



RESEARCH ARTICLE

“KNOWLEDGE, ATTITUDE AND PRACTICE REGARDING PHARMACOVIGILANCE AND ADVERSE DRUG REACTION AMONG DENTAL POSTGRADUATE STUDENTS AND INTERNS IN LUCKNOW: A CROSS-SECTIONAL STUDY”

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Abstract

Objective:The purpose of this research paper is to evaluate the perception of pharmacovigilance and adverse drug reaction among dental postgraduate students and interns of Lucknow.

Method:After obtaining the Institutional Ethical Committee approval(No.625/Ethics/2024 dated 20/6/24),a structured self-administered questionnaire was sent via mail in the form of Google forms to the participants regarding Knowledge, Attitude and Practicetoward pharmacovigilance and adverse drug reaction. The answers were recorded in percentage and categorized as poor (0-33%), fair (34-66 %) and good (67-100%), Knowledge/Attitude/Practice of pharmacovigilance and ADR.

Results:In the present study, most dental postgraduate students and internshaveacceptable knowledge, attitude, and practice on pharmacovigilance and adverse drug reaction. There was also a favourable association discovered between pharmacovigilance training and ADR reporting by healthcare professionals.

Conclusion:In conclusion, this study found that majority of dental interns and postgraduate students had considerable knowledge and attitudes concerning pharmacovigilance and understood the need of reporting.

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Introduction:-

Dr. W. Mc Bride, who has linked general prenatal abnormalities to thalidomide for the first time, founded Pharmacovigilance (PV) in December 1961.An organization was created in 1963, within WHO the Programme for International Drug Monitoring begun simply as an initial intent of PV.^{1,2} Unlike premarketing PV, the post marketing surveillance of medication safety will occur after commercialization and will alert the organization to adverse drug events in realistic settings.³ Under the aegis of 12 regional centres started from 1986, India is conducting clinical trials at world level.⁴ The Indian government became a member of the WHO adverse drug reaction monitoring project in 1997 and it is based in Uppasala, Sweden. Further, in the year 2005, India firmly took a step forward by introducing the Pharmacovigilance Program of India (PvPI).⁵

PV involves research and practices related to the assessment and interpretation of a drug, its perception, and prevention of negative effects or another undesirable aspect of a certain medicine. ADR is defined as an adverse and unpredictable response to a drug at doses normally utilized in human for chronic use/or for diagnosis, treatment, or altering of biologic functions. ADR is ranked among the top 10 basic drivers of death and illness.⁶Antibiotics and

analgesics are often prescribed by dentists and are the leading causes of adverse drug reactions. There have been instances of ADRs induced by mouthwashes, toothpastes, and topical anaesthetics often administered by dentists.⁷ Materiovigilance is the process of monitoring ADR caused by materials used by a dentist like few patients may develop latex allergies because of the rubber dam isolation utilized.⁸ The use of alginate as an imprint medium has been linked to fatal anaphylactic shock. Fissure sealant, the most primitive type of prophylactic intervention, has been associated with asthma and urticarial reactions.⁹ The commonest metal amalgam was identified to have higher probability of ADR by three-fold when compared to resins.¹⁰ Several case studies have revealed the adverse effects of root canal sealers and obturating agents.¹¹

It can also be observed within practitioners as indicated by instances like Type I allergic response due to the existence of powder in latex gloves. One study^{12, 13} reported that 14% of dental practitioners and 18% of dental students experienced hand eczema due to the wet nature of dentistry where their hands are often washed. Frequent exposure to chemical compounds has also been identified as a primary cause of allergic contact dermatitis.¹⁴ The prevalence of occupational dermatitis was higher with dental items than with latex gloves. The occurrence of volatile methacrylate among dental practitioners and patients has also been linked to respiratory adverse events.^{15,16}

Perhaps, increasing the level of participation of health professionals in spontaneous reporting may require the establishment of strategies that will alter the following intrinsic factors: knowledge, attitude, and practice level of the health professionals updated; as well as the extrinsic factors which include the relationships between the members of the health professions team and their patients, the health care organizations, and the regulatory bodies. An example of what a KAP study can present is inherent variables and why underreporting takes place. Therefore, this questionnaire survey was administered to dental residents and interns with an intention of evaluating their knowledge about it, why they had not incorporated its use and their perceived training requirements in this aspect.

Methods:-

The study was conducted including 287 participants after obtaining institutional ethical approval (No. 625/Ethics/2024 dated 20/6/24). Participants were briefed on the study's objectives and were given an assurance of privacy. It was ensured that only the participants who affirmatively expressed themselves about their voluntary nature of participation in the study were selected into the study. The number of participants was defined with the help of statistical calculations. A questionnaire was set and validated to assess knowledge, attitude, and practice by multiple experts of the relevant field.

The questionnaire for this study was emailed to the dental postgraduate students and interns in Lucknow, which helped to create the dataset for this study. To collect data from the study participants, self-completion of the standardized structured questionnaire was employed, and the details sought were concerning sociodemographic aspects, awareness and KAP regarding pharmacovigilance and ADR. These questions were designed based on earlier studies for assessing KAP of ADR reporting. The demographic data and responses to questionnaire and the KAP toward pharmacovigilance and adverse drug reaction were collected and recorded. The scores of all the domains (Knowledge, Attitude and Practices) were calculated and categorized as poor (0-33%), fair (34-66%) and good (67-100 %) on the basis of percentage.

