

Knowledge, Attitude and Practice of Pharmacovigilance and Adverse Drug Reaction Reporting among Dental Students

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ABSTRACT

Introduction: Pharmacovigilance plays a key role in identifying adverse drug reactions (ADR). The under reporting of ADR by health care professionals is the major drawback for the success of pharmacovigilance program. The dental students are the future prescribers who can play a major role in strengthening the program. The objective of the study was to evaluate the knowledge, attitude, and practice (KAP) of dental students about pharmacovigilance and ADR reporting.

Materials and Methods: A descriptive cross-sectional study was conducted among the third, fourth, final year BDS students and interns of Kantipur Dental College. The study was conducted on January- March 2021 using a structured online questionnaire. A convenience sampling method was used. The median scores were calculated and compared among different subgroups.

Result: A total of 118 students participated in the study. The median attitude score was significantly higher among respondents 20-22 years age group ($p=0.003$). The total median KAP score was also higher among 20-22 years age group. Most of the students 112 (94.9%) atleast knew the definition of adverse drug reactions.

Conclusion: The study showed that students had moderate knowledge and inadequate practice but had positive attitude toward pharmacovigilance. This study highlights the need on awareness about pharmacovigilance among dental students to improve reporting of ADRs and increase the number of reported ADRs.

Keywords: adverse drug reaction; attitude; dentists; knowledge; pharmacovigilance.

INTRODUCTION

Medicines have contributed substantially to treating diseases in the modern era. The use of medicine not only results in beneficial effects but can also cause some unexpected or noxious effects known as adverse drug reactions (ADR). There is a worldwide concern about increasing number of adverse effects caused by drugs.¹ Studies have reported, adverse drug reactions (ADR) as an important cause of morbidity and mortality.² Around 0.2% to 41.3% of emergency hospitalization were due to ADRs, and 28.9% of these were preventable.³ Hence, adverse drug reaction reporting and monitoring is very essential to identify and minimize the adverse reactions and prevent harm to the patients.

Spontaneous reporting of ADRs is an integral part of pharmacovigilance. But under-reporting is the major threat to pharmacovigilance (PV) programs. Study reported that the rate of under-reporting was about 94% and only 6-10% of all ADRs were reported.⁴ This may be due to a lack of knowledge and awareness regarding

detection, communication and spontaneous monitoring of ADRs among the health care providers including physicians, dentists, pharmacists, and nurses. The risk of ADRs cannot be neglected in dentistry as dentists prescribe antibiotics, analgesics, anti-inflammatory drugs and use local anaesthetics during surgical inventions. As a future practitioner and being an important part of the health care system, dental students must be trained to recognize and report ADRs spontaneously. Many studies have been conducted to assess the knowledge, attitude, and practice (KAP) regarding PV among the health care professionals (HCP) and dentists but none of the studies have been conducted among the dental students in Nepal. The objective of this study was to evaluate the KAP of dental students towards PV and ADR reporting in a private dental college.

MATERIALS AND METHODS

A cross-sectional questionnaire-based study was conducted at Kantipur Dental College Teaching Hospital and Research Centre from January to March 2021 among

the third, fourth, final year dental students and interns. Ethical approval was obtained from the institutional review board of the college (Reference Number: 41/020). The convenience sampling method was used to collect the data.

A previously validated questionnaire was used and modified according to the need of the present study.^{3,5-7} Due to the COVID-19 pandemic all face-to-face college activities were suspended so it was not possible to collect the response directly from the students. Hence, a structured online questionnaire was used. The data was collected after taking the respondents' consent online and questionnaire was sent via the social networking sites. Online sessions were conducted for each batch of students to explain the objectives of the study. The time for completing the questionnaire was 30 minutes. The questionnaire included demographic details such as; age, gender and year of study. Section I contained 10 questions to evaluate participants' knowledge of ADR reporting and PV. Each question had a single correct response. The correct response was scored 1 and wrong response was scored 0. The second section contained 5 questions related to the attitude of the participants which were measured using a 5-point Likert scale (viz 5= strongly agree, 4= agree, 3= neutral, 2= disagree, 1= strongly disagree). The third section had 5 questions related to the practice of ADR reporting measured using Yes/No.

The response obtained was analysed using IBM SPSS version 21. Descriptive statistical analyses; frequencies and percentages were used to represent the respondents' demographic information. One sample Kolmogorov

Smirnov test was used to test the normality of the data. The number and percentage of respondents with correct answers to knowledge and practice questions were calculated. The median scores were compared among subgroups of respondents using appropriate statistical tests and p-value less than 0.05 was taken as statistically significant.

RESULT

A total of 118 students participated in the study. The knowledge, attitude, and practice score among the different subgroups of the respondents were compared. The median knowledge score was not statistically significant among the different subgroups. The median attitude score was found to be significantly higher for the students aged 20-22 years as compared to the age group of 23-27 years ($p=0.003$). Similarly, the median total KAP scores were found to be significantly higher for the same group of respondents ($p<0.001$) (Table 1).

