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Evaluation of knowledge, attitude, and practice of medical and dental postgraduates toward reporting of adverse drug reactions in a teaching hospital, South India

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ABSTRACT

This study aims to assess medical and dental postgraduates' knowledge, attitude, and practice (KAP) toward reporting adverse drug reactions (ADRs) and compare the KAP between the medical and dental postgraduates. A cross-sectional questionnaire-based study was conducted on 208 postgraduates (medical and dental postgraduates combined). The medical postgraduates belong to a tertiary care teaching hospital that is 2,000 bedded, serving a population of 1,177,361 in the southwest part of Karnataka, whereas the Dental postgraduates belong to teaching Dental hospitals from the same region as the above hospital received their accreditation by the Dental Council of India in 1970. Both the postgraduates had low KAP about the reporting system of ADRs and the ADR reporting system situated in this hospital. This study also found that the majority of the postgraduates had not attended the training sessions regarding the reporting of ADRs. This study concludes that the ADR reporting is crucial for all healthcare providers so that it initiates the exact actions by healthcare providers through which adverse events can be prevented, and will help in better drug management and thus the reputation of the hospital can be upgraded.

INTRODUCTION

Since 1789, many doctors and professors have emphasized "undesirable effects" due to the patients' intake of therapeutic drugs (van Grootheest and de Jong-van den Berg, 2005; van Grootheest, 2003). These undesirable effects are now termed "Adverse drug reactions" or "ADRs" for short (Edwards and Aronson, 2000). Considering the "Prontosil effect" and "Thalidomide disaster" (Ridings, 2013), a Pharmacovigilance team was launched by North-western University, which conducted RADAR. Since then, i.e., from 1968, WHO has been united with the Uppsala Monitoring Centre in Sweden and started tracking ADRs (Mehta *et al*., 2014). In India, the genesis of pharmacovigilance began in 1986 as a proposed monitoring center extended to a population of 50 million. Our country later joined the WHO ADR Monitoring Program in 1997, but operations only began on January 1, 2005 (Cleveland, 2008; Kumar, 2011; Masurkar, 2017) The National Pharmacovigilance Advisory Committee established under CDSCO, New Delhi, supervises this program (Cleveland, 2008; Kumar, 2011). In 2010, "Pharmacovigilance Programme of India" was instigated by the health bureau to better the ADR reporting in the country. Many ADRs monitoring centers were initiated under this program in the MCI approved hospitals across the countries (Patil, 2014).

The term pharmacovigilance means "Drug safety." It is also termed "PV" for short. The definition is given by WHO is "The science and activities relating to the detection of assessment, understanding, and prevention of adverse effects or any other drug problem" (Giofrè *et al*., 2013; Pinto *et al*., 2012). Pharmacovigilance is required as it monitors the hostile responses to drugs and promotes the safer and more effective use of drugs (Jeetu and Anusha, 2010; Opadeyi *et al*., 2018). The

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pharmacovigilance activities include preparing drugs, monitoring drugs primarily for their adverse effects, disclosing ADRs, reconnaissance of products, post advertising, and legislation (Rosenberg *et al*., 2015). These activities assist in the secured usage of drugs but also help in the identification of substandard drugs. Every country must have its pharmacovigilance team. The same drug can have different effects on people in different countries as the drug's action depends upon their genetics, food habits, culture and customs, method of preparation, distribution of drugs, prescription patterns, intake patterns of patients, etc. The data derived from reporting ADRs are sometimes different from the region within the same country. So, the Pharmacovigilance team notes these things and takes care of the exertions (Shamim *et al*., 2016).