Statistical Procedures

The descriptive analysis of the data was done using the software SPSS latest available version (Version 30.0.0) and MS Excel. Variables with an interval scale and meeting the normality assumption were presented on mean \pm standard deviation.

Quantitative data was expressed as numbers and percentages. In within group comparison either the ANOVA test, unpaired t test or its nonparametric counterpart was used. In comparing the proportion data, the χ^2 test was used to determine the p values between the groups. Other suitable statistical tests were conducted. In all the statistical analyses, the P value different from 0 was taken as significant $P < 0.05$ was statistically significant.

Results:-

Demographic characteristics of participants

A total of 287 subjects participated in the study, out of which, 204 (71.1%) were interns and 83 (28.9%) postgraduate students.

There was no significant difference among the postgraduate students and the interns about the knowledge of pharmacovigilance definition (44.1% interns and 57.8% postgraduates) **Fig.1** and awareness of any official reporting system available in India (34.3% interns and 41.0% postgraduates) both showed fair knowledge (**Fig. 1, Table 1**).

Knowledge regarding definition of ADR was found good and not found to be significantly different among Interns and postgraduates. Good number of interns (69.1%) and post graduate student responded correct answer (**Fig.1, Table 1**).

When interns and postgraduate students were asked about any drug that has been banned in India due to ADR, postgraduate students (80.7%) were found to be significantly more aware than interns (58.8%). (**Fig.2, Table-2**).

The knowledge about the location of an international centre for adverse effect reaction monitoring was significantly different among interns and postgraduate students. Significantly higher number (44.6%) of postgraduate students answered correctly to this question. (**Fig.2, Table-2**).

Both interns and postgraduate students have fair knowledge regarding risk factor of ADR 37.7% interns 41.0% postgraduates responded 'all of the above'. (**Fig.2, Table-2**).

The knowledge about the identification of ADR, when the interns and postgraduate students were asked about "**Identify the type of ADRs**", 41.2% interns responded with 'Do not know' and fair number of postgraduates (45.8%) and interns (33.30 %) responded with correct answer shown in (**Fig.3, Table-3**).

Both interns and postgraduate students showed poor knowledge about **the WHO online database for reporting ADRs** (**Fig.3, Table-3**) only 26.5% interns and 30.1% postgraduates responded with correct answer 'Vigibase'.

The attitude towards the reporting of common side effects **like headache, fever and vomiting showed significant difference among interns and postgraduate students** (**Fig.3, Table-3**). Significantly higher number of postgraduate students (45.8%) disagreed whereas fair number of interns (34.1%) agreed with the reporting of these side effects.

Though both good number of interns (79.4%) and postgraduate students (86.7 %) agreed about the necessity of reporting of adverse drug reactions (**Fig.3, Table-3**).

Significantly good number of interns (78.4%) and postgraduate students (86.7%) have positive attitude towards pharmacovigilance education to healthcare professionals (**Fig.4, Table-4**).

Fair number of interns (42.6%) and postgraduate students (49.4%) responded yes to the question, have you read any article on prevention of adverse drug reaction. (**Fig.4, Table-4**).

Attitude of the both dental postgraduate students and interns was good regarding establishing ADR monitoring centre in every hospital, 75% interns and 81.9% postgraduates responded positively. (**Fig. 4, Table-4**).

Fair number of (45.60 %) interns and (47%) postgraduates had not experienced any ADR in their dental practice (**Fig.4, Table-4**).

The practice of ADR reporting was fair and showed no significant difference among interns and postgraduate students, 50% interns and 56.6 % postgraduates agreed that they have shared information about ADR with any one as shown in (**Fig.4, Table-4**).

Significantly more Interns (28.9 %) were found to practice reporting of adverse drug reaction to the pharmacovigilance centre (**Fig. 5, Table-5**) whereas significantly a greater number of postgraduate students (27.7%) reported to see the ADR reporting form (**Fig. 5, Table-5**).

The training for the reporting of ADR is not adequate among Interns and postgraduate students, 60.8% interns and 63.9% postgraduates had never been trained about the ADR reporting system. Very large number of the dental postgraduate students (84.3%) and interns (73.5%) had not reported any ADR (**Fig. 5, Table-5**).

The response to “**have you faced any hurdles while reporting ADR**” was found to be significantly different as shown in (Fig. 5, Table-5). Significantly higher number of Interns (31.9%) responded ‘yes’ when asked this question.

Discussion:-

The present study is based on a cross-sectional survey, which was carried out on dental postgraduate students and interns of government and private hospitals of Lucknow city. This is supposed to be the first study done in the city concerning ADR reporting. The knowledge, attitude, and practice of ADR reporting and the factors influencing ADR reporting that formed the basis of the study are also evaluated. The study group consisted of 28.9% postgraduate students and 71% interns.

Precise knowledge is very crucial when it comes to reporting of ADR. It greatly depends on the fact that dental interns and postgraduates should have extensive knowledge regarding, ADR and the procedure for the reporting of ADR.