Most of the respondents 112 (94.9%) knew the definition of ADR. One hundred and four (88.1%) of the study participants knew that the department of drug administration (DDA) is the regulatory body responsible for monitoring ADR in Nepal. However, only 18 (15.3%) were aware of the existence of the national pharmacovigilance program. In our study 77 (65.3%) students have come across an ADR during their clinical posting but only 6 (5.1%) had reported an ADR to the pharmacovigilance centre (Table 2).

Out of 118 students, females were more 80.5% as compared to males 19.5% and this may be because more female

Table 1: Median scores and interquartile range for different variables among subgroups of respondents

Characteristics		Median knowledge scores (IQR)	P value	Median attitude scores (IQR)	P value	Median practice scores (IQR)	P value	Median total scores (IQR)	P value
Age	20-22 years	6 (2)	0.040	24 (2)	0.003	1 (2)	0.912	31 (3)	<0.001
	23-27 years	6 (3)		23 (3)		1 (1)		30 (4)	
Gender	Female	6 (2)	0.139	24 (3)	0.605	1 (2)	0.056	30 (4)	0.081
	Male	6 (2)		23 (3)		1 (1)		32 (2)	
BDS Year	3 rd year	6 (2)	0.623	24 (2)	0.201	1 (1)	0.907	31 (3)	0.133
	4 th year	6 (2)		23.5 (2)		1 (2)		31 (3)	
	5 th year	5 (3)		24 (3)		1 (1)		31 (4)	
	Interns	6 (2)		23 (3)		1 (2)		30 (4)	

Table 2: Respondents correct answer to the statements for knowledge and practice (n =118)

Knowledge & Practice Statement	n (%)
Pharmacovigilance deals with	83 (73.3)
The main aim of Pharmacovigilance is	79 (66.9)
ADR is defined as	112 (94.9)
The health care professionals responsible for reporting ADRs in hospital is/are	90 (76.3)
Which regulatory body is responsible for monitoring ADR in Nepal?	104 (88.1)
The international center for monitoring adverse drug reaction is located in	52 (44.1)
Do you know the existence of a National Pharmacovigilance program in Nepal?	18 (15.3)
Which of the following scales is most commonly used to establish the causality of an adverse drug reaction?	45 (38.1)
Which one of the following is the WHO online database for reporting ADR?	54 (45.8)
Rare ADR can be identified during which phase of a clinical trial?	43 (36.4)
Have you anytime read an article on prevention of ADRs?	49 (41.5)
Have you ever seen any patient experiencing an ADR?	77 (65.3)
Have you ever seen the ADR reporting form?	6 (5.1)
Have you ever reported ADR to the pharmacovigilance center?	6 (5.1)
Have you ever been trained on how to report adverse drug reaction?	7 (5.9)

Table 3: Demographic characteristics of respondents (n =118)

Characteristic		n (%)
Gender	Female	95 (80.5)
	Male	23 (19.5)
Age (in years)	20-22 years	47 (39.8)
	23-27 years old and above	71 (60.2)
BDS Year	3rd year	34 (28.8)
	4th year	34 (28.8)
	5th year	26 (22.0)
	Interns	24 (20.3)

students are being admitted to the dentistry program in Nepal. Most of the participants 71 (60.2%) were of age 23-27 years and students from the third and fourth year BDS students were more 28.8% (Table 3).

DISCUSSION

This study evaluated the KAP of dental students about ADR reporting and pharmacovigilance. Though numerous studies have been conducted among medical professionals and students, our study focused on the dental students. As dentistry is an important aspect of health care and dentists also prescribe and use medicines such as local anaesthetics, antibiotics, analgesics and anti-inflammatory drugs, etc. all of which can cause ADRs, hence the risk of ADR cannot be ignored in dentistry and the contribution of dentists in improving spontaneous reporting cannot be underestimated.⁸ The total median KAP score of the

respondents was moderate which is similar to the study done by Chhabra et al.⁹ In contrast to our study, the KAP score was low in studies done by Palaian et al.⁷

The main aim of pharmacovigilance is to ensure the patients' safety and the rational use of medicines. The important outcome of pharmacovigilance is to prevent the patients from being affected by the unnecessary negative consequences of medicinal therapy.¹⁰ Under-reporting of ADRs is a common problem in pharmacovigilance programs. The effectiveness of any PV program depends on the participation of all HCPs, and dentists are crucial HCPs for pharmacovigilance activities and ADR reporting. Increased awareness about ADRs among them can improve ADR reporting.

