

KNOWLEDGE, ATTITUDE AND PRACTICES REGARDING PHARMACOVIGILANCE AMONG STUDENTS, HOUSE SURGEONS AND TEACHING FACULTY IN A DENTAL COLLEGE IN KERALA

ABSTRACT

Background: Adverse Drug Reactions (ADR's) are currently a problem of major concern. Studies reveal that ADR reporting in India is just less than 1% compared to world-wide figure of 5%. Adverse drug reaction reporting is the foundation of any pharmacovigilance system and the timely identification and reporting of ADRs to the regional or national drug-regulating authorities are critical. Dental students can play a pivotal role and bringing a paradigm shift in successful implementation of pharmacovigilance program provided they possess adequate knowledge and skill. The study objective was to assess the Knowledge, Attitude and Practices regarding Pharmacovigilance among students, house surgeons and teaching faculty in a Dental college in Kerala.

Methodology: The study was a cross-sectional questionnaire based survey. A prefabricated validity tested questionnaire was devised for use based on previous studies. The questionnaire consisted of questions on professional data designation, grade; and 18 questions assessing the knowledge, attitude and practices on Pharmacovigilance. Results were expressed as a number and percentage of respondents for each. Chi-square test was performed to compare the response in relation to year of study and designation.

Results: The total sample size was 162. 28% knew that doctors, nurses, pharmacists and dentists can report Adverse drug reactions. About 25% knew about the existence of a pharmacovigilance program in India. 65% knew the regulatory body responsible for monitoring ADR's in India. About 96% felt that ADR reporting should be mandatory. 93.8% opined that pharmacovigilance should be taught in detail to health care professionals. About 35% reported to experiencing ADR's during their practice, yet none of the 162 respondents have reported an ADR to the pharmacovigilance centre. Only 2.5% had seen a reporting form and only 1.2% had received a prior training on reporting of the same.

Conclusion: The study showed that although the respondents had a positive attitude towards pharmacovigilance, their knowledge and practice was poor.

Key Words: Adverse drug reactions, pharmacovigilance, dental students, dentists, house surgeons.

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INTRODUCTION

Adverse Drug Reactions (ADR's) are currently a problem of major concern.¹ They are noxious, unintended and undesirable effect that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis and treatment.² ADR are indeed complex issues requiring special attention; involving patients, medical and paramedical professionals, nurses, pharmaceutical companies, drug regulatory agencies and academic scientists.¹ ADR's affect patients of all age groups - young and old with varying degrees of morbidity and at times mortality.^{1,3} ADRs are reported to be the 4-6th leading cause of death in United States of America (USA). The burden of ADRs is even higher in developing countries. The most common contributory factors being the widely prevalent self-medication, availability of adulterated and fake medicines.³ Adverse drug reactions thus have a major impact on public health. Spontaneous ADR reporting is an important aspect in monitoring known and unknown adverse effects of medicines. Spontaneous reporting of ADRs has played a pivotal role in the detection of serious and unusual ADRs during marketing of the drug in actual practicing in the market. It can aid in preventing new medicine tragedies and enhancing the safety profile of drugs.⁴

Studies reveal that ADR reporting in India is just less than 1% compared to world-wide figure of 5%.⁵ The World Health Organization (WHO) defines pharmacovigilance (PV) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem". Pharmacovigilance aims at enhancing patient safety by assessing the risk-benefit profile of medicines (WHO,2002a). As such, adverse drug reaction (ADR) reporting is the foundation of any pharmacovigilance system and the timely identification and reporting of ADRs to the regional or national drug-regulating authorities are critical.⁶

To promote drug safety WHO started Program for International Drug Monitoring in 1961 and subsequent to that it promoted pharmacovigilance program at country level in collaboration with Center for International Drug Monitoring, Uppsala.⁷ The Uppsala Monitoring

Centre (UMC), Sweden maintains the international database of ADR report received from different countries. India is an active participant in this program.^{1,3,7}

Pharmacovigilance Programme of India (PvPI) was formed in July 2010. Its is established as a combined initiative of Central Drugs Standard Control Organization (CDSCO), New Delhi, MoHFW, Government of India, presently having 202 ADR reporting centres countrywide.⁸

Medical and Dental students can play a pivotal role and bringing a paradigm shift in successful implementation of pharmacovigilance program provided they possess adequate knowledge and skill.⁷ The major lack of spontaneous reporting is due to decreases awareness among healthcare personnel regarding the same. The knowledge, attitude, and practice (KAP) studies are one of the best tools in assessment of ADR reporting among healthcare professionals and to understand their perspective towards Pharmacovigilance and safety of patients.⁸

Hence, this study was conducted with an objective of assessing the Knowledge, Attitude and Practices regarding Pharmacovigilance among students, house surgeons and teaching faculty in a Dental college in Kerala.