The knowledge of the dental postgraduate students about **any drug that has been banned in India due to ADR** was found to be significantly different from interns. They were found to be significantly (80.7%) more aware than interns (58.8%). Similar findings were reported by Zisa NU et al (2018)¹⁷ where the 49% respondents answered with ‘No’ and 24.3% answered with ‘Yes’. The possible reason for the same could be more exposure regarding ADR during post-graduation course.

The responses of interns and postgraduate students to “**Where is an international centre for adverse effect reaction monitoring located**” differed significantly, fair number (44.6%) of postgraduate students answered correctly to this question. The same observation was made by Gupta et al (2015)¹⁸ in their study that identified that 41.6% were aware of the International Centre for ADR monitoring. The possible reason for the same could be lack of educational training related to ADR among interns.

Significantly higher number of postgraduate students (45.8%) disagreed with avoiding of reporting of side effects like headache, fever and vomiting. The dental postgraduate students and interns have fair attitude towards reporting of side effects. Zisa NU et al (2018)¹⁷ also observed the above similar results where majority of the respondents 63.8%, stated that serious ADR should be considered, more important to be reported while only 12.5% believed that unusual and unexpected reaction should also be reported. The possible reason for the same could be lack of knowledge and unawareness regarding the ADR reporting protocols and casual attitude towards ADR reporting.

When the interns and postgraduate students were asked the question “**Have you ever reported adverse drug reaction (ADR) to the pharmacovigilance centre**”, very few were found to report adverse drug reaction to the pharmacovigilance centre though significantly more (28.9%) Interns reported this. Rishi et al (2012)¹⁹ revealed that similar findings as they noted that majority of the respondents 88.3 % never reported ADR and only 11.7% said they have reported ADR and out of them only 9.1% reported to ADR to the Ministry of Health.

The response of the dental postgraduate students and interns when both were asked about **the ADR reporting form**, then significantly a greater number of postgraduate students (67.5%) reported to see the ADR reporting form. Similar findings were reported by Gupta et al (2015)¹⁸ where they found that 58.4% had seen the ADR reporting form.

The response to “**Have you faced any hurdles while reporting ADR**” was found to be significantly high among Interns as 31.9% responded with ‘yes’. The possible reason for the same could be lack of educational training related to ADR among interns.

As per the current available literature, very limited studies have been done to assess the KAP of pharmacovigilance among the dental postgraduates and interns of Uttar Pradesh, specifically in Lucknow city. In addition to dental postgraduate students, interns were also involved in the study because they share the responsibility and competence in the detection and reporting of ADRs as health care providers. Limited sample size and restriction of sample to the postgraduate students and interns only could be considered as the limitation of the study, while there are other health care professionals also involved like dental practitioners and paramedical staff like nurses. Moreover, other

limitations of the study are recall bias and bias arising from people's attitude and beliefs, as it is a type of self-reporting study which could have impacted the study results in the same way.

Question	Year of Study	n	%	P Value	Options	Responses (n)	%
Define pharmacovigilance	Interns	204	100.00%	0.051 NS	Science of monitoring ADRs in a hospital	47	23.00%
					Process of improving drug safety	39	19.10%
					Detection, assessment, prevention of adverse effects	90	44.10%
					Detecting type and incidence of ADR after drug marketing	28	13.70%
	Postgraduates	83	100.00%		Science of monitoring ADRs in a hospital	19	22.90%
					Process of improving drug safety	6	7.20%
					Detection, assessment, prevention of adverse effects	48	57.80%
					Detecting type and incidence of ADR after drug marketing	10	12.00%
	All	287	100.00%		Science of monitoring ADRs in a hospital	66	23.00%
					Process of improving drug safety	45	15.70%
					Detection, assessment, prevention of adverse effects	138	48.10%
					Detecting type and incidence of ADR after drug marketing	38	13.20%
Define ADR	Interns	204	100.00%	0.103 NS	Option A	141	69.10%
					Option B	0	0.00%
					Option C	23	11.30%
					Option D	24	11.80%
					Option E	16	7.80%
	Postgraduates	83	100.00%		Option A	65	78.30%
					Option B	1	1.20%
					Option C	10	12.00%
					Option D	4	4.80%
					Option E	3	3.60%
	All	287	100.00%		Option A	206	71.80%
					Option B	1	0.30%
					Option C	33	11.50%
					Option D	28	9.80%
					Option E	19	6.60%
Aware of Formal Reporting System in India	Interns	204	100.00%	0.567 NS	Yes	70	34.30%
					No	95	46.60%
					Maybe	39	19.10%
	Postgraduates	83	100.00%		Yes	34	41.00%
					No	35	42.20%
					Maybe	14	16.90%
	All	287	100.00%		Yes	104	36.20%
					No	130	45.30%
					Maybe	53	18.50%

Table 1:- Pharmacovigilance Study Participants Demographics.

