Research Article

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Knowledge, Attitude, and Practice of Pharmacovigilance among the Dental Doctors and Interns of Nepal

Ashish Kumar Bhattarai,[1] Marina Vaidya Shrestha,[2] Bhagabat Bhattarai[3]

[1]Department of Pharmacology, Kathmandu Medical College, Duwakot, Bhaktapur, Nepal;
[2]Department of Community Medicine, Kathmandu Medical College, Sinamangal, Kathmandu, Nepal;
[3]Department of Periodontics and Oral Implantology, Dental Programme, Kathmandu Medical College, Duwakot, Bhaktapur, Nepal.

Correspondence :
Dr. Ashish Bhattarai. Email: ashishakb33@gmail.com

ABSTRACT

Introduction: The risk of adverse drug reactions (ADRs) in dentistry is significant. While pharmacotherapy is crucial in treating and managing various dental diseases and conditions, there is often a lack of knowledge, positive attitude, and consistent practice regarding ADR reporting among dentists and other health personnel.

Objective: To evaluate the knowledge, attitude, and practice of dental doctors and interns about the pharmacovigilance.

Methodology: This analytical cross-sectional study was conducted from 2022 January to 2023 February. A convenient sampling method was applied requesting 384 dental professionals directly or online. Participants provided informed consent before completing a semi-structured online questionnaire. The questionnaire consisted of five sections: demographics, knowledge, attitude, practice of pharmacovigilance, and reasons for underreporting ADRs. Ethical approval was obtained, and participant identity was protected. Data were analysed using descriptive statistics (percent, frequency, median), and a p-value <0.05 was considered statistically significant.

Result: Only 214 (55.7%) were aware of the term pharmacovigilance and more than 90% did not know about the reporting site and ways of it. More than 85% agreed the need of it to be trained or taught to dental practitioners. But the practice of institutional reporting of ADR was very low, 240 (62.5%) had never reported the ADR.

Conclusion: These findings reveal that there is lack of knowledge and practice among Nepali Dental practitioners, while most of them are eager to learn and implement. So intervention is required to make aware and train all the practicing Dentist and incorporation of this topic in syllabus of dental schools.

Keywords: Adverse drug reaction; dental; health; pharmacovigilance.

INTRODUCTION

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug effects or drug-related problems and that has expanded to include herbals, traditional medicines, biologics, blood

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products, vaccines, and medical devices.[1] Its goals are to enhance patient care and safety, improve public health, and promote rational and effective medicine use.[2]

In dentistry, pharmacotherapy is crucial for treating and managing various diseases and conditions. Dentists commonly prescribe drugs like antibiotics, analgesics, and anaesthetics, carrying a risk of Adverse Drug Reactions (ADRs).[3] Different dental materials are also attributed to cause adverse drug reactions.[4] Dentists can also identify oral manifestations of ADRs caused by medications patients take for other conditions.[5]

Studies have revealed a lack of knowledge, attitude, and practice regarding ADR reporting among doctors and medical personnel, resulting in low reporting rates in many countries. Despite the presence of numerous Pharmacovigilance centres, reporting remains inadequate.[6] There are many drugs and materials used in dentistry and the absence of rigorous quality control at the government level, it is crucial to raise awareness and encourage reporting among dental practitioners.[4] Proper ADR reporting and documentation are essential for developing improved treatment modalities and guidelines.[7]

This study aimed to assess dental doctors' knowledge, attitude, and practice concerning pharmacovigilance. The findings will highlight the need for increased emphasis on pharmacovigilance education within dental schools and trainings as continuing medical education programs.

