Original Article

Assessing Knowledge and Attitude of Dental Students and Staffs Towards Pharmacovigilance: A Cross Sectional Pilot Study

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ABSTRACT

Background: The aim of the study was to conduct a comprehensive evaluation of the knowledge and attitude towards pharmacovigilance among dental faculty and students at both the undergraduate and postgraduate levels within India.

Materials and Methods: A survey questionnaire with 18 questions covering participants, knowledge and attitude towards pharmacovigilance and adverse drug reaction reporting was developed in google forms and circulated to faculty and students in a private dental college in Chennai, India. Descriptive statistics were applied to analyse the data.

Result: A majority 38 (51.4%) accurately defined pharmacovigilance and grasped its primary aim of ensuring drug safety. Notably, "Post Marketing Surveillance" emerged as the most widely recognized 36 (48.6%) method for monitoring adverse drug reactions. A significant majority 43 (58.1%) correctly identified renal failure as a major risk factor for adverse drug reactions. Also, JIPMER, Pondicherry, was recognized as a regional center by 26 (31.5%), and Vigibase as the WHO's repository by 22 (29.7%). Respondents emphasized the importance of widespread adverse drug reaction reporting and comprehensive healthcare professional training.

Conclusion: This survey indicates a robust grasp of pharmacovigilance fundamentals among participants. While knowledge is intense, there are opportunities for enhancing specific details and promoting wider awareness in the field.

Keywords: Drug safety, Adverse Drug Reaction, Post Marketing Surveillance.

INTRODUCTION

Adverse drug reactions (ADRs) represent a significant challenge in medicine, constituting recognized hazards of drug therapy. Simply put, an ADR is any undesirable effect of a drug that goes beyond its intended therapeutic outcomes when used in clinical practice [1]. The World Health Organization (WHO) defines ADR as "any noxious, unintended, and undesired effect of a drug occurring at doses used for prophylaxis, diagnosis, therapy, or modification of physiologic function."[2]

ADRs are broadly categorized into two types: type A (augmented), which are dose-related effects, and type B (bizarre), which are related to abnormal interactions between the patient and the drug. [3] These reactions are a significant cause of morbidity and mortality[4] and account for a notable percentage of hospital admissions ranging from 0.3% to 11%[5,6]. Monitoring and reporting of ADRs are crucial in identifying trends and minimizing harm to patients caused by drugs.[7] The term "pharmacovigilance" originates from the Greek word "pharmakon" (meaning 'drug') and the Latin word "vigilare" (meaning 'to keep watch').[8] According to WHO, pharmacovigilance encompasses the science and activities related to the detection, assessment, understanding, and prevention of adverse effects and other potential drug-related problems, particularly the long-term and short-term effects of medicines.[9]

To enhance patient safety, it is recommended that every country establish its pharmacovigilance programs. However, underreporting of ADRs is a common challenge in pharmacovigilance[10,11] due to various reasons, including inadequate funds, lack of trained staff, and limited awareness about the detection, communication, and spontaneous monitoring of ADRs.[12,13]

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 centers consolidate reports from hospitals and pharmaceutical companies.[14]

Despite the global importance of ADR reporting, there is a lack of information regarding the knowledge and attitudes of dental students and dentists. Existing studies have assessed knowledge and attitude among doctors, pharmacists, nurses, and pharmacy students but have not adequately addressed dental students and dentists. This study aims to fill this knowledge gap and shed light on the understanding and behaviour of dental students and professionals in pharmacovigilance, ultimately contributing to the improvement of ADR reporting in the dental field.

METHODS

This study used a comprehensive survey on participants' knowledge and attitudes towards pharmacovigilance, as well as their understanding of adverse drug reaction (ADR) reporting, a structured questionnaire was developed in Google Forms format. This questionnaire comprised 18 questions carefully designed to cover various aspects of pharmacovigilance and ADR reporting. The study was approved by the ethics committee board of Dr. MGR Educational and Research Institute, Chennai, India.

A pilot study was conducted by circulating the above-mentioned survey to the faculty members and students in a private dental college in Chennai, India for a time period of 2 weeks and a total of 74 responses were obtained.

To analyse the data SPSS (IBM SPSS Statistics for Windows, Version 23.0, Armonk, NY: IBM Corp. Released 2015) was used to calculate frequency and percentage of the variables.

RESULTS

Demographics: Totally there were 74 responses with mean age of 24.47±4.37 of which females were predominant 57 (77%), including BDS students 23 (31.1%) and interns 24 (32.4%).

Understanding of Pharmacovigilance: Over half correctly defined it; 38 (51.4%), and most recognized its objective; 42 (56.8%).

Monitoring Methods: Post Marketing Surveillance (PMS studies) was favoured by 36 (48.6%).

Regulatory and Global Perspective: Preferred reporting time frame was 14 days; 21(28.4%), and the International Centre for Adverse Drug Reaction Monitoring was linked with Sweden; 24 (32.4%).

Understanding Risk Factors and Regulatory Bodies: Renal failure was identified as a risk factor by 43 (58.1%), and 34 (45.9%) recognized the Central Drugs Standard Control Organization.