Question	Year of Study	n	%	P Value	Options	Responses (n)	%
Aware of any drug banned in India due to ADR	Interns	204	100.00%	0.001, S	Yes	120	58.80%
					No	58	28.40%
					Maybe	26	12.70%
	Postgraduates	83	100.00%		Yes	67	80.70%
					No	8	9.60%
					Maybe	8	9.60%
	All	287	100.00%		Yes	187	65.20%
					No	66	23.00%
					Maybe	34	11.80%
International centre for adverse effect reaction monitoring	Interns	204	100.00%	0.012, S	Sweden	65	31.90%
					Germany	29	14.20%
					USA	29	14.20%
					Don't know	76	37.30%
					Didn't answer	5	2.50%
	Postgraduates	83	100.00%		Sweden	37	44.60%
					Germany	9	10.80%
					USA	3	3.60%
					Don't know	28	33.70%
					Didn't answer	6	7.20%
	All	287	100.00%		Sweden	102	35.50%
					Germany	38	13.20%
					USA	32	11.10%
					Don't know	104	36.20%
					Didn't answer	11	3.80%
Major risk factor for maximum ADR occurrence	Interns	204	100.00%	0.236, NS	Arthritis	11	5.40%
					Renal failure	62	30.40%
					Visual impairment	11	5.40%
					All of these	77	37.70%
					Don't know	43	21.10%
	Postgraduates	83	100.00%		Arthritis	4	4.80%
					Renal failure	25	30.10%
					Visual impairment	1	1.20%
					All of these	34	41.00%
					Don't know	19	22.90%
	All	287	100.00%		Arthritis	15	5.20%
					Renal failure	96	33.40%
					Visual impairment	12	4.20%
					All of these	102	35.50%
					Don't know	62	21.60%

Table 2:- Important Measures of ADR Reporting Awareness Levels.

Question	Year of Study	n	%	P Value	Options	Responses (n)	%
Identify the Type of ADRs	Interns	204	100.00%	0.277, NS	Type A B C D E F G	68	33.30%
					Type 1234567	20	9.80%
					Known, Unknown, Common, Uncommon	16	7.80%
					Reversible & Irreversible	16	7.80%
	Postgraduates	83	100.00%		Do Not Know	84	41.20%
					Type A B C D E F G	38	45.80%
					Type 1234567	4	4.80%
					Known, Unknown, Common, Uncommon	5	6.00%
	All	287	100.00%		Reversible & Irreversible	7	8.40%
					Do Not Know	29	34.90%
					Type A B C D E F G	106	36.90%
					Type 1234567	24	8.40%
WHO Online Database for Reporting ADRs	Interns	204	100.00%	0.302, NS	ADR Advisory Committee	33	16.20%
					Med Safe	17	8.30%
					Vigibase	54	26.50%
					Med Watch	9	4.40%
	Postgraduates	83	100.00%		Do Not Know	91	44.60%
					ADR Advisory Committee	17	20.50%
					Med Safe	6	7.20%
					Vigibase	25	30.10%
	All	287	100.00%		Med Watch	6	7.20%
					Do Not Know	28	33.70%
					ADR Advisory Committee	50	17.40%
					Med Safe	23	8.00%
Should Side Effects Like Headache, Fever, Vomiting Be Reported?	Interns	204	100.00%	0.002, S	Vigibase	79	27.50%
					Med Watch	15	5.20%
					Do Not Know	119	41.50%
	Postgraduates	83	100.00%		Strongly Agree	50	24.50%
					Agree	70	34.30%
					Disagree	57	27.90%
					Strongly Disagree	27	13.20%
	All	287	100.00%		Strongly Agree	6	7.20%
					Agree	26	31.30%
					Disagree	38	45.80%
					Strongly Disagree	13	15.70%
Do You Think Reporting of Adverse Drug Reactions Is Necessary?	Interns	204	100.00%	0.326, NS	Strongly Agree	56	19.50%
					Agree	96	33.40%
					Disagree	95	33.10%
					Strongly Disagree	40	13.90%
	Postgraduates	83	100.00%		Yes	162	79.40%
					No	20	9.80%
					Maybe	22	10.80%
	All	287	100.00%		Yes	72	86.70%
					No	6	7.20%
					Maybe	5	6.00%
					Yes	234	81.50%
					No	26	9.10%
					Maybe	27	9.40%

Table 3:- Response Distribution on the Effectiveness of Pharmacovigilance Training.

Question	Year of Study	n	%	P Value	Options	Responses (n)	%
Do You Think Pharmacovigilance Should Be Taught to Healthcare Professionals?	Interns	204	100.00%	0.26, NS	Yes	160	78.40%
					No	26	12.70%
					Maybe	18	8.80%
	Postgraduates	83	100.00%		Yes	72	86.70%
					No	7	8.40%
					Maybe	4	4.80%
	All	287	100.00%		Yes	232	80.80%
					No	33	11.50%
					Maybe	22	7.70%
Have You Read Any Article on Prevention of Adverse Drug Reaction?	Interns	204	100.00%	0.312, NS	Yes	87	42.60%
					No	78	38.20%
					Maybe	39	19.10%
	Postgraduates	83	100.00%		Yes	41	49.40%
					No	32	38.60%
					Maybe	10	12.00%
	All	287	100.00%		Yes	128	44.60%
					No	110	38.30%
					Maybe	49	17.10%
What is Your Opinion About Establishing ADR Monitoring Centres in Every Hospital?	Interns	204	100.00%	0.385, NS	Yes	153	75.00%
					No	22	10.80%
					Maybe	29	14.20%
	Postgraduates	83	100.00%		Yes	68	81.90%
					No	8	9.60%
					Maybe	7	8.40%
	All	287	100.00%		Yes	221	77.00%
					No	30	10.50%
					Maybe	36	12.50%
Have You Ever Experienced Adverse Drug Reactions in Patients in Your Dental Practice?	Interns	204	100.00%	0.115, NS	Yes	78	38.20%
					No	93	45.60%
					Maybe	33	16.20%
	Postgraduates	83	100.00%		Yes	38	45.80%
					No	39	47.00%
					Maybe	6	7.20%
	All	287	100.00%		Yes	116	40.40%
					No	132	46.00%
					Maybe	39	13.60%
Shared information about ADR with anyone	Interns	204	100.00%	0.504, NS	Yes	102	50.00%
					No	101	49.50%
					Maybe	1	0.50%
	Postgraduates	83	100.00%		Yes	47	56.60%
					No	36	43.40%
					Maybe	0	0.00%
	All	287	100.00%		Yes	149	51.90%
					No	137	47.70%
					Maybe	1	0.30%

