

PHARMACOVIGILANCE : KNOWLEDGE ATTITUDE AND PRACTICE (KAP) OF DENTAL HEALTH CARE PROFESSIONALS RELATED TO ADVERSE DRUG REACTIONS

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ABSTRACT: *Proper knowledge and training in the dental curriculum is a key factor for proper implementation of Pharmacovigilance Programme of India (PvPi) . This questionnaire based study was conducted on undergraduates of Government Dental College ,Srinagar to evaluate about Knowledge, Attitude and Practice of dental graduates on adverse drug reaction . 78% thought pharmacovigilance should be taught in detail to dental health care professional in their academic curriculum of their undergraduation.*

54% of the participants said they weren't ever trained to report Adverse Drug Reaction . 86% had a knowledge how to report Adverse Drug Reaction(ADR) using Redcard or Vigiline.

Keywords: *Pharmacovigilance, ADR, PvPi*

INTRODUCTION : Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problems by World Health Organization.¹

In India a pharmacovigilance (PV) program was started in July 2010 with the aim to safeguard people's health and Central Drugs Standard Control Organization (CDSCO) a regulatory body was responsible for monitoring Adverse Drug reactions .^{2,3} Adverse drug reaction which are noxious, unintended and undesired effect of a drug doses used for prophylaxis, diagnosis or therapy of disease are classified as type A which is augmented and has dose related effects and type B which is of bizarre type in which effects related to abnormal interaction between patient and drug are seen need to be reported timely.⁴

MATERIAL AND METHODOLOGY : A cross-sectional study was carried out on 102 dental graduates and interns of Government Dental College and Hospital, Srinagar, Jammu and Kashmir using a validated questionnaire that included demographic details and 19 survey items to evaluate the participants' knowledge, attitude, and practice (KAP) on adverse drug reactions (ADRs) and Pharmacovigilance through a whatsapp based survey. All participants had received an interactive educational intervention in the form of a presentation in their

undergraduation and ethical clearance was taken from the hospital where the study was conducted. The data was analyzed using the survey tool survey monkey.

Table 1

1. What is your gender?	A. Male	B. Female			
2. World Health Organisation defined pharmacovigilance as? (Knowledge)	A. Science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug related problem particularly long term and short term adverse effects of medicine	B. The science detecting the type and incidence of Adverse Drug Reaction after drug is marketed	C. The science of monitoring Adverse Drug Reactions happening in a hospital		
3. How do you report Adverse Drug Reactions in India using Redcard or Vigiline? (Knowledge)	A. Dial toll free helpline number 1800 180 3024 to report ADRs	B. Mailing ADR reporting form directly to pvc@ipcindia	C. Both A and B		
4. Are you aware of regulatory body responsible for monitoring ADRs in India is Central Drugs Standard Control Organization (CDSCO) and was established on June 2010? (Knowledge)	A. Yes and I know about it	B. No	C. CDSCO is the major regulatory body but I don't know much how it functions		
5. The important purpose of Pharmacovigilance	A. To identify safety of	B. To calculate incidence of	C. To identify predisposing	D. To identify unrecognized	E. All of the

is? (Knowledge)	drugs	ADRs	factors to ADRs	ADRs	above
6. Have you recently read any article on prevention of adverse drug reactions and protocol how to report them? (Knowledge)	A.Yes	B.No	C.I have read but i didn't go into complete detail		
7. What is inverted Black triangle in ADR (Knowledge)	Trade name of a British medicine indicates that the medication is new to the market or that an existing medicine (vaccine) is being used for a new reason or by a new route of administration	The need for surveillance of any adverse drug reaction (ADRs) that might arise from the use of a new medicatiuon	Both A and B		
8. Have you recently read any article on prevention of adverse drug reactions and protocol how to report them? (Knowledge)	Yes	No	I didn't go into the detail		
9. What is difference between Adverse Drug Event and Adverse Drug Reaction? (Knowledge)	If one finds the causality for adverse occurrence its adverse drug reaction and if one fails to find causality for adverse occurrence its called adverse drug event.	If one fails to find causality for adverse occurrence its called Adverse drug reaction and if one finds the causality for adverse occurrence then its called			

		adverse drug event.			
10. Which of the following scales is most commonly used to establish the causality of an ADR? (Knowledge)	Hartwig scale	Naranjo algorithm	Schumock and Thornton scale	Karch and lasagna scale	
11. Academic departments and university hospitals have proved effective places for national and regional pharmacovigilance centres because (Knowledge)	The dental health care worker finds it easy to report to the institution they are affiliated with	Spontaneous reporting can be incorporated in undergraduate and post graduate curriculum to educate	Academic detailing and feedback of individual cases is important	All of the above	