METHODOLOGY

The study was a cross-sectional questionnaire based survey. The target population was the clinical dental students (Third year and Final Year undergraduate students), House surgeons and teaching faculty of Indira Gandhi Institute of Dental Sciences, Nellikuzhy, Kothamangalam, Kerala. A prefabricated validity tested questionnaire was devised for use based on previous studies.

The questionnaire was divided into two parts. The first part consisted of questions on professional data designation and grade. The second part contained 17 closed ended and 1 open ended questions assessing the knowledge, attitude and practices on Pharmacovigilance.

The questionnaires were distributed by the house surgeons posted in the Department of Public Health Dentistry. The respondents filled the questionnaire on their own and were asked to return the questionnaire immediately.

Necessary ethical clearance for the study was obtained from the Institutional Ethical Committee. The respondents were briefed about the study and informed consent was obtained from all the participants prior to the administration of questionnaire. The final study sample was 183.

Statistical analysis

All returned questionnaires were coded and analysed. Results were expressed as a number and percentage of respondents for each question and were analysed using the SPSS Version 17 software. Chi-square test was performed to compare the response in relation to year of study and designation; and the level of significance was set at $p = 0.05$.

RESULTS

Respondent's Profile: The study was conducted among the clinical dental students (III year and Final year BDS), house surgeons and teaching faculty of the institution. Table 1 shows the profile of the respondents.

Table 1: Profile of the respondents

YEAR OF STUDY/DESIGNATION	NUMBER OF PARTICIPANTS n (%)
III YEAR BDS	28
FINAL YEAR BDS	58
HOUSE SURGEONS	38
FACULTY	38
TOTAL	162

Table 2 shows the response to the questions assessing the Knowledge, Attitude and Practices regarding Pharmacovigilance. It is observed that 28% knew that doctors, nurses, pharmacists and dentists can report Adverse drug reactions. Only about 25% knew about the existence of a pharmacovigilance program in India. Sixty five percent of the respondents knew the regulatory body responsible for monitoring ADR's in India. About 96% felt that ADR reporting should be mandatory rather than voluntary and 93.8% opined that pharmacovigilance should be taught in detail to health care professionals.

About 35% reported to experiencing ADR's

during their practice, yet none of the 162 respondents have reported an ADR to the pharmacovigilance centre. Only 2.5% had seen a reporting form and only 1.2% had received a prior training on reporting of the same. All respondents believed ADR reporting and monitoring will benefit the patients. Eighty four per cent opined that confidentiality of the patient must be maintained while reporting ADR's. About 46% were confident enough to report ADR to concerned authority.

Inferential analysis revealed the teaching faculty had significantly higher knowledge regarding the topic compared to house surgeons and students.

Table 2: Response to the questions assessing the Knowledge, Attitude and Practices regarding Pharmacovigilance.

QUESTION	RESPONSE %(n)
1. The healthcare professionals responsible for reporting ADR's in a hospital is/are (can tick multiple options).	Doctors 41.2% (66) Nurses 24% (40) Pharmacist 8.6% (14) Dentist 19.6% (32) All of the above 28% (46)
2. Do you know regarding the existence of a national Pharmacovigilance Programme in India?	YES 40 (24.1%) NO 122 (75.3%)
3. In India which regulatory body is responsible for monitoring ADRs?	(a) Central Drugs Standard Control Organization (CDSCO) 108 (b) Indian Council of Medical Research(ICMR) 26 (16.04%) (c) Indian Clinical Research Institute (ICRI) 16 (9.80%) (d) Medical Council of India(MCI) 16 (9.80%)
4. At present ADR reporting is voluntary, do you feel that it should made mandatory	Yes 156 (96.30%) No 6(3.70%)
5. Do you think Pharmacovigilance should be taught in detail to healthcare Professionals?	Yes 152 (93.80%) No 10 (6.20%)
6. What is your opinion about establishing ADR monitoring centre in every hospital?	(a) Should be in every hospital 124 (76.50%) (b) Not necessary in every hospital 12 (7.40%) (c) One in a city is sufficient 16 (7.70%) (d) Depends on number of bed size in the hospitals 10 (4.80%)
7. Have you ever experienced adverse drug reactions in your patient during your professional Practice?	Yes 58 (35.8%) No 104 (64.2%)
8. Have you ever reported ADR to the Pharmacovigilance centre?	(a) Yes 0 (0%) (b) No 162 (100%) (c) Don't know where to submit the ADR reporting form (d) Don't know how to fill up the ADR reporting form
9. Have you ever seen the ADR reporting form?	Yes 4 (2.5%) No 158 (97.5%)
10. Have you ever been trained on how to report Adverse Drug Reaction (ADR)?	Yes 2 (1.2%) No 160 (98.8%)

