



Original Research Article

Knowledge and attitude towards pharmacovigilance among the dental undergraduates in a private dental college and hospital

Venkatesan Gayathri¹, Subbiah Vijayalakshmi^{1,*}, T.A.R Raja¹

¹Dept. of Pharmacology, Melmaruvathur Adhiparasakthi Institute of Medical Sciences and Research, Tamil Nadu, India



ARTICLE INFO

Article history:

Received 02-09-2022

Accepted 08-09-2022

Available online 28-09-2022

Keywords:

Adverse drug reactions

Attitude

Dental undergraduates

Knowledge

Pharmacovigilance

ABSTRACT

Background: Pharmacovigilance(PV) plays an indispensable role towards patients safety by focusing on Adverse Drug Reactions(ADRs). Although, under reporting of ADRs remains its prime concern globally, mainly influenced by insufficient knowledge and poor attitude of health care professionals towards spontaneous ADR reporting. This current study includes budding second year dental graduates as they also form the futuristic circle on prescribing diverse forms of medications. Hence, aim of this study is to evaluate the knowledge and attitude towards PV and ADR reporting among dental undergraduates.

Materials and Methods: This questionnaire based cross sectional study was conducted in the department of Pharmacology with total 101 second year dental undergraduates, after receiving the proper IEC approval. A pre-validated questionnaire comprised of two division, first division (Q:1-10) analysed knowledge domain whereas second (Q:11-20) analysed attitude, were distributed to all participants with maximum time limit of 30 minutes. Then all the responses were tabulated & analyzed using SPSS 20.0 version.

Result: Mean age of study participants was 20.35 ± 0.67 involves 69.3% were female participants and 30.7% male. Out of 101 participants 78.6% has adequate knowledge about PV and 72.4% has better attitude towards ADR reporting.

Conclusion: The above results indicates that the knowledge and attitude towards PV and ADR reporting among dental undergraduates were satisfactory. Henceforth, this improving status affirms the positive tendency about PV and also conferring an assurance that our future professionals can minimize the under-reporting of ADR effectively.

This is an Open Access (OA) journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprint@ipinnovative.com

1. Introduction

“The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem” is called Pharmacovigilance(PV) as per the World Health Organization(WHO).¹ The main objective of PV is to enhance patient safety through tracking and reporting the adverse drug reactions(ADR). ADR surveillance during drug discovery and development; Encouraging health care professionals(HCP) on rationale prescription;

Enlightening knowledge about PV and ADR reporting to Health care students, professionals and public's are the vital elements necessary to effectuate the public health care system through PV.²In brief, PV significantly concerns on ADRs, which is an “noxious and unintended response to the drug occurring at doses normally used in human for the prophylaxis, diagnosis or treatment of disease or for the modification of physiological functions”. It also extended its target to include the blood products; vaccines; biological; medical devices; herbal drug products; traditional and complementary medicines.³

Though, India underwent series of formidable challenges earlier on PV programs. Later, the Indian

* Corresponding author.

E-mail address: racingvega123@gmail.com (S. Vijayalakshmi).

government recognized the significance and need for the refinement of ADR monitoring and launched an new framework called “The Pharmacovigilance Programme for India (PvPI)”.⁴ It is then coordinated by the Indian Pharmacopoeia Commission(IPC) as the National Coordination Centre(NCC) during 2011 with a goal to prompt ADR reporting nurture instead looking for the quality of reports and it was proposed to familiarize the HCP to report the ADRs despite of limited data available.^{4,5} After which, PVPI was functioning efficiently with 567 ADR monitoring centres(AMC), initiating with 22 centres in 2010 and a recent report asserts that India has contributed more than 2,80,000 individual case safety reports(ICSRs) to vigibase.^{5,6}

Although, under reporting being the massive hindrance of PV globally. For which, India has adopted an reporting methodology called spontaneous ADR reporting system, as it is worthwhile in discovering rare, unexpected ADRs as quick as possible.⁷ On that ground, Knowledge and Attitude being the critical elements directly influencing the spontaneous ADR reporting status.^{8,9} Hence, it is very essential for every health care worker to be aware of what to, where to, how to report ADRs. As dental professionals also embraced in prescribing diverse forms of medications, their ADR reporting culture is also tremendously required.^{10,11} Thus aim of the current study is to evaluate the knowledge and attitude towards Pharmacovigilance and ADR reporting among dental undergraduates.

