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Original Article

Assessment of Knowledge, Attitude and Practice of Pharmacovigilance among Medical Interns and Medical Post Graduates in Tertiary Care Hospital

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ABSTRACT

Background: Pharmacovigilance is defined by the European Commission (EU) as the "Process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicine". The purpose of this study is to evaluate medical interns and medical post graduate students' current pharmacovigilance knowledge, attitudes, and practices at tertiary care hospitals. **Materials and Methods:** A Cross-sectional questionnaire- based survey was employed and a convenience sampling was opted to collect the data among Medical Interns and Medical PG in tertiary care hospital from December 2022 to July 2023. **Results:** The study evaluated the understanding and attitude of Medical Interns and Medical PGs students towards pharmacovigilance. The majority of participants correctly comprehended the study's objectives, India's regulatory body, and the newly banned medications, which were statistically significant. In terms of attitude, most participants agreed on the importance of reporting Adverse Drug Reactions (ADR), which was statistically significant. Regarding the practice of pharmacovigilance, participants agreed to experience ADR in patients, see the ADR Reporting Form, and keep records of ADR, all of which were statistically significant. However, certain aspects such as the definition, methods, international monitoring center, suspected ADR system, training on reporting ADR, and willingness to report ADR were not statistically significant. Overall, the study suggests a fair knowledge among the participants regarding pharmacovigilance. **Conclusion:** This study determined the Assessment of Knowledge, Attitude and practice of Pharmacovigilance among Medical Interns and Medical Post Graduates in a tertiary care hospital. According to the current study, the majority of Medical Interns and Medical Post Graduates were knowledgeable and supportive of pharmacovigilance, however they are not as effective in practice. In view of the previously stated, actions are required to instruct, empower, and train Medical Interns and Medical Post Graduates in the field of pharmacovigilance.

Keywords: Medical Interns, Medical PG, Adverse drug reaction reporting, Pharmacovigilance center.

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INTRODUCTION

Pharmacovigilance is defined by the European Commission (EU) as the "Process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicine".[1] The History of Pharmacovigilance started 169 years ago, on January 29 1848, when a young girl (Hannah Greener) had an infected toenail that needed to be surgically removed. She passed away after being given chloroform anesthesia. The doctors were in the dark; they had no idea how Hannah Greener had died. She may have experienced pulmonary aspiration or a severe arrhythmia.[2] Yet, Hannah was not the first patient to pass away following chloroform anesthesia; other patients experienced the same outcome.

As a response, The Lancet Journal requested that England physicians record any anesthesia-related deaths, and in 1893 they did so. The US Federal Food and Drug Act, which was passed on June 30, 1906, established the requirement that medications be safe and free of any contamination. Furthermore, in 1911, the false medication therapeutic indications were prohibited by the organization.[3] In 1937, 107 persons in the USA lost their lives as a result of using sulfanilamide elixir, which contained diethyl glycol as the solvent. It was believed that the manufacturing industries were responsible for the fatality because they were unaware of the toxicity of the solvent at the time.[2,4] Consequently,

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the Federal Food, Drug and Cosmetic Act was formed in 1938 with the aim of enhancing the public health service. In fact, the new system introduced the ability of conducting factory audits and specified that drug safety must be proven before being approved for commercialization.[5] Douthwaite postulated that melena might be caused by Acetylsalicylic Acid (ASA) in 1938.[6] Research on the gastrointestinal toxicity of ASA produced varying results. Due to data published in 1955, suggesting that ASA can cause gastrointestinal issues, it is currently prohibited in people who have gastrointestinal ulcers.[7] More than 60 years ago, about 10,000 children were born with devastating malformations in various countries worldwide. The clinicians and researchers were confused and wondered about the cause of this disaster. During this time, treating morning sickness with thalidomide while pregnant was quite acceptable. Thalidomide was thought to be safe for use during pregnancy, according to doctors. Yet unfortunately, in addition to fetal defects, it led to abortion in a significant proportion of women. Thalidomide was also withdrawn from the market in the majority of nations between 1961 and 1962.[8]

