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Research Article

Knowledge, Attitude & Practice about Pharmacovigilance among 2nd year BDS students in a tertiary care teaching hospital

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ABSTRACT

Introduction: Medicines have contributed substantially to treating diseases in the modern era. There is a worldwide concern about increasing number of adverse effects caused by drugs. World Health Organization (WHO) defines Pharmacovigilance as "science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems. According to previous studies, there had been a lack of knowledge in dental students regarding Pharmacovigilance and reporting of adverse drug reactions. Hence, this study was planned to assess the knowledge, attitude, and practice of pharmacovigilance in dental student's at a tertiary care teaching hospital.

Material and Methods : This study was a cross-sectional, survey-based study conducted to assess the knowledge, attitude, and practice of pharmacovigilance at a tertiary care teaching hospital in India. The data for this study were collected through a self- designed, semi-structured, pre-validated questionnaire circulated through Google forms to 2nd year BDS students. The results were presented using descriptive statistics such as percentages.

Results : This study shows a knowledge gap about pharmacovigilance. The overall attitude of participants was positive. The study showed overall unsatisfactory practice among participants.

Conclusion : The Continuing Medical Education (CME), Training and group discussions will be required to enhance the knowledge, attitude and practice of IInd year dental students regarding pharmacovigilance

Keywords*: knowledge, attitude, practice, pharmacovigilance, BDS students*

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]World Health Organization (WHO) defines Pharmacovigilance as "science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug related problems."[2]

Central Drugs Standard Control Organization (CDSCO), New Delhi, Ministry of Health and Family Welfare Government of India, had initiated the National Pharmacovigilance (PV) Program in July 2010. The main reason behind initiating this program was to provide information regarding the safety of medicines to health-care professionals, to recommend the regulatory authorities for intervention and to create signals. Although Pharmacovigilance Programme of India (PvPI) contributes to Uppsala Monitoring Centre database due to the lack of vibrant ADR monitoring and reporting system among

the health-care workers, the reports contributed by India are very little only.[3]The major reason behind under reporting of ADRs is due to lack of trained and dedicated staffs and lack of awareness regarding detection, communication and spontaneous monitoring of ADRs among the physicians, dentists, nurses, pharmacists[4,5]

The success of any pharmacovigilance system relies on the active participation of all healthcare professionals, including dentists. Dentists play a crucial role in pharmacovigilance activities and ADR reporting during their practice. Several countries have initiated pharmacovigilance programs, and national centre's consolidate reports from hospitals and pharmaceutical companies.[6] Few studies have been conducted on undergraduate medical and dental students about KAP regarding Pharmacovigilance.[7]So this study was aimed to assess the knowledge, attitude and practice of Pharmacovigilance among 2nd year BDS students at Government Medical College and Hospital, Nagpur, Maharashtra India, regarding pharmacovigilance and ADR monitoring.

MATERIAL AND METHODS

Study design and setting:

This study was a cross-sectional, survey-based study conducted to assess the knowledge, attitude, and practice of pharmacovigilance among IInd year dental students at a tertiary care teaching hospital in India. A self-validated questionnaire consisting of open and close-ended questions were used. The study was conducted after obtaining approval from the Institutional Ethics Committee (IEC), with Reference number: 3642 EC/Pharmac/GMC/NGP/. Electronic informed consent was taken from all study participants.

Study duration:

The study was conducted for a duration of two months, starting from 21st February 2025.The inclusion criteria for participants in this study were IInd year dental students willing to participate in the study. The exclusion criteria were IInd year dental students who provided incompletely filled responses.

Data Collection Methods and Tools:

The data for this study were collected through a self- designed, semi-structured, pre-validated questionnaire circulated through Google forms to IInd year BDS students. The questionnaire consisted of questions related to knowledge, attitude, and practice of Pharmacovigilance. The questionnaire was validated by circulating it to a panel of 10 experts in the subject who were asked to review and evaluate the design, content, and relevance of the questionnaire as well as assess its comprehensibility and readability which was consequently modified slightly based on their feedback. The responses were then collected anonymously.