QUESTION	RESPONSE %(n)
11. Do you think proper ADR reporting and monitoring will benefit the patient?	Yes 162 (100%) No 0 (0%)
12. Do you feel that patient confidentiality should be maintained while reporting ADR	Yes 136 (84%) No 26 (16%)
13. Do you worry about legal problem while thinking about ADR reporting	Yes 76 (47.5%) No 84 (52.5%)
14. Do you feel that ADR reporting is a time consuming activity with no outcome?	Yes 30 (18.8%) No 132 (81.2%)
15. Which of the following factor discourage you from reporting ADRs? (You may tick multiple reasons)	a) Did not know how to report b) Not knowing where to report c) Lack of access to ADR Reporting forms d) Patient confidentiality issues e) Legal liability issues f) Concerns about professional liability
16. Are you confident enough to report an ADR to concern authority	Yes 74 (45.7%) No 88 (54.3%)

DISCUSSION

Drug therapy is a quintessential part in medical management of diseases. Although its benefits are many, there are a considerable number of side effects and adverse effects associated with drug usage.⁷ The dark history in 1961 by use of the drug thalidomide in pregnancy causing the birth of thousands of congenitally deformed babies led to the initiation of first organized international efforts to address drug safety issues. Further, this episode introduced the adoption of tougher testing, rigorous drug approval and monitoring systems like United States Food and Drug Administration (FDA). The expansion of scientific knowledge in drug safety is attributable to greater awareness and academic interest in this field.⁹

India is one of the largest drug consuming populations in the world. Estimates indicate that about 60,000-80,000 brands of drugs available in the Indian market that are irrationally prescribed and misused.¹⁰ It is thus a responsibility of all health care professionals, including the nurses and pharmacists to take

active participation in pharmacovigilance thereby reducing the morbidity and mortality associated with ADR's. Although many studies have been reported assessing the KAP among health care professionals, pharmacist and nurses, studies on dental students are a countable few. Hence this study was undertaken.

The study revealed that only 28% of the respondents knew who all were the health care professionals responsible for reporting ADR's. The result is comparable to the results of studies conducted among tertiary health care professionals in Chennai in 2017 (33%)⁸ and among dental students in Malaysia in 2015 (27%)¹¹. The results are in contrast with the studies conducted among medical students in Telangana in 2016⁹ and dental practitioners in Aurangabad in 2017¹², where the corresponding figures were 47% and 74.52% respectively. The high knowledge reported in the Aurangabad study may be due to the fact that the study samples were dental practitioners.

Only 27.5% knew regarding the existence of Pharmacovigilance program in India. The

results are similar to results obtained among dental teaching faculty in a dental college, attached to a medical college in Madhya Pradesh where the awareness was among 27%.¹³ It is noteworthy that over 64% had knowledge regarding the regulatory body responsible for monitoring ADR's in India - Central Drugs Standard Control Organisation. The results are comparable to the studies conducted among tertiary health care professionals in Chennai⁸ and medical students in Telangana⁹. The results are much better compared to studies conducted among dental practitioners in Aurangabad¹² and tertiary health care professionals in Vadodara⁴ where the knowledge reported was 10% and 36% respectively.

A vast majority (96%) felt that ADR reporting should be mandatory rather than voluntary. The observation is different compared to Malaysia study (84%).¹¹ Regarding the inclusion of pharmacovigilance as a topic in the undergraduate curriculum, about 94% agreed to, however in many other studies conducted among medical students, health care professionals and dental students^{7-9,11}, the figures are close to 80%, except Aurangabad study where it was 98%.¹² Only 34% of the respondents have experienced adverse drug reactions in patients during practice.

A very significant observation is that none of the respondents have ever reported a case of ADR's, an observation similar to Aurangabad study¹². However, studies conducted in tertiary health care establishments have reported cases of ADR's^{7,8,9}. Only 2.5% have seen the ADR reporting form and only 1.2% have received proper training on how to report an ADR. This shows the gap of knowledge as far as the dental curriculum and practice is concerned unlike the field of medicine. The main reason could be the absence of the topic in the dental undergraduate curriculum.

With all the respondents agreeing that proper monitoring and reporting of ADR will benefit the patient, the attitude regarding the same is highly positive. Thus an inclusion of the topic in the curriculum can improve the practice of reporting ADR's. Furthermore, on enquiring the factor(s) that discourage the respondents, it is clearly noted that lack of awareness is the

mainstay. Patient confidentiality issues, legal liability issues and professional liability concerns are not major factors responsible.

CONCLUSION

The study reveals that although the attitude of the respondents about pharmacovigilance was good, the knowledge and practice was poor. It is high time that these topics are given priority in the undergraduate syllabus to encourage adverse drug reactions reporting and helping the dental fraternity towards pharmacovigilance.

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