Table 4:- Comparison of Interns' and PGs' ADR Reporting Rates.

Question	Year of Study	n	%	P Value	Options	Responses (n)	%
Have You Ever Reported Adverse Drug Reaction (ADR) to the Pharmacovigilance Centre?	Interns	204	100.00%	0.008, S	Yes	59	28.90%
					No	115	56.40%
					Maybe	30	14.70%
	Postgraduates	83	100.00%		Yes	14	16.90%
					No	63	75.90%
					Maybe	6	7.20%
	All	287	100.00%		Yes	73	25.40%
					No	178	62.00%
					Maybe	36	12.50%
Have You Ever Seen the ADR Reporting Form?	Interns	204	100.00%	0.032, S	Yes	53	26.00%
					No	118	57.80%
					Maybe	33	16.20%
	Postgraduates	83	100.00%		Yes	23	27.70%
					No	56	67.50%
					Maybe	4	4.80%
	All	287	100.00%		Yes	76	26.50%
					No	174	60.60%
					Maybe	37	12.90%
Have You Ever Been Trained on How to Report ADR?	Interns	204	100.00%	0.111, NS	Yes	47	23.00%
					No	124	60.80%
					Maybe	33	16.20%
	Postgraduates	83	100.00%		Yes	24	28.90%
					No	53	63.90%
					Maybe	6	7.20%
	All	287	100.00%		Yes	71	24.70%
					No	177	61.70%
					Maybe	39	13.60%
How Many ADRs Have You Reported?	Interns	204	100.00%	0.241, NS	0	150	73.50%
					01-May	30	14.70%
					05-Oct	11	5.40%
					>10	13	6.40%
	Postgraduates	83	100.00%		0	70	84.30%
					01-May	9	10.80%
					05-Oct	3	3.60%
					>10	1	1.20%
	All	287	100.00%		0	220	76.70%
					01-May	39	13.60%
					05-Oct	14	4.90%
					>10	14	4.90%
Have You Faced Any Hurdles While Reporting ADR?	Interns	204	100.00%	0.003, S	Yes	65	31.90%
					No	95	46.60%
					Maybe	44	21.60%
	Postgraduates	83	100.00%		Yes	16	19.30%
					No	57	68.70%
					Maybe	10	12.00%
	All	287	100.00%		Yes	81	28.20%
					No	152	53.00%
					Maybe	54	18.80%

Table 5:- Summary of Challenges Identified in ADR Reporting Processes.