Assessment Tools: The Naranjo scale was favoured by 16 (24.3%).

Regional Centers and Databases: JIPMER, Pondicherry, was recognized as a regional center by 26 (31.5%), and Vigibase as the WHO's repository by 22 (29.7%).

Rare ADR Identification: Acknowledgment of potential rare ADRs during phase-4 trials by25 (33.8%).

Responsibility and Challenges: Most recognized their reporting responsibility 45 (60.8%), with 27 (36.5%) facing challenges in determining ADRs.

Future Considerations: Majority favoured hospital-based ADR centers; 40 (54.1%), emphasized ADR reporting by 30 (40.5%), and supported education by 40 (54.1%) for health care professionals.

Table 1: Demographic details of the participants:

	Options	Frequency	Percent
Gender	Male	17	23.0
	Female	57	77.0
Are you currently working in any private clinic	5-10 years	3	4.1
	Less than 5 years	23	31.1
	More than ten years	4	5.4
	No	24	32.4
	Yes	20	27.0

Table 2: Assessment of knowledge and attitude towards pharmacovigilance:

Questions	Options	Frequency	Percent
Which of the following statement defines the term pharmacovigilance	The science of monitoring Adverse Drug Reactions (ADR) happening in a hospital	11	14.9
	The process of improving the safety of Drugs	7	9.5
	The detection, assessment, understanding & prevention of adverse effects of medications	38	51.4
	The science detecting the type & incidence of ADR after drug is marketed.	14	18.9
	Don't know	4	5.4
The important purpose of pharmacovigilance is (most appropriate)	To identify safety of drugs	42	56.8
	To calculate incidence of ADR's	11	14.9
	To identify predisposing factors to ADR	13	17.6
	To identify unrecognized ADR's	3	4.1
	Don't know	5	6.8
Which of the following methods is commonly employed by the	Meta analysis	5	6.8
	Post Marketing Surveillance (PMS studies)	36	48.6
	Population studies	12	16.2

pharmaceutical companies to monitor adverse drug reactions of new drug once they are launched in market	Regression analysis	2	2.7
	Don't know	19	25.7
A serious adverse event in India should be reported to the regulatory body within	One day	9	12.2
	Seven Calendar days	17	23.0
	Fourteen calendar days	21	28.4
	Fifteen calendar days	8	10.8
	Don't know	19	25.7
The International centre for adverse drug reaction monitoring is located in	United states of America	18	24.3
	Australia	9	12.2
	France	5	6.8
	Sweden	24	32.4
	Don't know	18	24.3
One of the following is a major risk factor for the occurrence of maximum adverse drug reaction	Arthritis	5	6.8
	Renal failure	43	58.1
	Visual impairments	10	13.5
	Vacuities	7	9.5
	Don't know	9	12.2
In India which regulatory body is responsible for monitoring of adverse drug reaction	Central Drugs Standard Control Organization	34	45.9
	Indian Institute of Sciences	3	4.1
	Pharmacy Council of India	16	21.6
	National medical council (NMC)	9	12.2
	Don't know	12	16.2
Which of the following scales is most commonly used to establish the causality of an ADR	Hartwig scale	4	5.4
	Naranjo scale	16	24.3
	Schumock and Thornton scale	12	16.2
	Karch and Lasanga scale	8	10.8
	Don't know	32	43.2
Which among these is a regional pharmacovigilance centre in southern region	Kasturba Hospital, Manipal	6	8.1
	JIPMER, Pondicherry	26	31.5
	JSS Medical Collee & Hospotal, Mysore	10	13.5
	CMC Vellore	11	14.9
	Don't know	21	28.4
Which one of the following is the WHO online data base for reporting ADR	ADR advisory committee	15	20.3
	Medsafe	6	8.1
	Vigibase	22	29.7
	MedWatch	7	89.5
	Don't know	24	32.4
Rare ADRs can be identified in the following phase of a clinical trial	During phase-1 clinical trials	7	9.5
	During phase-2 clinical trials	10	13.5
	During phase-3 clinical trials	14	18.9
	During phase-4 clinical trials	25	33.8
The health care professional responsible for reporting ADR in a hospital	Doctors	8	10.8
	Pharmacists	7	9.5
	Nurses	8	10.8
	All of the above	45	60.8
	Don't know	6	8.1
	Non remuneration for reporting	6	8.1

What according to you discourages a practitioner from reporting Adverse drug reaction	Lack of time to report ADR	9	12.2
	A single unreported case may not affect ADR database	16	21.6
	Difficult to decide whether ADR has occurred or not	27	36.5
	Not encountered any patient with ADR	16	21.6
What is your opinion about establishing ADR monitoring centre in every hospital	Should be in every hospital	40	54.1
	Not necessary in every hospital	15	20.3
	One in a city is sufficient	11	14.9
	Depends on number of bed size in the hospitals.	8	10.8
Reporting of adverse drug reaction is necessary (statement question)	Strongly Agree	22	29.7
	Agree	12	16.2
	Neutral	9	12.2
	Disagree	1	1.4
	Strongly disagree	30	40.5
Have you anytime read any article on prevention of drug reaction	Yes	43	58.1
	No	31	41.9
Have you ever been trained on how to report adverse drug reaction	Yes	27	36.5
	No	47	63.5
Do you think pharmacovigilance should be taught in detail to all healthcare professionals?	Maybe	30	40.5
	Yes	40	54.1
	No	4	5.4

DISSCUSSION

Demographic Insights:

Our survey had total of 74 responses that comprised students and staffs of a private dental college in Chennai, India. The respondents were predominantly female, comprising 57(77%) of the total, highlighting a substantial presence of women in dental health care professions. Approximately 20 (27%) of respondents had practical experience in private clinics, indicating varied levels of professional exposure.