METHODOLOGY

This was an analytical cross-sectional questionnaire-based study that was conducted among Dental Consultants General practitioners, Postgraduate residents, and Interns working in different places within Nepal. The Convenient sampling method was done. The sample size was calculated using formula $n = Z^2P(1-p)/d^2$ where n = sample size; Z = level of confidence according to the standard normal distribution (for a level of confidence of 95%, Z = 1.96); p = prevalence of knowledge of pharmacovigilance = 0.517 (51.7%);[8] d = tolerated margin of error;

$n= (1.96)^2 0.517(1-0.517) /(0.05)^2 = 383.71 \approx 384$

All the Dental doctors and Interns working in Nepal were contacted directly or through online method. The purpose of the study was explained. After obtaining the informed consent, they were asked to fill up a semi-structured questionnaire through online questionnaire (Google form).

Ethical clearance and approval were obtained from the Institutional Review Committee (IRC) of Kathmandu Medical College before data collection (Reference number: 0812202103). Verbal and written consent of the participants was taken. Participants' identity was not disclosed.

A 24-item questionnaire which mainly was composed with four sections was used to achieve the study objectives.

Section one: It included four items with main focus on the demographic information of the participant doctors and interns.

Section two: This section was to evaluate the knowledge about the meaning and importance of the Pharmacovigilance. This section comprised of nine questions and answers was classified into yes/no options. A total of more than or equals to four is considered as good knowledge and less than four as poor knowledge. Responses to questions with yes as wrong answer were given negative scoring in analysis.

Section three: This section was to evaluate the attitude of the study population about the importance of the Pharmacovigilance and need of reporting the adverse events. This section comprised of five questions and answers was classified into strongly Disagree, Disagree, Not sure, Agree, strongly agree options. The scores >10 were considered as positive attitude and ≤10 as negative attitude.[9]

Section four: This section was to evaluate the practice of the Pharmacovigilance. This section comprised of five questions and answers was classified into Always, Occasional and Never options. A total score of five or more is taken as good practice and less than five as poor practice.

Section five: This section was to identify the most important reasons for none or under reporting the ADRs.

Day to day supervision of questionnaires was done. Incomplete questionnaires was not selected.

Data were collected from 2022 January to 2023 January, compiled tabulated in Microsoft Excel sheet 2019 and analysed with IBM SPSS Statistics for Windows, version 21 (IBM Corp., Armonk, N.Y., USA). Descriptive data were expressed as percentage, frequency and mean ± standard deviation (SD), p-value of <0.05 was considered to be statistical relevant.

RESULT

Out of a total of 384 participants, 213 (55.5%) were female. The largest group of participants was under 30 years of age, comprising 207 (53.9%) individuals who were general practitioners. Additionally, participants from all the province of Nepal were included, and the majority of participants 199 (51.8%) were from Bagmati province (Table 1).

Knowledge, attitude, and practice regarding pharmacovigilance (Table 2). Only 214 (55.7%) were aware of the term pharmacovigilance and more than 90% did not know about the reporting site and ways of it. More than 85% agreed the need of it to be trained or taught to dental practitioners. But the practice of institutional reporting of ADR was very low, 62.5% had never reported the ADR.

The relationship between demographic variables (age, sex, and level) and knowledge, attitude, and practice scores of pharmacovigilance which revealed several significant findings (Table 3). A strong association was observed between age and knowledge scores (p <0.001). Younger age groups (20-25) showed lower percentages of good knowledge (29%) compared to older groups like 41-45, where 81.6% had good knowledge. There was a significant difference in knowledge scores based on sex (p = 0.02). Males had a higher percentage of good knowledge (67.8%) compared to females

Table 1: Baseline characteristic of the study.

Characteristic		Frequency (%)
Gender	Male	171 (44.5)
	Female	213 (55.5)
Agewise distribution (in years)	20-25	31 (8.1)
	26-30	118 (30.7)
	31-35	71 (18.5)
	36-40	92 (23.9)
	41-45	49 (12.8)
	46 and above	23 (6)
Level	Consultant	130 (33.9)
	General practitioners	207 (53.9)
	Interns	33 (8.6)
	Postgraduate residents	14 (3.6)
Province	Koshi	26 (6.8)
	Madhesh	42 (10.9)
	Bagmati	199 (51.8)
	Gandaki	30 (7.8)
	Lumbini	25 (6.5)
	Karnali	30 (7.8)
	Sudurpaschim	32 (8.3)

Table 2: Knowledge, attitude, and practice of study group towards pharmacovigilance, n (%).