Study procedure: The questionnaire was structured to obtain the demographics of the participants and total 23 questions– 12 about knowledge, 7 about attitude and 4 about practice designed specifically to answer the awareness about pharmacovigilance. Before commencement of the questionnaire, the objectives of the study were mentioned in the google forms. It was assured that the data which was collected would be used only for research purposes and the findings will not be revealed to anybody.

Statistical analysis:

The collected data and the results were presented using descriptive statistics such as percentages.

RESULTS

A total of 75 IInd year BDS students were involved in questionnaires of pharmacovigilance Among the participants, 57 (76%) were women while 18 (24 %) were men. [Table 1]

About 81.3% participants were aware about pharmacovigilance. About 38.7% participants had the knowledge of the existence of ADR reporting and monitoring systems in India. Participants' awareness regarding location of the National Pharmacovigilance Centre of India was only 11%. According to participants ADR reporting is a professional obligation (61.3%). About 21.3% participants said that they have seen an ADR form by CDSCO. [Table 4]

Table 1: Demographic characteristics of Participants (n=75)

Females	76%
Males	24%

Table 2: Knowledge about Pharmacovigilance among Participants (n=75)

Sr. No	Questions	(Yes)(%)	(No) (%)
1.	**Are you aware of Pharmacovigilance?**	61(81.3)	14(18.7)
2.	**'Pharmacovigilance' is related to?**		

Sr. No	Questions	(Yes)(%)	(No) (%)
	The detection, assessment, understanding and prevention of adverse effect	37(49.3)	38(50.7)
3.	**Do you know the meaning of adverse drug reaction?**	52(69.3)	23(30.7)
4.	**Are adverse drug reactions and adverse drug events the same?**	14(18.7)	61(81.3)
5.	**Are you aware of the existence of ADR reporting and monitoring systems in India?**	29(38.7)	46(61.3)
6.	**Is GMCH Nagpur a recognized reporting centre for Pharmacovigilance?**	70(93.3)	5(6.7)
7.	**Do you know how to report an ADR?**	24(32)	51(68)
8.	**Which of the following should be applicable to ADR reporting?**		
	Compulsory	23(30.7)	52(69.3)
	Voluntary	36(48)	39(52)
	Remunerated	10(13.3)	65(86.7)
	Conceal identity of prescriber	36(48)	39(52)
	Conceal identity of reporter	34(45.3)	41(54.7)
9.	**In India, which regulatory body is responsible for monitoring ADRs?**		
	Central drug standard control organization (CDSCO)	46(61.3)	29(38.7)
	Indian council of medical Research	23(30.7)	52(69.3)
10	**Location of National Pharmacovigilance Centre in India (Ghaziabad)**	8 (11)	67 (89.3)

Figures in parentheses indicate percentages, ADR=Adverse drug reactions, PV=Pharmacovigilance

11. Which of the following Health Professionals are qualified to report adverse reactions of a drug?

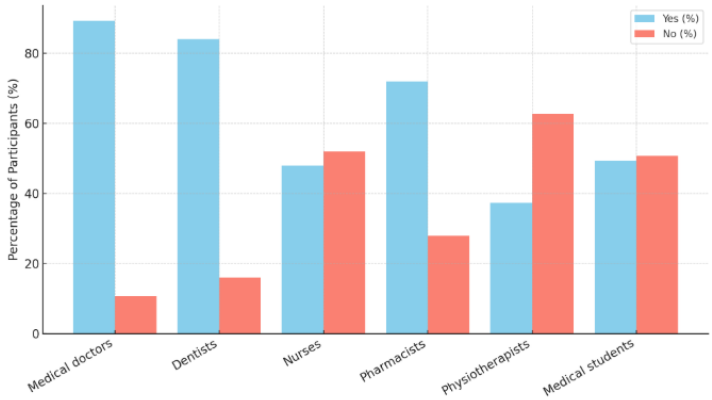

Figure:1 Health care professionals qualified to Report Adverse Drug Reactions

12. What can be done to increase awareness about Pharmacovigilance?

When asked about how to increase awareness about pharmacovigilance, 80% of the participants answered awareness by educational campaign, while 20% answered awareness by Mass media and social media