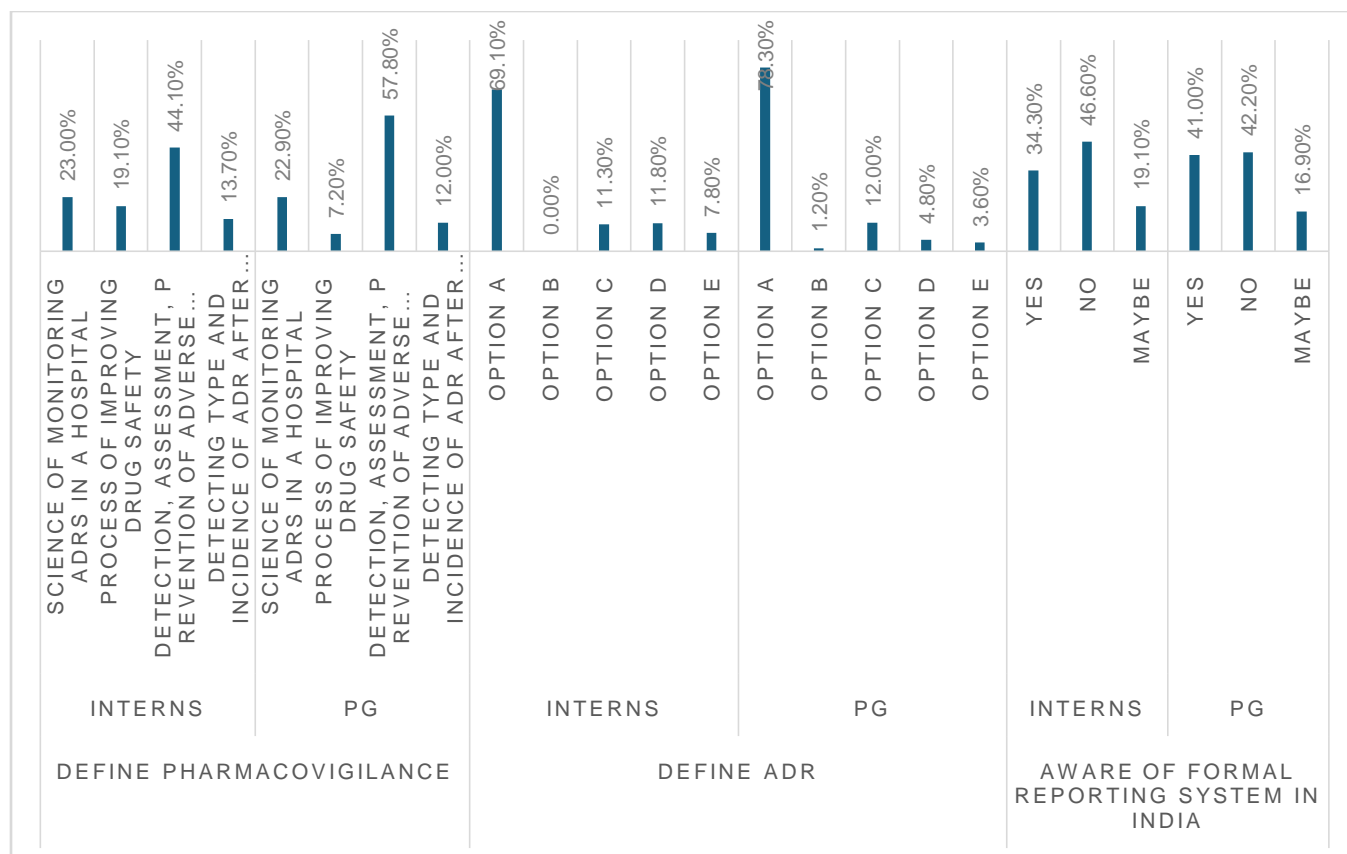


Fig. 1:- Summary of Interns and PG's Knowledge and Comprehension of Pharmacovigilance Concepts.

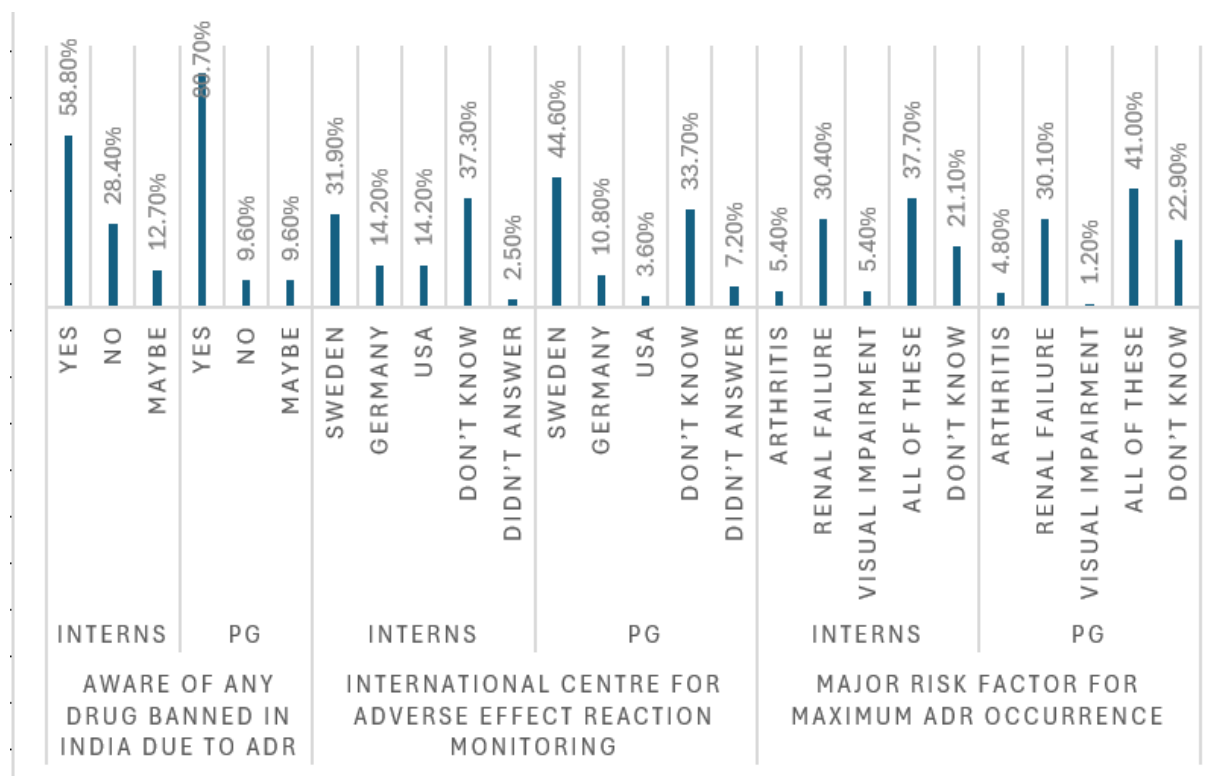


Fig. 2:- Intern's and PG's Views and Practices in ADR Reporting.