The knowledge score in our study was low which is similar to other studies.^{8,9,11} In contrast, other researchers have

observed moderate knowledge scores.^{6,12,13} The median knowledge scores were also compared among subgroups of respondents according to the demographic variables like age, gender, and level of qualification, though no significant difference was obtained. In terms of age, both the younger (20-22 years) and older (23-27 years) age group had the same level of knowledge. In the younger age group, most of the students had just completed their basic sciences and had been taught about ADRs and PV topics in their pharmacology classes. However, the older age groups are not exposed to the ADR reporting and pharmacovigilance program. Our college does not have a pharmacovigilance centre because of which the students are unaware of ADR reporting and the significance of pharmacovigilance. In the United Kingdom and United States, most medical and dental schools have introduced sessions on the ADR reporting system in the undergraduate syllabus and their skills are also assessed, due to which they have better knowledge scores.^{14,15} In most developing countries including Nepal, the pharmacovigilance program is still at the nascent stage, and this could have contributed to the low knowledge score. To facilitate the activity of PV, it has now become essential to include the Pharmacovigilance activities and ADR reporting system in the early undergraduate curriculum.

A better attitude score among the study participants in this study demonstrates their willingness to contribute to the pharmacovigilance program. A significant difference was seen between the younger and older age group. This indicates that the younger groups are more enthusiastic about being involved in PV-related activities and are aware of the importance of ADR reporting. Comparison with the results of various studies among health care professionals also showed similar findings.^{16,17}

The practice score was low among the study participants which correlates with the study done by Gupta et al, Rani et al and Datta et al.^{6,18,19} This low score can be attributed to the fact that even though they were taught about ADR and Pharmacovigilance during their Pharmacology class, they were not trained to apply this knowledge in practice. Information about the national pharmacovigilance program and its centre and ADR monitoring should be included in the curriculum. Visiting a pharmacovigilance centre, studying its operations, and undertaking the task of completing the ADR reporting form and ADR causality assessment should be included in the practical curriculum.²⁰

Among the three groups, the median total KAP score was

significantly higher among the age group of 20-22 years. This could be explained as the younger age group has just completed their basic science courses as mentioned before; also, they had a better attitude as compared to other subgroups. Knowledge is an important factor that influences attitude and practice. With better knowledge and a positive attitude toward ADR reporting, many interventions can be done such as workshops and seminars to strengthen the system and improve the ADR reporting culture in Nepal. Participants' knowledge regarding the various aspects of PV was average to low. The maximum number of students knew about the definition and aim of pharmacovigilance (73.3% & 66.9%). This result is consistent with the findings by Datta et al and Era et al^{19,21} but is greater in comparison to the study by Rani et al (41%) in Hyderabad and Vakade et al (34%) in Ahmednagar, India.^{18,22} Similarly, 94.9 % of the respondents gave the correct response for the definition of ADR. Our result correlates with other studies.²⁰ For the location of the international centre for monitoring of ADR and the existence of the National Pharmacovigilance program in Nepal, more than half of the participants did not have any idea about it. Our result is consistent with the study conducted by Garg et al and Parthasarathi et al.^{23,24}

The result obtained in our study regarding the practice demonstrated that there was a huge gap between ADRs encountered and ADRs being reported. 65.3% of the participants had come across an ADR during their posting in clinical OPD but only 5.1% had ever reported an ADR to the PV centre. Various studies done among the medical undergraduates and health care professionals had also revealed a huge difference in ADRs encountered and reported. Era et al revealed that 50% of their respondents encountered ADRs but only around 20% were reported.²¹ Similar studies done by Kumari M et al, Meher at al, Gaude at al, Datta S et al showed 75%, 60%, 38.9% 50%, 75% have encountered ADRs among the patients; nevertheless only 25%, 10%, 6.3%, 2.27% 4% had ever reported ADR to a pharmacovigilance center.²⁵⁻²⁸ In countries like England and Sweden, the reporting rate is as high as 70% as reporting is mandatory there.^{29,30}

Under-reporting can be addressed with the coordination and integration of specialists like pharmacologists, skilled physicians, and dentists about PV and ADR reporting. Along with these, strict implementation of legislative norms concerning reporting of ADR can boost spontaneous reporting.

The study was conducted only in one institution so the result obtained cannot be generalized to all the dental

students. Information was collected using a questionnaire and was not triangulated with that obtained from other sources.

CONCLUSION

Our students had moderate knowledge and inadequate practice but have a better attitude toward Pharmacovigilance and ADR reporting. There is an urgent need for the inclusion of PV and ADR reporting in the dental curriculum not only on the theoretical aspects but also on practical implications of the same. This should be incorporated from the first year of study. This will make them aware of pharmacovigilance and ADRs which will certainly help them realize that all medicines can cause adverse effects. Moreover, by participating in the

workshop, and seminars conducted in coordination with the national pharmacovigilance program, they can detect and be able to report any adverse effects. This will help in reducing the rate of underreporting of ADR. Also, the positive attitude of the study participants in the present study can be important for the success of PV activities among dentists in Nepal.

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