Healthcare industries can improve their treatments and pharmaceutical conditions only when the reporting systems are proper, primarily when related to ADRs (Shamim *et al*., 2016). Our country has been monitoring the adverse reactions of drugs in patients, particularly those suffering from chronic kidney diseases (Ghewari *et al*., 2014). However, this monitoring is not that effective because of insufficient understanding of pharmacovigilance. It was reported that in India, there were only about 6.7% of patients experienced unpleasant drug outcomes. This is also one of the causes of hospital admissions and re-admissions, creating severe problems for the hospital's reputation (Charu Bahri, 2016; Dhamija *et al*., 2017; Khjauria *et al*., 2015). Although we know that under-reporting and negligence are the leading causes of Pharmacovigilance programs' improper functioning in India, other reasons should also be considered. A systematic review found different reasons for the attitude toward underreporting among the healthcare providers like uncertain feelings about the drug, anxiety about getting involved with lawsuits, the anxiety of being guilty that the drug that had been administered to the patient might be ineffective, ignorance in creating the notification, insecurity about reporting of ADRs, and postponing the ADR reporting due to unavailability of time, other excuses (Varallo *et al*., 2014). However, in India, along with these attitudes, we also lack knowledge, time for reporting, and lack training for the healthcare professionals. Along with these attitudes, we also perceive that the reporting process is tedious and complicated (Varallo *et al*., 2014). As the lack of training is a well-known contributor to nonadherence to any good practice, there is a need to create awareness and improvise the knowledge of students in the medical field and among health care providers regarding pharmacovigilance that could change the attitude and improve the reporting process.

We conducted a study to evaluate and compare knowledge, attitude, and practice (KAP) of reporting ADRs in Medical and Dental Postgraduates in multispeciality teaching hospitals.

METHODOLOGY

A cross-sectional study was conducted on 208 postgraduates (medical and dental). The study was carried out in a tertiary care teaching multispeciality hospital located in coastal Karnataka, India. The hospital caters to both medical and dental students of all super specialities. A total of 208 postgraduates (both medical and dental) were involved. Students who had completed their under graduation and were pursuing their postgraduation were eligible for the participation. Students unwilling to participate were removed from the analysis and study.

A questionnaire consisting of 14 questions was developed following evidence synthesis and expert advice. Each correct answer received a score of 1, and each incorrect response received 0 scores, and the results were tabulated and managed in Microsoft Excel. The questionnaire's content validity and face validity were done with three expert evaluations from the Pharmacology and Medicine Physician department. Internal consistency of the questionnaire was validated through Chronbach's Alpha; the score was 0.7734, which was a good score in a range of 0 to 1.0. Post validity, the questionnaires were distributed to them personally, and they were asked to fill them. Care had been taken that these postgraduates had not used any internet sources or discussed with their colleagues while answering. The sample size was calculated using the proportional formula by OpenEpi, in which the population size was assumed as 449 and the frequency anticipated was 47%. The sample size has come out as 207 at a 95% confidence interval. Population size (for finite population correction, 449) (N = 449). We considered hypothesized% frequency of outcome factor in the population: 47% ±5(p); confidence limits as % of 5% 100 (absolute ±%) (d): 5% and design effect (for cluster surveys-DEFF): The following equation was used to estimate the required sample size:

$$\text{Sample size } n = [\text{DEFF}^*Np(1-p)]/[d2/z21-\alpha/2^*(N-1) + p^*(1-p)]$$

The study's objectives were to assess the KAP of medical and dental postgraduates reporting ADRs to compare the KAP between the medical and dental postgraduates. We assume that if medical graduates had formal training, they practice what they have learned through training as they have finished their junior residency program.

Institutional Ethics committee was obtained before the commencement of the study, IEC 789/2018.

We proposed the following hypotheses based on the above objectives:

Hypothesis 1

H0: More than 95% of medical and dental postgraduate students know to report ADR.

Ha: Less than 95% of medical and dental postgraduate students know to report ADR.

Hypothesis 2

H0: More than 95% of medical and dental postgraduate students have an attitude toward reporting ADR.

Ha: Less than 95% of medical and dental postgraduate students have an attitude toward reporting ADR.

Hypothesis 3

H0: More than 95% of medical and dental postgraduate students practice reporting ADR.