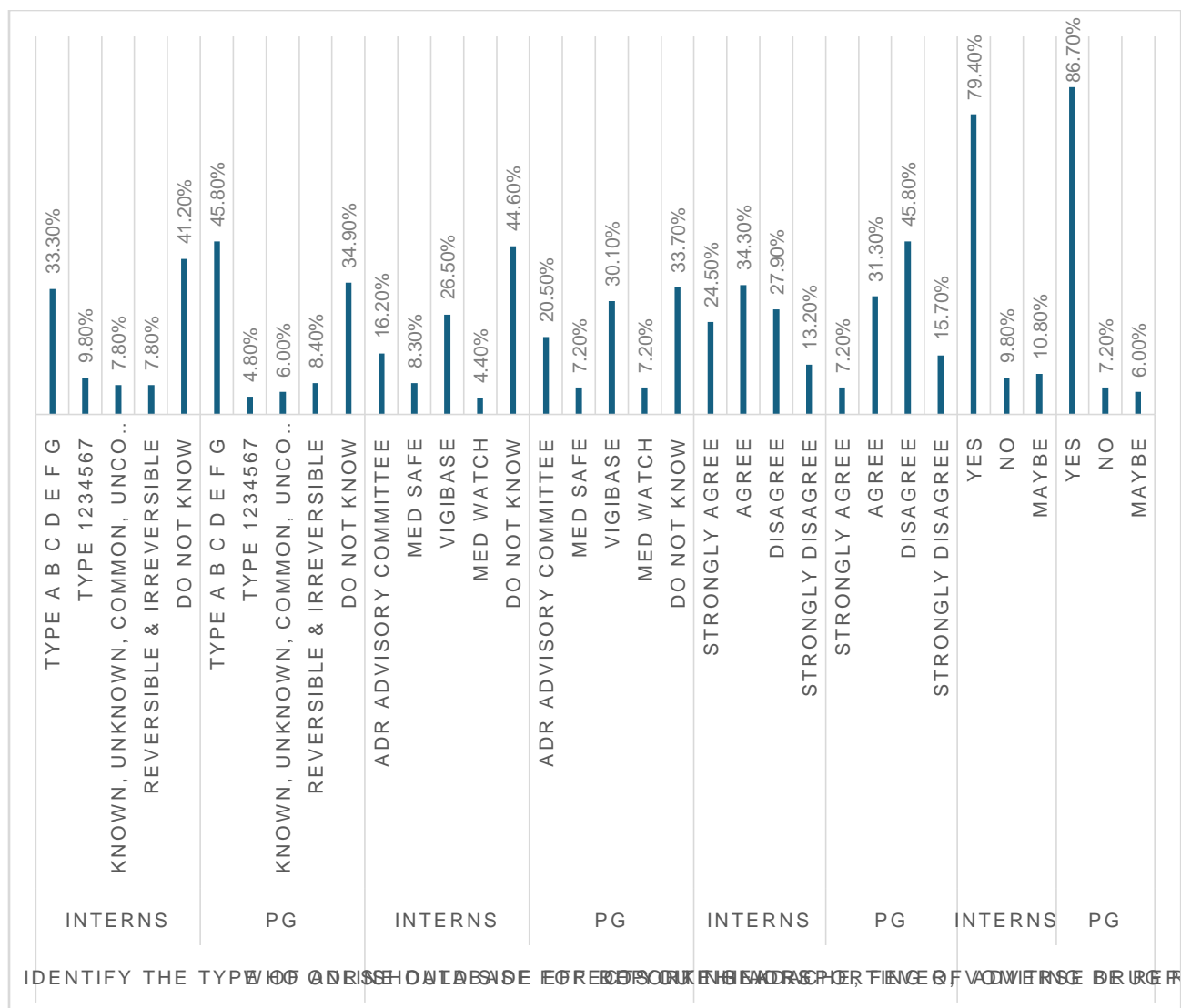


Fig. 3:- Pharmacovigilance Education and ADR Monitoring Centre Knowledge and Consensus.

