%)	10 (34.5%)	13 (44.8%)	0 (0%)	0 (0%)
A pharmacist is one of the most important health care professional to report ADRs.	6 (18.8%)	13 (40.6%)	12 (37.5%)	0 (0%)	1 (3.1%)	1 (3.4%)	11 (37.9%)	16 (55.2%)	0 (0%)	1 (3.4%)
In my opinion, reporting of known ADRs will make no significant contribution to the reporting system.	1 (3.1%)	5 (15.6%)	14 (43.8%)	8 (25.0%)	4 (12.5%)	1 (3.4%)	5 (17.2%)	14 (48.3%)	8 (27.6%)	1 (3.4%)
With my present knowledge, I am very well prepared to report any ADRs notice in my future practice.	1 (3.1%)	6 (18.8%)	22 (68.8%)	2 (6.3%)	1 (3.1%)	2 (6.9%)	5 (17.2%)	8 (27.6%)	5 (17.2%)	9 (31.0%)

the most contributing factor among the doctors.[26-28] also stated in their study that a main reason for under reporting of ADRs was the clinical negligibility of the adverse reaction due to lack of time and little knowledge about the types of reactions to be preferentially reported. Pre-final year students were better aware that the pharmacovigilance centre in Malaysia was established under Drug Control Authority (DCA). However, overall the knowledge was poor. The results show that knowledge among students on what a serious event is was better however; there was no significant difference among the pre-final and final year students. Unfortunately, none of the students were aware on the time period within which a serious adverse event should be reported to the Regulatory body in Malaysia. Only few students were aware that dentists are also important health care professionals to report ADR. This suggests that pharmacovigilance topic is either not incorporated sufficiently or not incorporated in the curriculum and there is need of information regarding the topic among these students. Educational training programs on the topic can enhance their knowledge and perception as recommended by different researchers.[22,29] Pharmacovigilance modules taught to the undergraduate students must be associated to modules on the rational use of medicines.[30]

The results of the present study showed that most of the students had positive perception towards ADR reporting. Most of the students agreed that ADR reporting is a professional obligation. ADR reporting as a professional obligation will have moral binding to healthcare professionals and ethical issues. Previous studies have also reported that ADR reporting should be a professional obligation.[30-32]

About 18.8% of students disagree that only serious and unexpected ADRs must be reported. Similar attitude was also been reported in another study[23] and the study findings are also consistent with Malaysian guidelines for reporting ADRs. About more than 50% of the students in the present study agreed that the topic on pharmacovigilance should be taught to all health care students during their curriculum. This indicated their positive perception for importance of pharmacovigilance. This finding is similar to that of previous report involving healthcare professionals.[22,29,33] Three fourth of the students also agreed that the information on ADR reporting shall be better learnt during internships. But only one- half of the participants perception was that pharmacist is one of the most important health care personnel to report ADR. These findings are similar to the results of healthcare professionals in other studies.[24,33-36]

CONCLUSION

It is essential that ADRs are to be reported and their significance is communicated effectively to the audience for which knowledge and attitude of health care professionals exert a strong influence. The lack of knowledge and negative perceptions about pharmacovigilance and ADR reporting would lead to ADR under-reporting. Overall, the final year dental students had better knowledge that pre-final year students. Fortunately, in the present study, the attitude of the students were positive, however their knowledge has to be increased in some of the aspects of ADR reporting. Creating awareness through educational intervention or training among these health care profession students would help these students to gain knowledge which is very essential for their future practice. This survey will also serve as a preparative measures among these students if they have realized that they are unaware of the answers.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interests

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