Ha: Less than 95% of medical and dental postgraduate students practice reporting ADR.

Hypothesis 4

H0: There is no difference in the knowledge score of medical and dental postgraduate students.

Ha: There is a significant difference in the knowledge score of medical and dental postgraduate students.

Hypothesis 5

H0: There is no difference in attitude scores of medical and dental postgraduate students.

Ha: There is a significant difference in attitude scores of medical and dental postgraduate students.

Analysis of data was done using IBM. SPSS software version 16. Codes have been developed for the options. The coded data was verified systematically. For the analysis of data, descriptive and inferential statistics were applied. Median is used across the age groups. The chi-square test was used to determine the significant difference in categorical data.

RESULTS

Demographic characteristics

Two hundred eight students took part in the study, where 138 medical and 70 dental postgraduates were included. These 138 students were medical postgraduates from Gynaecology, General Medicine, Cardiology, Paediatrics, Urology, General Surgery, Neurosurgery, Orthodontics, Pulmonary Medicine, Anaesthesiology, Psychiatry, Dermatology, Ophthalmology, Community Medicine, Pathology, Gastroenterology, Transfusion Medicine, Radiology and Oncology, and ENT.

The remaining 70 postgraduates were from dentistry college from the department of Periodontology, Oral Medicine and Radiology, Oral Pathology, Pedodontics, Prosthodontics, Oral and Maxillofacial Surgery, Orthodontics, Conservative and Endodontics, and Public Health Dentistry, respectively.

All the 208 questionnaires were answered, giving a response rate of 100%. Of which, 42.3% were male, 30% were dental, and 48.6% were medical postgraduates; 57.7% were female, and among them, 70% were dental, and 51.4% were medical postgraduates. Figure 1 represents the age of participating medical and dental postgraduate students.

Hypothesis 1 and 4

All medical practitioners must know about pharmacovigilance, and we found the gap in overall knowledge was statistically significant $p < 0.05$ with 95% CI. We reject the null hypothesis-1 as both postgraduates in the sample group do not have adequate knowledge of pharmacovigilance $p < 0.001$ with 95% CI on 1-proportion exact test. Both medical postgraduates (MPs) and dental postgraduates (DPs) have less knowledge than desired (95% CI) on what pharmacovigilance ($p < 0.0000$) is. There is no statistically significant difference ($p > 0.05$) in the knowledge score of MPs and DPs. Both the PG groups had equal knowledge of pharmacovigilance; hence, we accept the null hypothesis-4 that both groups had similar knowledge of pharmacovigilance. Table 1 represents the knowledge score of students on pharmacovigilance.

Hypothesis 2 and 5

Both groups have statistically significantly lower reporting attitudes $p < 0.001$ with 95% CI. Therefore, we reject null hypothesis-2 and accept the alternate hypothesis. We found that individual groups MP and DP hold equal attitudes toward reporting ADRs, $p > 0.05$ with 95% CI; hence, we accept the null hypothesis 5 (Tables 2 and 3).

89.4% of the postgraduates had agreed that ADR reporting is a professional obligation. 10.1% of postgraduates had responded that ADR reporting is not a professional obligation. However, 1% of participants answered that they were not aware.

87.5% of the postgraduates responded that all the healthcare professionals have a role in reporting the ADRs. However, 0.5% of the postgraduates had responded that only doctors, clinical pharmacists, and therapeutics committees have a role in reporting. 1%