12. Do you think pharmacovigilance should be taught in detail to dental health care professional? (Attitude)	Yes it should be taught in the undergraduate curriculum	It should be made compulsory to attend CDE (continuing dental education) on it	Online app should be made to educate and spread awareness on Adverse drug reaction	
13. Do you feel it's important to record ADR for APT database and its duty too? (Attitude)	Yes	No	I want to but am not aware how to	
14. Adverse drug reaction is underreported in dental practice in India because (Attitude)	A. Dentist have no clue how to report ADRs in India	B. Nurse and pharmacist play pivotal role in reporting most of the cases in dental practice but he forgets to inform	C. Many a times reporting of adverse drug reaction is neglected because dentist thinks it to mild/moderate reaction	D. The Belief that a single unreported will not affect the database

15.A serious adverse event should be reported to the regulatory body within? (Attitude)	Single day	Seven calendar days	Fourteen calendar days	Fifteen calendar days
16. Have you ever been trained on how to report ADR?(Practice)	Yes properly	Never	I have read a lot but don't know how to report	
17.The health care professionals responsible for reporting ADR in a hospital is/are Practice	Doctors	Nurses	Pharmacist	All of the above
18.Have you ever seen adverse drug reaction in your clinical practice? Practice	Yes	No	A mild ADR	
19. After noticing an adverse drug reaction in your work place did you intervene to rectify by using suitable measures? (Practice)	A. Yes always	B.Never	C.I am apprehensive and refer to a specialist	D.I have never encouraged a case of ADR
20. Rare ADRs can be identified in the following phase of a clinical trial (Practice)	During phase 1 clinical trials	During phase 2 clinical trials	During phase 3 clinical trials	During phase 4 clinical trials

Results : The questionnaire (Table 1) was administered to 102 dental undergraduates including interns and students who were asked to complete responses . The average time taken to complete the questionnaire was a minute. Knowledge analysis and comparison on knowledge of final and prefinal dental students and interns was done and results for knowledge on pharmacovigilance and ADRs reporting based questions were tabulated in Table 2.

Out of the 102 participants, 84% were female and 16% were male (Figure 1) and 98% of participants correctly answered the definition of pharmacovigilance and were well knowledgeable about the definition.

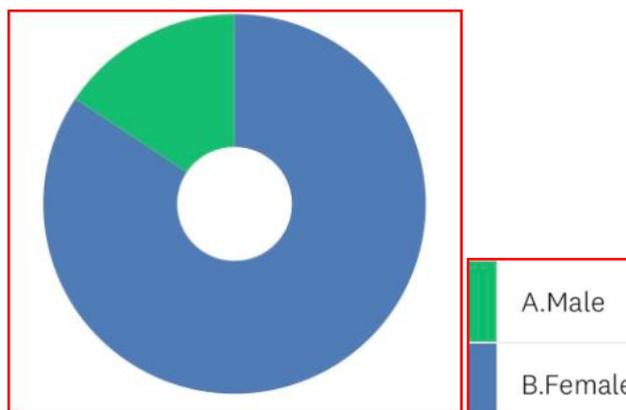


Figure 1

Table 2

Q.NO	A %age (n)	B %age (n)	C %age (n)	D %age (n)	E %age (n)	SKIPPED
1.	16% (16)	84% (86)				
2.	98% (100)	2% (2)				
3.	12% (12)	2% (2)	86% (84)			4
4.	34% (34)	32% (32)	34% (34)			2
5.	4% (4)	4% (4)	0%	0	92% (94)	
6.	29% (28)	49% (48)	22% (22)			4
7.	13% (12)	13% (12)	74% (68)			10
8.	25% (26)	51% (52)	24% (24)			
9.	66% (62)	34% (32)				8
10.	32% (26)	51% (42)	12% (10)	5% (4)		20
11.	15% (14)	7% (6)	4% (4)	74% (68)		10
12.	78% (78)	16% (8)	28% (14)			2
13.	73% (70)	2% (2)	25% (24)			6