Knowledge related questions	Yes	No
Are you aware of the term "pharmacovigilance"?	214 (55.7)	170 (44.3)
Pharmacovigilance is the science related to detection, assessment, understanding and prevention of adverse effects	267 (69.5)	117 (30.5)
Do you believe all drugs available in the market are safe?	9 (2.3)	375 (97.7)
Is adverse drug reaction reporting important?	356 (92.7)	28 (7.3)
The healthcare professionals are responsible for reporting adverse drug reactions in a hospital	326 (84.9)	58 (15.1)
The purpose of the pharmacovigilance is to report the ADRs due to allopathic and non-allopathic drugs	191 (49.7)	193 (50.3)
The rare adverse effects of drugs are included in Phase II clinical trial	69 (18)	315 (82)
Is there any pharmacovigilance committee in your institute?	25 (6.5)	359 (93.5)
Is there any nearby adverse drug reactions reporting and monitoring centre in your knowledge?	32 (8.3)	352 (91.7)

Attitude related questions	Strongly Disagre n (%)	Disagree n (%)	Not sure n (%)	Agree n (%)	Strongly agree n (%)
Adverse drug reaction reporting is time consuming with no definite outcome.	103 (26.8)	147 (38.3)	99 (25.8)	26 (6.8)	9 (2.3)
Reporting adverse drug reactions will increase patient safety.	9 (2.3)	1 (0.3)	28 (7.3)	201 (52.3)	145 (37.8)
You worry about legal problems while you think of adverse drug reactions reporting.	27 (7)	70 (18.2)	131 (34.1)	129 (33.6)	27 (7)
Pharmacovigilance should be taught in detail to healthcare professionals.	20 (5.2)	-	15 (3.9)	206 (53.6)	143 (37.2)
Adverse drug reactions reporting should be taught in pharmacology practical.	13 (3.4)	4 (1)	21 (5.5)	198 (51.6)	148 (38.5)

Practice related questions.	Always (%)	Occasional (%)	Never (%)
Have you come across any patient experiencing adverse drug reactions in your clinical practice?	13 (3.4)	248 (64.8)	122 (31.8)
Have you ever played any role in reporting Adverse Drug Reactions in your institution or any Pharmacovigilance centre?	25 (6.5)	119 (31)	240 (62.5)
Have you ever counseled patient regarding Adverse Drug Reactions?	121 (31.5)	199 (51.8)	64 (16.7)
Do you keep records of ADR?	41 (10.7)	127 (33.1)	216 (56.3)
Have you ever been trained on how to report adverse drug reaction?	9 (2.3)	24 (6.3)	351 (91.4)

(52.1%). The level of work significantly influenced knowledge scores ($p = 0.02$). Consultants had a higher percentage of good knowledge (55.6%) compared to interns (36.4%). The attitude scores also exhibited a significant relationship with age ($p = 0.015$), indicating that older individuals tended to have more positive attitudes. The highest positive attitude scores were noted in the 26-30 age group. The practice scores do not show significant correlations with any demographic factors.

There is a significant positive correlation (<0.001) between total knowledge score and practice score. The correlation of 0.239 indicates a moderate relationship; as the knowledge score increases, the practice score tends to increase as well. There is

a significant positive correlation (0.004) between attitude score and practice score. The correlation of 0.149 suggests a weak positive relationship; as attitude scores increase, practice scores also tend to increase. There is no significant correlation between total knowledge score and attitude score. The negative value suggests a very weak inverse relationship, but it is not statistically significant, indicating that changes in one score do not predict changes in the other (Table 4).