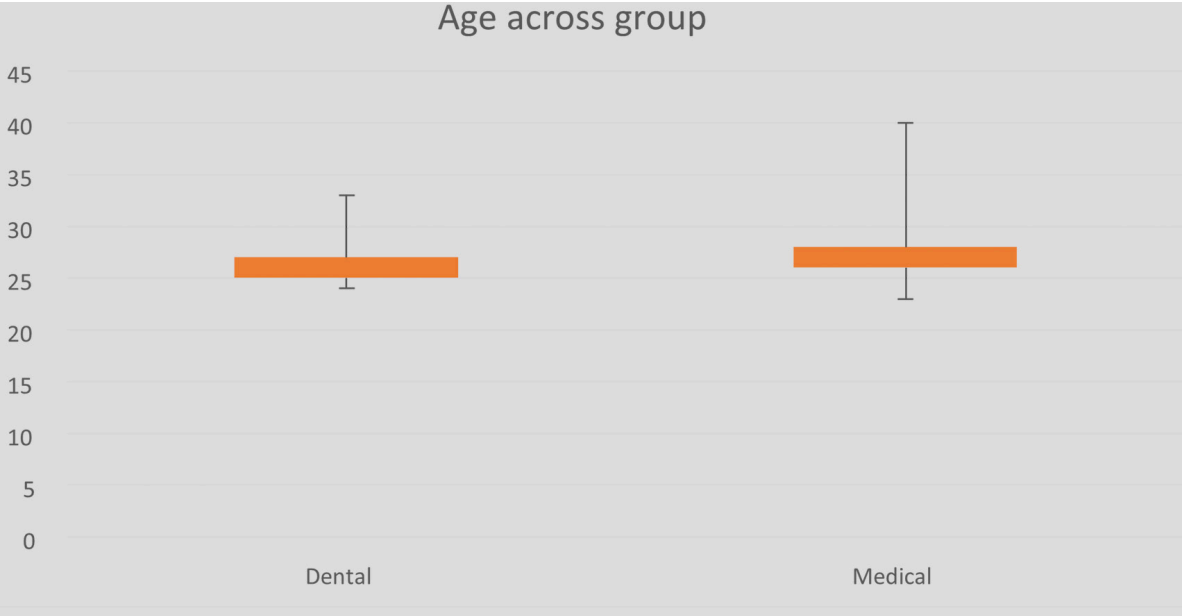

Figure 1. Age of participated medical and dental postgraduate students.

Table 1. Knowledge score of students on pharmacovigilance.

Questions asked	Options	MP *n* (%)	DP *n* (%)	Total *n* (%)	*p*-value
Pharmacovigilance deals with?	Collection and detection of adverse effects with pharmaceutical products	15 (10.9%)	4 (5.7%)	19 (9.1%)	>0.05
	Assessment and monitoring of adverse effects with pharmaceutical products	23 (16.7%)	8 (11.4%)	31 (14.9%)	
	Prevention of adverse effects with pharmaceutical products	3 (2.2%)	1 (1.4%)	4 (1.9%)	
	All the above	97 (70.3%)	57 (81.4%)	154 (74.0%)	
Ceftriaxone induced rash is an example of which type of reaction.	Photosensitive	0 (0.0%)	3 (4.3%)	3 (1.4%)	>0.05
	Hypersensitive	98 (71.0%)	55 (78.6%)	153 (73.6%)	
	Idiosyncrasy	36 (26.1%)	9 (12.9%)	45 (21.6%)	
	Toxic effect	4 (2.9%)	3 (4.3%)	7 (3.4%)	
Do you believe that herbal products and herbal medicines cause adverse drug reactions?	All the herbal medicines and products cause adverse drug reactions	3 (2.2%)	0 (0.0%)	3 (1.4%)	>0.05
	All the herbal medicines and products do not cause adverse drug reactions	2 (1.4%)	2 (2.9%)	4 (1.9%)	
	Herbal medicines and herbal products may cause or may not cause adverse drug reactions	130 (94.2%)	67 (95.7%)	197 (94.7%)	
Which of the following factors affect the occurrence of adverse drug reactions?	None of the above	3 (2.2%)	1 (1.4%)	4 (1.9%)	>0.05
	Patient comorbidities	7 (5.1%)	3 (4.3%)	10 (4.8%)	
	Medication errors	16 (11.6%)	12 (17.1%)	28 (13.5%)	
	Abrupt discontinuation of the drug	4 (2.9%)	1 (1.4%)	5 (2.4%)	
	All the above	111 (80.4%)	54 (77.1%)	165 (79.3%)	
Are you aware of the Pharmacovigilance program in India?	No	91 (65.9%)	62 (88.6%)	153 (73.6%)	<0.05
	Yes	47 (34.1%)	8 (11.4%)	55 (26.4%)	
Is there any specific form for reporting adverse drug reactions in this hospital?	No	24 (17.4%)	22 (31.4%)	46 (22.1%)	<0.05
	Yes	114 (82.6%)	48 (68.6%)	162 (77.9%)	
Is there an online portal for reporting adverse drug reactions in this hospital?	No	47 (34.1%)	24 (34.3%)	71 (34.1%)	>0.05
	Yes	89 (64.5%)	46 (65.7%)	135 (64.9%)	
	Not sure	2 (1.4%)	0 (0.0%)	2 (1.0%)	
Are you aware of different Pharmacovigilance programs globally? If yes, name two companies conducting Pharmacovigilance programs?	No	115 (83.3%)	62 (88.6%)	177 (85.1%)	>0.05
	Yes	23 (16.7%)	8 (11.4%)	31 (14.9%)	