14.	29% (30)	8% (8)	45% (46)	18%(18)		0
15.	34% (32)	43% (40)	11% (10)	13% (12)		8
16.	8% (8)	54% (52)	38% (36)			6
17.	21% (20)	4% (2)	9% (8)	68% (64)		8
18.	9% (8)	70% (66)	21% (20)			8
19.	33%(34)	2%(2)	4%(4)	61%(62)		
20.	14% (14)	12% (12)	18%(18)	55% (27)		4

49% (n=48) were not sure how to report Adverse drug reactions and had not read any article on prevention of adverse drug reactions and protocols how to report them.

66% knew the difference between Adverse Drug event and Adverse Drug Reaction.

74% of participants knew inverted Black triangle in ADR is Trade name of a British medicine which indicates that the medication is new to the market or that an existing medicine (vaccine) is being used for a new reason or by a new route of administration and the need for surveillance of any adverse drug reaction (ADRs) that might arise from the use of a new medication (Figure 2).

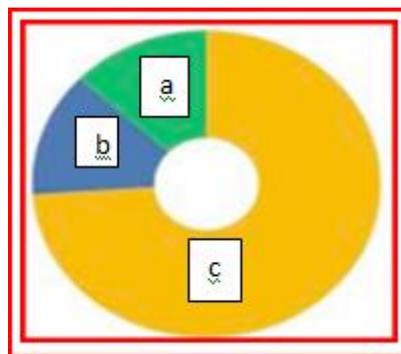


Figure 2

42% of these undergraduate dental students knew how to record ADRs in India using helpline number 1800180 3024 to report ADRs or by mailing ADR directly to pvpi@ipcindia (Figure 3).

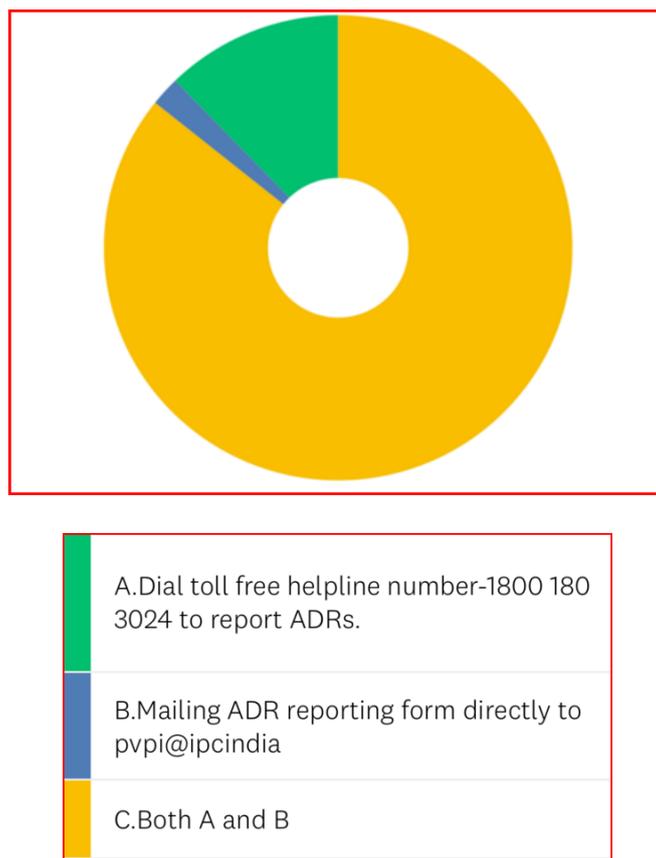


Figure 3

51% answered correctly that Naranjo algorithm is most commonly used scale to establish the causality of an ADR.

38% of the participants never knew how to report ADR and 73% felt its important to record ADR for appropriate data base .74% answered academic departments and university hospitals have proved effective places for national and regional pharmacovigilance centres because dental health care worker finds it easy to report to the institution they are affiliated with, and spontaneous reporting can be incorporated in undergraduate and post graduate curriculum to educate them about it and academic detailing and feedback of individual cases is important.

The results on the attitude towards pharmacovigilance and adverse drug reaction reporting among the pre-final and final year dental students and interns are presented in Table 2. 78% thought pharmacovigilance should be taught in detail to dental health care professional.