Table 3 : Attitudes about Pharmacovigilance among Participants (n=75)

Sr. No	Questions	Yes (%)	No (%)	Don't Know (%)
1.	**Do you think that reporting an ADR is a professional obligation?**	46(61.3)	15(20%)	14(18.7)
2.	**Do you feel that ADRs should be reported for newly marketed drugs?**	70(93.3)	5(6.7)	0(0)
3.	**Do you think that dental students can play a role in ADR reporting?**	70(93.3)	5(6.7)	0(0)

4.	**Do you think that reporting benefits both the doctors and the patient?**	70(93.3)	5(6.7)	0(0)
5.	**Do you think reporting of adverse drug reaction is necessary?**	66(88)	9(12)	0(0)
6.	**It is only necessary to report serious or unexpected ADRs?**	30(40)	45(60)	0(0)

Figures in parentheses indicate percentages, ADR=Adverse drug reactions, PV=Pharmacovigilance

7. ADRs with which of the following should be reported?

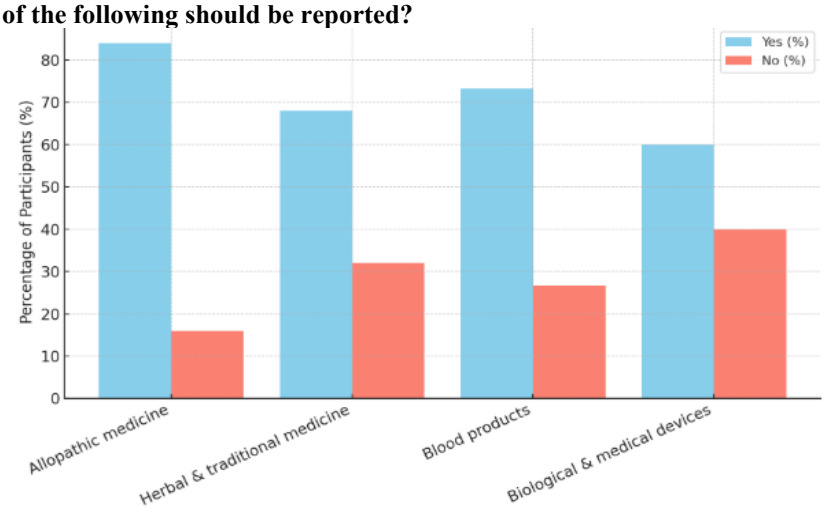

Figure 2: ADRs which should be reported

Table 4 : Practice questions about Pharmacovigilance among Participants (n=75)

Sr.No	Questions	(Yes) (%)	(No) (%)
1.	**Have you ever observed any ADR in a patient?**	22(29.3)	53(70.7)
2.	**Have you seen an Adverse Drug reporting form by CDSCO?**	16(21.3)	59(78.7)
3.	**Which of the following factors discourages you from reporting ADRs?**		
	No remuneration for reporting	22(29.3)	53(70.7)
	Lack of time to report ADR	21(28)	54(72)
	A single unreported case may not affected ADR database	27(36)	48(64)
	Difficult to decide whether ADR has occurred or not	41(54.7)	34(45.3)

Figures in parentheses indicate percentages, ADR=Adverse drug reactions, PV=Pharmacovigilance, CDSCO = Central Drug Standard Control Organization

4. What can be done to facilitate reporting of ADRs?

When asked about what can be done to facilitate reporting of ADRs, 90% of the participants responded to increase awareness about ADRs reporting and 10% didn't have any idea.