2. Materials and Methods

After receiving the approval from IEC (MAPIMS/IEC/52/2021 - 180(12)2021) this cross sectional questionnaire based study was conducted in the department of Pharmacology, Melmaruvathur Adhiparasakthi Institute of Medical Sciences and Research in collaboration with Adhiparasakthi Dental College and Hospital, Melmaruvathur Tamil Nadu. Total 101 second year dental students were included in the study with prior acquirement of written informed consent from them. A Pre-validated questionnaire were distributed to all participants, those questions are derived from extensive search of literatures and were validated by the experts of Pharmacovigilance committee – AMC, MAIMSR. It is comprised of two division, first division to analyse knowledge domain (Q:1-10) whereas second to analyse attitude domain (Q:11-20). Each participants were given maximum time limit of 30 minutes to fill questionnaire. For any clarification needed in understanding the questions additional time were provided. All the collected data are tabulated & analyzed statistically using SPSS 20.0 version and expressed in terms of frequency, mean, or percentages.

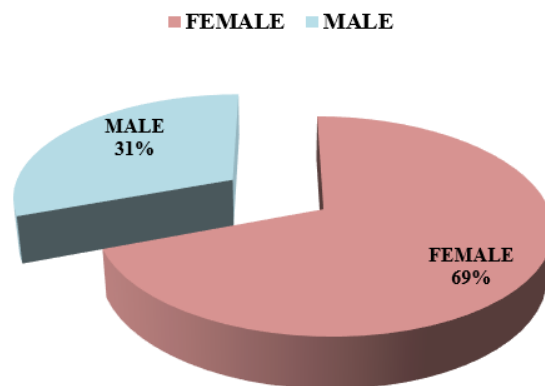


Fig. 1: Shows gender distribution

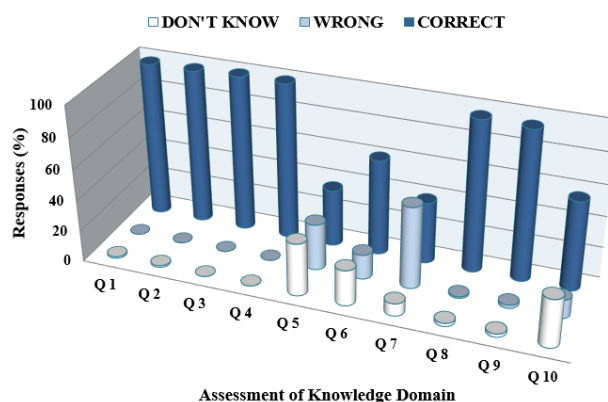


Fig. 2: Shows the participants responses for knowledge assessment questions about Pharmacovigilance and ADR reporting.

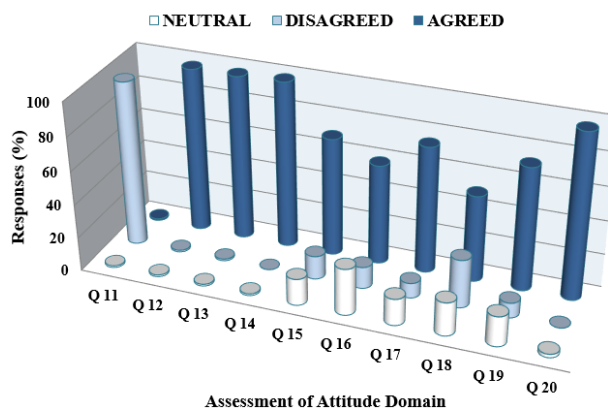


Fig. 3: Shows the participants responses for attitude assessment questions about Pharmacovigilance and ADR reporting.