43 % of the participants reported a serious adverse event should be reported to the regulatory body within seven days of noticing it. 54% of the participants reported that they were never trained how to report ADR and felt this as a shortcome in the curriculum.

70% of participants had never seen adverse drug reaction in clinical practice (Figure 4).



Figure 4

61% said they never encountered a case of Adverse drug reaction (Figure 5)

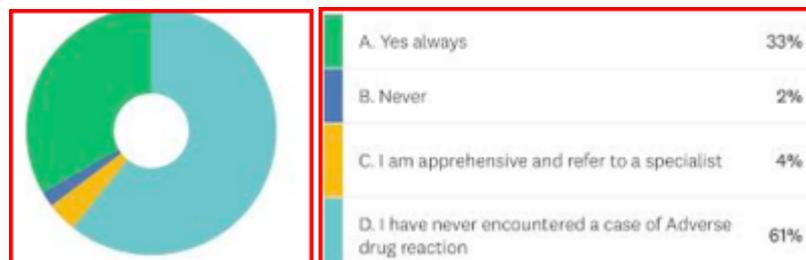


Figure 5



Figure 6

32% of the participants didn't know about Central Drugs Standard Control Organization which was established on July 2010.(Figure 6)

DISCUSSION :

Pharmacovigilance derived from Pharmakon (Greek word for 'drug') and vigilare (Latin word for 'to keep watch') modules must be taught to the undergraduate students and must be associated to modules on the rational use of medicines.⁵

Knowledge is a very important factor that influences attitude and practice. Various studies had been carried out in different countries to assess the knowledge of pharmacovigilance among the medical, pharmacy, dental students and practitioners. The present study was

conducted among the pre-final, final year dental students and interns. From the results, it was noticed that the overall knowledge on the definition of pharmacovigilance was good among these students but they didn't know how and when to report them. Only few dental students were aware of their role in reporting ADR suggesting pharmacovigilance topic is either not incorporated sufficiently or not incorporated in the curriculum and need of hour is to aware dentists on it.

Most dental graduates agreed that dentists need ADR reporting and realized its a professional obligation but were unaware about the role of pharmacist as most important health care personnel to report ADR.

Hence, there is a requirement for constant training, enactment of regulations for ADR reporting, and it is recommended that all drug related issues should be governed and addressed through proper pharmacovigilance cells. Our response rate was similar to the studies conducted by **Arjun et al.** (100%) but higher than **Gupta and Udupa** (77.2%) and **Desai et al.** (77.7%) because it was a whats app based survey and investigator approached all the participants in person who were their students.⁶

However, 74% (agreed) expressed that ADRs reporting is necessary. This is very much higher than the study conducted by **Arjun et al.** (72.53%). Similarly, 73% acclaimed that reporting ADRs is a professional obligation which is very much higher percentage in comparison to Arjun et al. which was 35.91%).⁶

With regard to pharmacovigilance related to their practice, only 9% have experienced ADRs, which is less in comparison with **Arjun et al.** where 34.5% of dentists in their study group have encountered patients with ADRs. **Arjun et al.** have further stated that dentists and nursing staff have never reported ADRs cases during their work with institutions which is alarming observation because it may be due to less training and awareness in them and its impact on health care is very disturbing..

Chabra KG stated 64% of respondents had never heard about the term pharmacovigilance which was surprising and a significant association between age, knowledge ($p=0.045$) and attitude ($p=0.016$) was seen in his survey.⁷ According to survey conducted by **Gupta SK** 75.2% of health care workers were aware regarding the existence of a National Pharmacovigilance Program of India and 97% of health care professionals agreed reporting of ADR is necessary.⁸

Kumar B in his survey noted knowledge of reporting of pharmacovigilance excellent in 39.48%, good 32.61% and poor in 27.89% of respondents and about 89% respondents were found to be favouring pharmacovigilance system in hospital.⁹

CONCLUSION :

Its mandatory to report augmented and bizarre categories of ADRs and incomplete knowledge and negative perceptions about pharmacovigilance in health care professionals would lead to ADR under-reporting. In the present study the attitude of the students was

positive, however their knowledge has to be increased in some of the aspects of ADR reporting as it was less. So educating and bringing awareness through educational intervention, CDE or training on ADR amongst health care professionals is important for better future preparative measures to prevent underreporting and for timely reporting.

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