of them had responded that it is nurses' duty only to report the ADRs, whereas 3.8% of them responded that only clinical pharmacists and therapeutics committees have a role in reporting.

Hypothesis 3

There is no statistically significant difference in the practice of the MP and DP with 95% CI $p > 0.05$; however, both groups had statistically significant lower practice score $p < 0.001$ with 95% CI. Hence, we reject null hypothesis-3 and accept the alternate hypothesis.

78.4% of the postgraduates responded to all hindrances mentioned in the question as reasons for the lack of reporting of ADRs. 23% of them responded that underreporting of ADRs is due to lack of knowledge. 10% of participants responded that reason for underreporting is time constraints.

82.2% of the postgraduates responded that all the challenges mentioned in the questionnaire are reasons for the country's poor implementation of pharmacovigilance programs.

About 71.2% of the postgraduates had responded that they had never attended the training sessions or programs regarding ADR reporting in the hospital. 19.2% of them had responded that they had attended the programs sometimes only.

About 41.8% of the postgraduates responded that they want the training every 6 months. 34.6% responded that training is required every year, and about 21.6% of the postgraduates wanted training every 3 months. However, only 1.9% of the postgraduates had responded that they did not need training concerning ADR reporting.

DISCUSSION

It was found that the postgraduates (both medical and dental) had the same KAP toward reporting ADRs. Even the attitude toward training taken and requirement of training by them is similar. No educational programs were conducted after assessing their KAP. Only an education module was developed with the help of the Pharmacy practice and Pharmacology departments.

Table 2. Attitude of postgraduates on pharmacovigilance.