3. Results

Out of total 101 participants, predominant were females with 69% and males were 31% (Figure 1). Mean age of study population were 20.35 ± 0.67 . All the 101 participants agreed that the important purpose of PV is to identify the safety of drug and drug related problems. 99% of participants were familiar with the term PV and its WHO definition. Awareness regarding ADR definition and WHO online database were 97% and 96% respectively, whereas regarding ADR causality assessment scale only 36.6% were aware. 61.4% responded that ADRs can also be identified during phase 4 clinical trial and 57.4% participants know that IPC, located at Ghaziabad functioning as NCC for PvPI since 2011. But only 39.6% were aware of international ADR monitoring centre location.

On assessing attitude towards ADR reporting only 1% agreed to report other ADRs apart from serious and unexpected ADRs, 99% consent that PV is essential in the curriculum of health care students. 98% admit that ADR might result in prolonged hospitalization or even death and in extreme cases, NCC can ban particular drug. 98% accepted that ADRs can be reported by health professionals other than doctor. 75.2% are agreed to the availability of consumers ADR reporting form, whereas only 59.4% sensed on android application ADR-PvPI And 70.3% knows that Haemovigilance, Materiovigilance, Biovigilance comes under PvPI. 51.5% stated that ADR form can be submitted to NCC-PvPI directly and 73.3% accepted that NCC-PvPI involved in final analysis before forwarding to global database. Thus, on average 78.6% has responded correct for knowledge domain assessment and 72.4% has showed better and appropriate attitude towards PV and ADR reporting.

4. Discussion

The genuine attempt of this present questionnaire based study has explored a satisfactory result, showing an average of 78.6% participants had adequate knowledge and 72.4% had better attitude towards PV and ADR reporting. On assessing knowledge domain 100% of the participants precisely aware of the purpose of PV, which is considered the most superior result of our study. Similarly > 95% exhibited higher level of knowledge upon ADR definition and WHO online database. Hence these results are highly satisfying compared to other similar KAP studies.^{12,13}

But, while assessing the attitude domain, one of the result were unanticipated that 99% of the participants disagreed to report ADRs other than serious and unexpected ADR which is highly contrasting the result of an Malaysian KAP study.¹³ This provides an implicit result that student still unclear on "what to report". Even though indirectly delivers an positive approach that 99% were agreed to report serious and unexpected ADR, which is the most appropriate attitude that is required for further enhancement of the spontaneous ADR reporting culture. Similarly 98%

dental students attitude towards the essentiality of PV in curriculum is comparatively elevated from other similar studies.¹³⁻¹⁵

This results imply that basic understanding about Pharmacovigilance among the dental students is enhancing and they also show relative interest towards ADR reporting. Henceforth, this improving status conferring an assurance that our future professionals can minimize the under-reporting of ADR effectively, ultimately it will influence the furtherance of PV and ADR reporting system. To sustain the progress, we emphasize the concerned authoritative to adhere constantly on organization of awareness and training programs regarding what to, who to, where to report for the upcoming pillars of practice, to improve the patient safety. This will also benefit the aspiring future doctors by slendering the distance between academic knowledge and clinical practice. Hence, we conclude our dental undergraduates possess appreciable knowledge and attitude towards PV and ADR reporting and affirms students positive tendency about PV.

5. Source of Funding

None.

6. Conflict of Interest

None.

7. Acknowledgement

We would like to express our sincere thanks and gratitude to all participated dental undergraduate students for their valuable time and support.