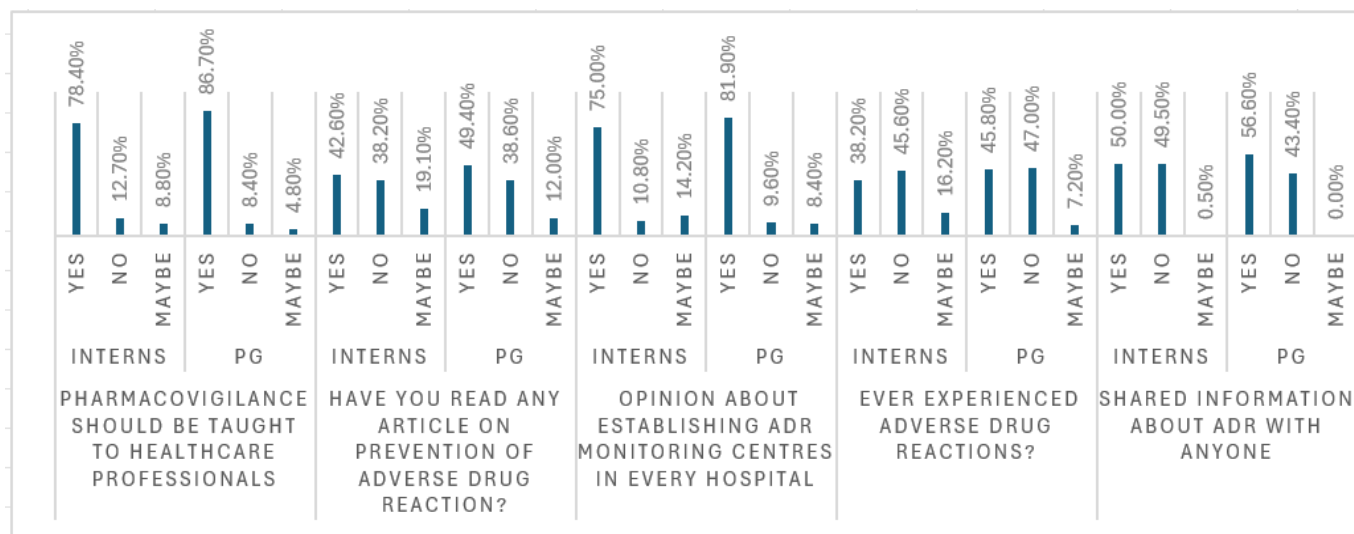


Fig. 4:- Intern's and PG's Experiences and Frequencies with ADR Reporting.

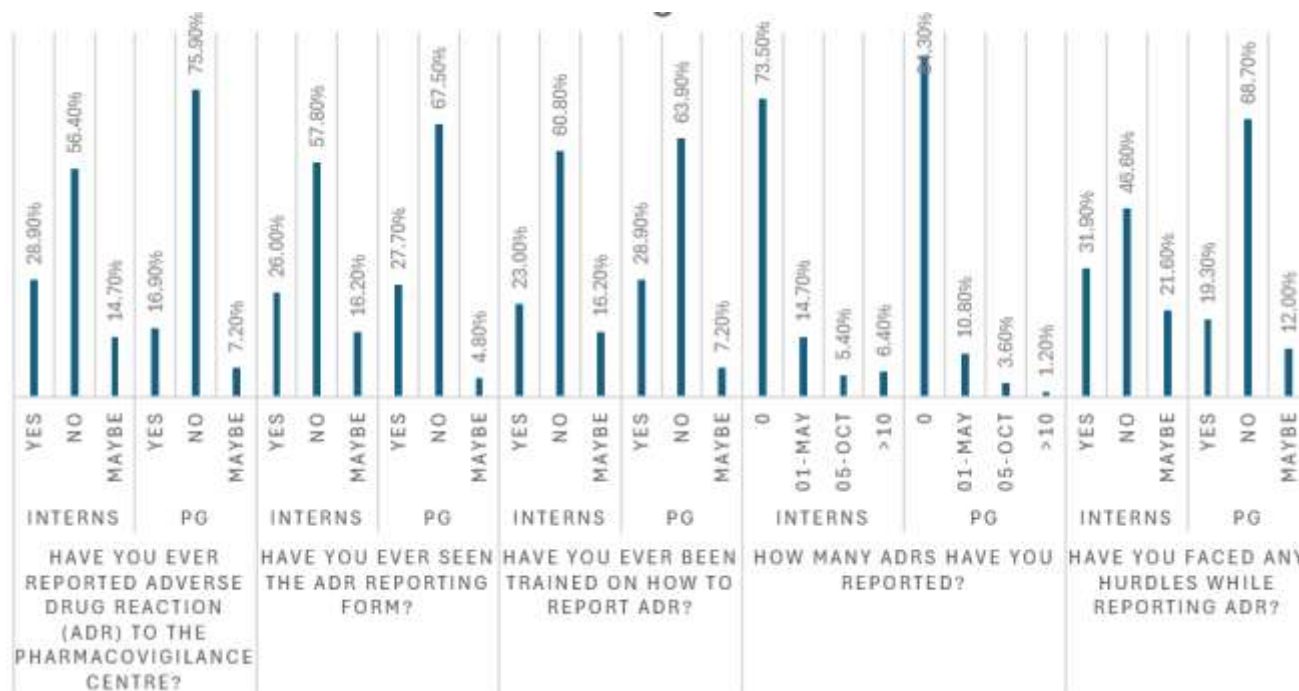


Fig. 5:- ADR Reporting Difficulties and Intern's and PG's Training Status.

Conclusion:-

This study revealed that the overall perception of dental postgraduate students and interns toward pharmacovigilance was positive. A positive correlation was also established between pharmacovigilance training with ADR reporting by the health care professionals. We may infer that respondents understand the importance of pharmacovigilance since most of them realized that ADR reporting is mandatory, as well as the fact that pharmacovigilance needs to be taught in detail to health care professionals. More elaborated studies with higher number of samples are required to evaluate the precise status of knowledge, attitude, and practice of ADR among healthcare professionals, so that in future the ADR reporting system can be practiced adequately.

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