Questions asked	Options	MP *n* (%)	DP *n* (%)	Total *n* (%)	*p*-value
Do you think adverse drug reaction reporting is a professional obligation of healthcare professionals	No	16 (11.6%)	5 (7.1%)	21 (10.1%)	>0.05
	Yes	121 (87.7%)	65 (92.9%)	186 (89.4%)	
	Not Sure	1 (0.7%)	0 (0.0%)	1 (0.5%)	
According to you who should take the role in reporting adverse drug reactions?	Physicians	9 (6.5%)	6 (8.6%)	15 (7.2%)	>0.05
	Physician and Clinical pharmacist and therapeutics committee	0 (0.0%)	1 (1.4%)	1 (0.5%)	
	Nurses	2 (1.4%)	0 (0.0%)	2 (1.0%)	
	Clinical pharmacist and therapeutics committee	7 (5.1%)	1 (1.4%)	8 (3.8%)	
	All the above	120 (87.0%)	62 (88.6%)	182 (87.5%)	
What do you think are the hindrances for reporting adverse drug reactions?	Lack of knowledge regarding the importance of reporting adverse drug reactions	13 (9.4%)	10 (14.3%)	23 (11.1%)	>0.05
	Lack of knowledge regarding the importance of reporting adverse drug reactions. And Time constraints.	1 (0.7%)	0 (0.0%)	1 (0.5%)	
	Lack of knowledge regarding the importance of reporting adverse drug reactions. And Complexity of adverse events	2 (1.4%)	0 (0.0%)	2 (1.0%)	
	Time constraints.	9 (6.5%)	1 (1.4%)	10 (4.8%)	
	Time constraints. And Complexity of adverse events.	2 (1.4%)	0 (0.0%)	2 (1.0%)	
	The complexity of adverse events.	6 (4.3%)	1 (1.4%)	7 (3.4%)	
	All the above.	105 (76.1%)	58 (82.9%)	163 (78.4%)	
What do you think are the challenges for implementing pharmacovigilance programs in India?	Lack of awareness and knowledge about pharmacovigilance	8 (5.8%)	5 (7.1%)	13 (6.3%)	>0.05
	Lack of awareness and knowledge about pharmacovigilance. Lack of trained personal.	2 (1.4%)	0 (0.0%)	2 (1.0%)	
	Lack of awareness and knowledge about pharmacovigilance. Insufficient reporting process.	0 (0.0%)	1 (1.4%)	1 (0.5%)	
	Lack of trained personal.	2 (1.4%)	0 (0.0%)	2 (1.0%)	
	Lack of trained personal. Insufficient reporting process	1 (0.7%)	0 (0.0%)	1 (0.5%)	
	Insufficient reporting process	17 (12.3%)	1 (1.4%)	18 (8.7%)	
	All the above	108 (78.3%)	63 (90.0%)	171 (82.2%)	

A study was conducted in Vadodara among the postgraduates (n = 101) of different departments by using a questionnaire of 22 in number. 64.08% of the postgraduates had incorrect knowledge about ADRs. 90.76% of the postgraduates agreed that reporting ADRs is necessary, but only 7.92% had reported to the ADR reporting center. This is because the majority of the postgraduates had no proper knowledge about ADRs and were also not aware of reporting systems (Vora *et al*., 2015).

The systematic review and meta-analysis study was conducted by health professionals by doing a systemic review through PubMed, Scopus, Embase, and Google Scholar. Twenty-eight systematic review studies and 18 meta-analysis studies were taken and observed for KAP toward ADR reporting in India. It was found that there was a considerable gap in KAP in India, and also, there is a necessity to educate healthcare professionals regarding the ADRs (Vora *et al*., 2015).

Similar questionnaire-based studies are conducted in Kuwait among pharmacists (n = 342) by using a questionnaire consisting of 25 questions and in Islamabad among physicians and pharmacists (n = 384) by using a questionnaire consisting of 27 questions in secondary and tertiary hospitals in both countries (Alsaleh *et al*., 2017; Zaka Un Nisa and Ayesha Zafar, 2018). Both the studies had suggested the need for improvement in the knowledge and attitude to improve the awareness of reporting ADRs to the ADR reporting centers.

Though the rate of reporting in India has doubled in the last 3 years, it is still lower than average compared to the reporting rate of ADRs in other developed countries (Varallo *et al*., 2014).

One of the reasons for such a low rate could be under-detection and under-reporting. Another reason could be the centrally nonavailability of real-time data.

Table 3. Assessing the training practice among the participants.