The predominant reason for underreporting ADRs is "Do not know whom to report" (38.5%). Other Notable Reasons were insufficient clinical knowledge (14.32%) and lack of follow up (11.71%). This indicates a there is significant lack of knowledge among participants regarding the filling and reporting the ADR forms (Figure 1).

Table 3: Demographics of respondents and relationship between KAP score

Variables	Knowledge score		P-value	Attitude score		p-value	Practice score		p-value
	Good n (%)	Poor n (%)		Positive n (%)	Negative n (%)		Good n (%)	Poor n (%)	
Age									
20-25	9 (29)	22 (71)	**<0.001**	24 (6.9)	7 (19.4)	**0.015**	-	31 (9.4)	0.085
26-30	66 (55.9)	52 (44.1)		106 (30.5)	12 (33.3)		9 (22)	107 (32.3)	
31-35	43 (60.6)	28 (39.4)		64 (18.5)	7 (19.4)		12 (29.3)	53 (16)	
36-40	62 (67.4)	30 (32.6)		82 (23.6)	10 (27.8)		11 (26.8)	78 (23.6)	
41-45	40 (81.6)	9 (18.4)		49 (14.1)	-		7 (17.1)	41 (12.4)	
Above 45	7 (30.4)	16 (69.6)		23 (6.6)	-		2 (4.9)	21 (6.3)	
Sex									
Male	116 (67.8)	55 (32.2)	**0.02**	156 (44.8)	15 (41.7)	0.716	21 (51.2)	138 (41.7)	0.245
Female	111 (52.1)	102 (47.9)		192 (55.2)	21 (58.3)		20 (48.8)	193 (58.3)	
Level									
Consultant	115 (55.6)	92 (44.4)	**0.02**	191 (55)	16 (44.4)	0.085	22 (53.7)	176 (53.2)	0.174
General practitioner	90 (69.3)	40 (30.8)		119 (34.2)	11 (30.6)		17 (41.5)	110 (33.2)	
Interns	12 (36.4)	21 (63.6)		26 (7.5)	7 (19.4)		-	33 (10)	
Postgraduate residents	10 (71.4)	4 (28.6)		12 (3.4)	2 (5.6)		2 (4.9)	12 (3.6)	

Table 4: Correlations between KAP scores of pharmacovigilance.

		Total Knowledge score	Attitude Score	Practice Score
Total knowledge score	Pearson Correlation	1	-0.015	0.239**
	Sig.		0.772	0.000
Attitude score	Pearson Correlation	-0.015	1	0.149**
	Sig.	0.772		0.004
practice score	Pearson Correlation	0.239**	0.149**	1
	Sig.	0.000	0.004	