Understanding of Pharmacovigilance:

The survey uncovered a commendable grasp of pharmacovigilance principles among participants. Over half 38 (51.4%) correctly defined pharmacovigilance as the systematic process encompassing the detection, assessment, comprehension, and mitigation of adverse medication effects. Moreover, an overwhelming majority 42 (56.8%) aptly recognized the paramount objective of pharmacovigilance, which is to ensure the safety of pharmaceutical products. According to the study by Nisa et al, healthcare professionals have strong understanding of pharmacovigilance (83.1%).[15]

Monitoring Methods:

Our findings spotlighted Post Marketing Surveillance (PMS studies) as the go-to mechanism employed by pharmaceutical enterprises to scrutinize adverse drug reactions (ADRs). Impressively, nearly half 36 (48.6%) of the respondents endorsed this method, demonstrating an acute awareness of the practical applications of pharmacovigilance.

Regulatory and Global Perspective:

The present study unraveled variations in the reporting time frame for serious adverse events in India. Notably, the most favored time frame was 14 calendar days as reported by 21 (28.4%) of the study participants. Furthermore, the study population commonly associated the International Centre for Adverse Drug Reaction Monitoring with Sweden 24 (32.4%), reflecting a global perspective on pharmacovigilance networks.

Understanding Risk Factors and Regulatory Bodies:

A substantial majority 43 (58.1%) correctly identified renal failure as a pivotal risk factor for ADRs. This reflects an acute awareness of the significance of identifying such risk factors. Additionally, the Central Drugs Standard Control Organization was appropriately recognized as India's primary regulatory body for ADR monitoring by 34 (45.9%) of respondents, indicating familiarity with regulatory oversight in the field. Also, according to "A Pharmacovigilance study conducted by the medicine department of a Tertiary care hospital in Chhatishgarh, Jagdalpur, India, gastrointestinal side effects were most commonly reported, followed by skin and subcutaneous problems.[16]

Assessment Tools:

In the context of causality assessment, the Naranjo scale emerged as the favored tool, with 16 (24.3%) of participants indicating its use. This choice highlights the practicality and relevance of this assessment scale.

Regional Centers and Databases:

It was noteworthy that a significant portion of participants 26 (31.5%) identified JIPMER, Pondicherry, as a regional pharmacovigilance center in the southern region, reflecting awareness of regional hubs. Additionally, 22 (29.7%) recognized Vigibase as the WHO's online repository for reporting ADRs, showcasing their familiarity with international pharmacovigilance resources.

Rare ADR Identification:

The survey results revealed that a substantial number of participants, 25 (33.8%), acknowledged the potential for identifying rare ADRs during phase-4 clinical trials, underlining the importance of ongoing drug safety monitoring.

Responsibility and Challenges:

An encouraging majority 45 (60.8%) of the study participants expressed a recognition of their responsibility in reporting ADRs. Nevertheless, a notable challenge emerged in the form of the difficulty in determining whether an ADR had occurred, cited by 27(36.5%) of respondents. This underscores the complexity of pharmacovigilance and the need for enhanced reporting mechanisms. The study was conducted in Spain, where the primary issue reporting of ADRs, was discovered as difficulty in ADR diagnosis. [17]. Chatterjee et al. conducted a study revealing clinical negligence or insufficient reporting of ADRs by doctors. This was attributed to a lack of time and limited understanding of the types of reactions that should be recorded.[18]

Future Considerations:

Looking ahead, the survey portrayed a prevailing sentiment among respondents. A majority 40 (54.1%) advocated for the establishment of ADR monitoring centers in every hospital, emphasizing their commitment to advancing drug safety. Furthermore, reporting adverse drug reactions was deemed necessary by 30 (40.5%) of participants, reinforcing the significance of this practice. Additionally, a substantial proportion 40 (54.1%) supported comprehensive pharmacovigilance education for all health care professionals, underscoring the importance of continued learning in this critical domain. A survey done in the UAE indicated that 81% of medical doctors were unaware of how to report an ADR and 56% were unclear of where to submit an ADR.[19]

CONCLUSION

The present study underscores the critical importance of pharmacovigilance within the healthcare domain. While prior research has primarily targeted physicians, nurses, and pharmacists, a discernible knowledge gap exists among dental students and staff. There exist challenges in reporting adverse drug reactions and causality assessment emphasizing the need for continuous education and robust support. Establishing ADR monitoring centers and offering comprehensive training emerge as promising strategies for the future, ensuring enhanced patient safety and elevated health care standards.

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