Questions asked	Options	MP *n* (%)	DP *n* (%)	Total *n* (%)	*p*-value
Have you attended the training sessions or programs for reporting adverse drug reactions in this hospital?	Always attended	3 (2.2%)	2 (2.9%)	5 (2.4%)	>0.05
	Sometimes attended	32 (23.2%)	8 (11.4%)	40 (19.2%)	
	Not sure	11 (8.0%)	4 (5.7%)	15 (7.2%)	
	Never attended	92 (66.7%)	56 (80.0%)	148 (71.2%)	
How frequently do you think training for reporting adverse drug reactions is required so that awareness regarding this will improve?	Every 3 months	27 (19.6%)	18 (25.7%)	45 (21.6%)	>0.05
	Every 6 months	53 (38.4%)	34 (48.6%)	87 (41.8%)	
	Every 1 year	54 (39.1%)	18 (25.7%)	72 (34.6%)	
	Not required at all	4 (2.9%)	0 (0.0%)	4 (1.9%)	

The reports recorded in databases were minimal in Nigeria, ranging from 0 to 26. Even the documentation of medicines-related admissions and other pharmacovigilance activities was poor (Opadeyi *et al*., 2018).

In Pakistan, there was no active participation in pharmacovigilance as 80% of the hospitals had no proper ADR reporting system (Amin *et al*., 2016). The condition is similar in other gulf countries as mentioned above. Nevertheless, few countries like Malaysia, Italy, and the UK use the results of these studies to improve their pharmacovigilance activities (Borg *et al*., 2015; Giofrè *et al*., 2013; Tew *et al*., 2016).

A comparative study among the BRIC countries was conducted to learn about pharmaceutical regulatory trends. In this study, it was found that every country had its lacunae in regulating drugs. In China, it was found that chains were complex in manufacturing and regulating drugs. Russia makes tough and strong decisions and legislation systems. In Brazil, proof of bioequivalence was not given to the registration of drugs since 2003. It leads to the production and distribution of substandard drugs within the country. This system needs to be taken care of in Brazil. The drug regulatory system in India is congested, where they hold on to the regulation of drugs is not appropriately distributed. Issues related to licensing, proper regulations for Pharmacovigilance systems, potential administration toward the regulation of drugs, etc., should be under check (Vashisth *et al*., 2012), with these things under check, pharmacovigilance in India can be improved.

Underreporting of ADRs persists even in the developed countries like the USA. In 2016, a study conducted among healthcare professionals concluded that the healthcare professionals lacked proper knowledge in determining the adverse action and had time constraints in reporting. Also, there is the presence of poor integration and uncertainty about the reporting systems (Stergiopoulos *et al*., 2016).

Therefore, the following literature review states that every healthcare professional should have the proper knowledge and attitude toward ADRs. The government should improve reporting systems for ADRs and should be made aware and accessible of these reporting systems to all healthcare professionals. Thus, we can prevent the allergic conditions and deaths that lead to ADRs and strive for the better development of drugs.

The critical factor found in this study was that the postgraduates lacked knowledge about the reporting system present in the hospital. Only 64.9% of the postgraduates were aware of the online portal system present in the hospital. At the same time, 77.9% of the postgraduates responded positively regarding a specific form for reporting ADRs in the hospital, which is not present. However, they had a positive attitude toward training programs.

Previously, a similar study was conducted in the same place among healthcare professionals (2011) to assess their KAP toward pharmacovigilance. Pre and posttests were conducted on doctors, nurses, and pharmacists. Significant improvement among the healthcare professionals was seen in the post-test (Rajesh *et al*., 2011).

A questionnaire-based survey was conducted in 2012 among 1,600 practitioners; the results showed that their attitude toward ADR reporting was positive although their actions contradicted (Kharkar and Bowalekar, 2012).

Similarly, a study conducted on 50 postgraduates in 2012 resulted in inadequate knowledge and required training (Prerna Upadhyaya *et al*., 2012).

An interventional study lecture was conducted in 2013, among 220 doctors, where the response was 90% of them had a positive attitude toward ADR reporting but were not aware of how to report the ADRs. Attitude toward training was 100% positive (Sanghavi *et al*., 2013). A similar interventional study was conducted among 250 physicians in 2014 on whom the Continuing Medical Education (CME) program for reporting ADRs was conducted. Physicians who attended the CME had adequate knowledge about ADR reporting than those who did not attend (Bisht *et al*., 2014).