References


1. Jeetu G, Anusha G. Pharmacovigilance: a worldwide master key for drug safety monitoring. *J Young Pharm.* 2010;2(3):315-20.
2. Rohilla A, Singh N, Kumar V, Sharma MK, Dahiya A. Ashok Kushnoor; Pharmacovigilance: Needs and Objectives. *J Adv Pharm Edu Res.* 2012;2(4):201-5.
3. Kumar M, Garg R, Patil HC, Patil RK. Effective Communication in Pharmacovigilance : Role & Set Up. *Int J Emerg Technol Innov Res.* 2020;7(4):1593-1602.
4. Gupta M, Kharb P, Kalaiselvan V, Shridhar M, Singh GN, Kshirsagar N. Safety of Med. *Safety of medicines WHO Drug Information.* 2018;32(1):10-7.
5. Vivekanandan K, Rishi K, Prasad T, Arunabh T, Singh GN. Status of documentation grading and completeness score for Indian individual case safety reports. *Indian J Pharmacol.* 2015;47(3):325-7.
6. Pharmacovigilance Programme of India. . Available from: <https://www.ipc.gov.in/PvPI/adr.html>.
7. Era N, Mukherjee S, Bordoloi SK. Assessment of Knowledge, Attitude, and Practice of Pharmacovigilance among Undergraduate Medical Students in a Tertiary Care Teaching Hospital of Eastern India: A questionnaire-based study. *Natl J Physiol Pharm Pharmacol.* 2020;10(06):460-3.
8. Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance Programme of India: Recent developments and future perspectives. *Indian J Pharmacol.* 2016;48(6):624-8.

9. Jadhav A, Chandrikapure A, Tarte P. Pharmacovigilance in Dental Practice: A study to evaluate Knowledge, Attitude and Practices (KAP) of reporting of Adverse Drug Reactions (ADR) among Dental Practitioner in a city of central region of Maharashtra India. *Int J Dent.* 2017;2(2):14-8.
10. Chhabra C, Chhabra KG, Sharma A, Goyal A, Rajesh G, Binnal A. Pharmacovigilance: the least understood and least practiced science in dentistry. *World J.* 2019;10(5):402-6.
11. Sankaran S, Madhavan A, Balasubramani S. Attitude of dentists toward pharmacovigilance and reporting adverse drug reactions: A cross-sectional study. *J Adv Clin Res Insights.* 2016;29(2):242-7.
12. Shalini S, Mohan S. Knowledge and Attitude towards Pharmacovigilance and Adverse Drug Reaction Reporting among Dental Students in a Private University Malaysia. *J Young Pharm.* 2015;7(2):118-25.
13. Chhabra KG, Sharma A, Chhabra C, Reddy JJ, Deolia SG, Mittal Y. Knowledge, Attitude, and Practices regarding Pharmacovigilance and Adverse Drug Reaction reporting among Dental Students in a Teaching Hospital Jodhpur India: A Cross-sectional Study. *J Contemp Dent Pract.* 2017;18(10):964-9.
14. Gore R, Arora N, Aggarwal N, Gupta N. A Study to evaluate the Knowledge, Attitude and Practice of Pharmacovigilance among Dental practitioners in a dental college in Greater Noida. *World J Pharm Med Res.* 2020;6(4):81-4.
15. Kumar M, Deolia S, Totade S, Chhabra KG, Chhabra C, Nagpure S. Knowledge Attitude and Practices of Pharmacovigilance among Health Care Professionals in a Medical and Dental Institute: A comparative study. *Int J Curr Res.* 2017;9(07):55139-44.

Author biography

Venkatesan Gayathri, PG Resident  <https://orcid.org/1234-5678-9101-1236>

Subbiah Vijayalakshmi, Professor and Head  <https://orcid.org/1234-5678-9101-1236>

T.A.R Raja, Professor  <https://orcid.org/1234-5678-9101-1236>

Cite this article: Gayathri V, Vijayalakshmi S, T.A.R Raja. Knowledge and attitude towards pharmacovigilance among the dental undergraduates in a private dental college and hospital. *International Dental Journal of Student's Research* 2022;10(3):92-95.