Discussion

The current study aimed to assess the knowledge, attitude, and practice of 2nd year BDS students regarding pharmacovigilance and ADR monitoring. A total of 75, 2nd year BDS students were involved in questionnaires of pharmacovigilance. Among the participants, 57 (76%) were women while 18 (24 %) were men in our study. similar findings were seen in study conducted by (Chhabra KG et al, 2016).[8]

In our study, the awareness about the term pharmacovigilance in BDS students was good (81%), however only half of them knew the standard definition of Pharmacovigilance. Similar findings were seen in study carried out by (Gupta et al, 2017).[9]

One of the positive findings of our study was more than half of the participants knew the meaning of adverse drug reaction and majority of the participants were aware that adverse drug reactions and adverse drug events are not the same. These findings are similar to the study conducted by (M Alwhaibi et al, 2020).[10]

Around 40 % of the participants were aware of the existence of ADR reporting and monitoring systems in India. These findings were in contrast to the study conducted by (SA khan et al, 2015) where only very few participants were aware of the existence of ADR reporting and monitoring systems in India. [11]One third of the participants of our study knew how to report an ADR whereas only very few participants knew how to report an ADR in a study carried out by (ZE Ozgen et al, 2021).[12]

In our study, 30 % of the participants reported that it is compulsory to report ADR. These findings were in contrast to the study conducted by (Sidhu GS et al, 2023).[13] Interestingly our study found that majority of the participants agreed that dentists are qualified health professionals to report ADR. These findings are similar to the study conducted by (Kalaikar et al, 2020).[14]

More than half of the participants from our study knew that CDSCO is the regulatory body responsible for monitoring ADRs. These findings were consistent with a study carried out by (Kumar s et al, 2020).[15] Only very few participants were aware that National Coordination Centre (NCC) for Pharmacovigilance is located at Ghaziabad. In contrast to this finding more than half of the participants were aware about that the NCC for Pharmacovigilance is located at Ghaziabad in a study conducted by (Gayathri V et al, 2022).[16]

In our study, Around 61% participants regard ADR reporting as a professional obligation in contrast to in a study conducted by (Era N et al, 2020).[17] Majority of the participants in our study think that ADRs due to Allopathic medicine and for newly marketed drugs should be reported and it benefits both doctors and patients which was similar to the findings in a study conducted by (Kalaikar et al, 2020).[14] Majority of the participants in our study think that it is necessary to report an ADR which was similar to a study conducted by (Kharadi D et al, 2021).[18]

In our study 60% of the participants think that all ADRs should be reported not just serious or unexpected ones. These findings were in contrast to a study carried out by (Khan SA et al, 2015).[11]

In the present study, practice-oriented questions revealed important insights into the engagement of dental students with pharmacovigilance. Only a few of them (29%) had actually observed an adverse drug reaction (ADR) in a patient, in contrast to findings of the study by (Prasad et al, 2021) where 36.4% had observed ADR.[19]

When asked about awareness of the Central Drugs Standard Control Organization (CDSCO) reporting form, only few of them had ever seen the official ADR reporting form. Similar findings have been documented in study done by (Reddy L et al, 2017).[20]

The question on discouraging factors for ADR reporting further highlighted the practical challenges. Half of the participants cited that there was uncertainty in deciding whether ADR has occurred or not lack of time for the reporting ADR (28%), and a single unreported case may not affected ADR database (36%). Contrast results have been seen in study done by (Srinivasan et al, 2017).[21] Although Attitude of the participants were good but knowledge and practice was unsatisfactory.

LIMITATIONS

The study only includes participants from a specific hospital, limiting generalizability of results to other settings or populations. The knowledge and attitudes of healthcare professionals can vary widely based on location and experience. Self-reported data is subject to recall bias and respondent's answer does not justify the actual practice as actual practice was not assessed in the present study.

CONCLUSION

IInd year BDS students showed a positive attitude toward pharmacovigilance, but their knowledge and practice of pharmacovigilance were limited. This findings suggests to incorporate structured training of the pharmacovigilance] to promote patient safety.

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