Even the studies, which were questionnaire-based, similar to the above ones, were conducted on 95 dentists in 2015 and on 241 dental students recently in 2017 resulting that the dentists and dental students lacked knowledge and practice toward ADR reporting, and this is the leading cause for underreporting (Khan *et al*., 2015; Sharma *et al*., 2017).

A similar questionnaire-based study was conducted in Nigeria in 2011 among healthcare workers, where only 47% of them reported ADRs, but 75% were primarily verbal (Fadare *et al*., 2011).

A similar study conducted in 2016 in Iran among 350 general practitioners showed that the practitioners lacked knowledge in reporting ADRs (Peymani *et al*., 2016).

In Malaysia, in 2016, a cross-sectional, questionnaire-based survey was conducted among 30 doctors and pharmacists, which concluded that 43.8% of the participants were not aware of the "blue card system" for ADR reporting, present in the country and the remaining 69.2% of them agreed that they were not trained in the reporting process for ADRs (Tew *et al*., 2016).

The situation of the results was the same in a similar study conducted in Saudi Arabia in 2018. This study was conducted among 148 healthcare professionals and Medical students (Ashraf Tadvi *et al*., 2018).

Countries like the UK and Italy conduct surveys very frequently on the reporting system present in their respective countries to check the level of improvement in the reporting of ADRs. These surveys add value to the nation and stand as an example for nations (Avery *et al*., 2011; Giofrè *et al*., 2013).

The change in mindset and attitude, which are vital for the success of an effective Pharmacovigilance system, can be brought by proper training to the healthcare providers, imparting knowledge to patients, increasing awareness among the general public, and utilizing new techniques such as monitoring of web markets, global electronic databases, education, associating stakeholders and by regulating herbal medicine standards and allied medicinal systems, awareness programs, etc (Mittal *et al*., 2016)

In our country, we have an excellent ADR reporting system in place. Every citizen has the authority to report to the National Coordination Centre. This center had developed a website available to the people in their respective mother tongues. All reactions due to various medicines or medical devices can be reported (Vivekanandan, 2015). However, this website's use is minimal as the people are unaware and sometimes due to lack of availability. Though the people are aware and available, their perceptions and attitudes prevent them from reporting ADRs.

RECOMMENDATIONS

Awareness regarding the importance of ADR reporting and the prevailing ADR reporting system in the hospital (both online and offline systems) must be provided to the Postgraduates.

We need to implement a separate reporting form exclusively for ADRs in the hospital.

Training must be given to the postgraduates at an interval period of at least six months on how to use of prevailing ADR reporting system (both online and offline systems) in the hospital.

Spontaneous reporting of ADRs must be promoted.

It should be made mandatory that daily or a least every week, one person (preferably PharmD or B. Pharm) in every department should collect the reported forms and send them to the vigilance department in the hospital.

CONCLUSION

Therefore, this study emphasizes that every healthcare professional should have proper KAP for ADRs and reporting. Although there are proper reporting systems for ADRs in India, they can still be improved by the government and should be made aware and accessible of these reporting systems to all the healthcare professionals and citizens of the country in a simple and accessible format. At least, the hospitals that have reporting systems for ADRs should make sure that they train their staff regarding it. Thus, we can prevent serious adverse events and strive for better development of drugs.

FURTHER SCOPE OF THE STUDY

1. The study was limited only to medical and dental postgraduates, where it can also be conducted on interns and undergraduates.
2. Awareness regarding pharmacovigilance can be brought by giving seminars and lectures to all the students in the institution.
3. If possible, students can be asked to form a "vigilance club" for reporting ADRs, where they can keep track of ADRs occurring during their case treatments.

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CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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CONFLICTS OF INTEREST

The authors report no financial or any other conflicts of interest in this work.

ETHICAL APPROVALS

Institutional Ethics committee approval was obtained before the commencement of the study (IEC 789/2018).

DATA AVAILABILITY

All data generated and analyzed are included within this research article.

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