**. Correlation is significant at the 0.01 level

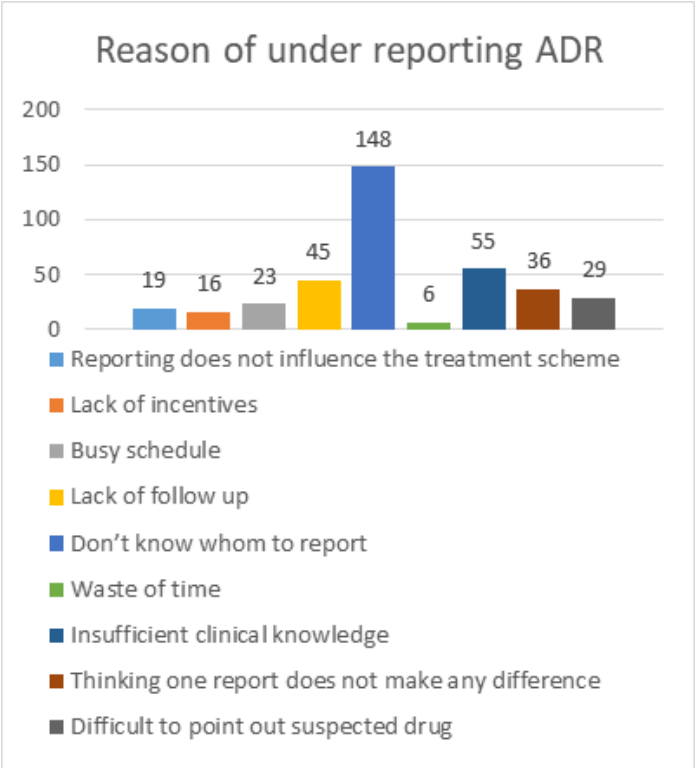

Figure 1: Reasons for not reporting adverse drug reactions.

DISCUSSION

The findings of this study highlight critical gaps in knowledge, attitude, and practice regarding pharmacovigilance among dental practitioners. Notably, only 55.7% of participants recognized the term "pharmacovigilance," indicating a significant need for educational initiatives aimed at enhancing awareness in this area. The fact that over 90% of respondents were unaware of reporting sites and procedures underscores a concerning deficit in practical knowledge that could impact patient safety. Studies done by Chhabra et al.[6] and Khan et al.[10] revealed the similar findings.

Moreover, the overwhelming majority (85%) of participants acknowledged the necessity of training in pharmacovigilance for dental practitioners. This consensus suggests that educational interventions could play a pivotal role in improving both awareness and practice. However, the reported low institutional reporting of ADRs, with 62.5% of participants never having reported any ADRs, emphasises disconnect between knowledge and practice. Similar findings was with the study done with Health care workers (HCW) at Manipal Teaching hospital, Pokhara, Kaski, Nepal.[11] This gap may stem from a lack of confidence in the reporting process or inadequate institutional support.[12]

The analysis demonstrated a strong association between age and knowledge scores ($p < 0.001$), revealing that older dental practitioners possess a significantly higher level of knowledge. Specifically, only 29% of the youngest age group (20-25 years) exhibited good knowledge compared to 81.6% in the 41-45 age group. This trend suggests that years of experience and exposure to clinical practice enhance understanding of pharmacovigilance concepts. Targeted training programs could be beneficial, particularly for younger practitioners, to bridge this knowledge gap. Similar findings was there with the study done by Yip et al.[13] where it was found that higher the duration of the practice more was the awareness on ADR reporting.

The significant difference in knowledge scores based on sex ($p = 0.02$), with males demonstrating a higher percentage of good knowledge (67.8%) compared to females (52.1%), raises questions about the factors contributing to these disparities. There were positive correlations between knowledge and practice scores (correlation = 0.239, $p < 0.001$) and between attitude and practice scores (correlation = 0.149, $p = 0.004$). These findings suggest that increasing knowledge can lead to improved reporting practice. Similar findings were present with the study done by Shakya-Guring et al.[14] where there was weak positive correlation between knowledge and practice and also for attitude and practice among HCWs in one of the tertiary centre in Nepal.

The predominant reason for underreporting ADRs identified in this study- "Do not know whom to report" (38.5%)—along with insufficient clinical knowledge (14.32%) and lack of follow-up (11.71%), underscores a critical area for intervention. These barriers illustrate a significant knowledge gap regarding the ADR reporting process, suggesting that practitioners require clearer guidelines and support systems to facilitate reporting. Such findings are also highlighted in other studies.[10]

This study clearly illustrates the present status of Pharmacovigilance among dental practitioners of Nepal. The need of more training on ADRs and even incorporating in the undergraduate and postgraduate program and need of collaboration with other professions like pharmacy is highly recommended. It has been suggested by other studies as well.[14]

This study was based on cross-sectional design, capturing data at a single point in time, which may overlook evolving attitudes and practices.

CONCLUSION

The knowledge and practice status regarding pharmacovigilance was found to be very poor among Nepali Dentist and interns. There is need of awareness through continuing medical education programs or directly incorporating the subject in the BDS and MDS curriculum.

Conflict of interest: None.

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