The thalidomide disaster in 1961 marked the beginning of a major shift in European Pharmacovigilance. Australian doctor Dr. McBride linked thalidomide to congenital deformities in children in a letter to the editor of the Lancet Journal. He discovered that the incidence of congenital malformations in neonates (1.5%) was actually increased by thalidomide use during pregnancy by up to 20% in women.[9] During a German paediatric conference, Dr. Lenz proposed a connection between thalidomide and abnormalities around the same period. His theory was then published in the German newspaper (Welt am Sonnatag).[10] In the US, A 1973 retrospective study found a link between the use of thalidomide during pregnancy and congenital defects in the foetus.[1] The tragedy of thalidomide brought to light a variety of problems including the efficacy of animal experiments, the industrial company's strategy, and the significance of medications that have been marketed, drug monitoring. Moreover, these tragic events alter the Pharmacovigilance system because the spontaneous reporting of adverse drug reactions evolved into methodical, ordered, and controlled. This letter already has all the elements required to create an unexpected report, as well as to determine the cause-effect relationship between the medicine and the side effect.[11] In 1964, the "Yellow card" was organized by the United Kingdom. A specific form called Yellow Card is used to compile an unexpected report of medication toxicity.[12] The 1962 amendment in the United States required safety and Drug efficacy information was approved prior to premarketing submission. Due to this modification, the safety information has to incorporate tests for teratogenicity on three different animal species.[1] The thalidomide accident in Europe in 1965 caused the establishment of a European regulation with the EC Directive 65/65.[13] The Collaborative Drug Surveillance Programme began in 1966 with a preliminary survey of Boston. They were the first group to monitor potential side effects of drug usage in hospitals using quantitative epidemiology studies, and they were also essential in the development and application of drug epidemiology techniques.[14]

Ten members took part in the WHO Programme for International Drug Monitoring, which was established in 1968 (Australia, United Kingdom, United States, Germany, Canada, Ireland, Sweden, Denmark, New Zealand, and Netherlands). Italy participated in this programme in 1975.[15] Several studies of adverse drug reactions were documented between 1968 and 1982.[2]

International collaborating of Pharmacovigilance is known as the Uppsala Monitoring Centre (UMC, WHO), Sweden, keeps the global database of known suspected adverse drug reactions. Investigation on hospitalized Patients databases (Vigibase) have shown staggering statistics on the frequency of severe ADRs. Only 6-10% of ADRs are thought to be reported globally, according to studies.[16] Only 2% of the UMC database is from India.[17] VigiBase, the WHO's global database of reported potential drug side effects, is routinely checked for potential safety signals requiring additional research and action to protect people.[18] All healthcare providers are required to disclose ADRs. The ADR reporting system uses two different approaches: national scenario and international scenario. The National Pharmacovigilance Center is receiving reports from the national scenario. Using specific documents, the Ministry of Health's Directorate General of Pharmacy Affairs and Drug Control. The hospital's clinical pharmacy division and medication information centre oversee its coordination. In the international scenario, the national centre collaborates with an international pharmacovigilance center maintained by the Uppsala Monitoring Center of the World Health Organization.[19] Healthcare professionals voluntary reporting of Adverse Drug Reactions (ADRs) is essential to the efficacy of pharmacovigilance programmes and reducing the risk of ADRs from pharmaceutical products. Pharmacovigilance is still in its infancy despite numerous attempts and the existence of a sizable number of tertiary care centres. Results from numerous studies have demonstrated a relationship between ADR reporting and KAP of medical interns and post graduates.[20] One of the most significant factors contributing to this under-reporting is a lack of knowledge regarding pharmacovigilance. The primary method used by pharmacovigilance studies to collect data on ADRs is thought to be spontaneous reporting systems. So, this study was conducted to evaluate medical interns and post graduates in a tertiary care hospital's knowledge, attitude, and practice regarding pharmacovigilance.[17]

The need of the study is to assess the knowledge among Medical Interns and Medical PGs for ADR monitoring and reporting. They belong to the clinical section as well. Therefore, we need to raise awareness among medical PGs and interns.

MATERIALS AND METHODS

A Cross Sectional study was conducted among Medical Interns and Medical PGs in tertiary care hospital. The study involves Medical Interns and Medical PGs to evaluate Knowledge, Attitude and Practice of Pharmacovigilance and their importance. The Study was conducted from the period of February 2023- June 2023. The Study duration is from December 2022 to July 2023 and the Study site is Sri Ramachandra Hospital, G-block and Sri Ramachandra Medical Centre, Udayar block. The study protocol was approved by the Institutional Ethics Committee of Sri Ramachandra Institute of Higher education and Research, (DU), Porur, Chennai, Tamil Nadu, India (CSP/23/FEB/122/84) and prior to participation, each subject provided written informed permission. Medical PGs and interns participated in the study using a self-framed, validated KAP questionnaire, and the data was then evaluated. The sample size was determined by using n master software with Prevalence of Knowledge for Medical Interns is 59% (referred by Garg *et al.*) and Knowledge for Medical PGs is 34.83% (referred by Upadhyaya *et al.*) with relative precision of 20% and 95% of confidence level. Therefore, suspected responses from Medical Interns and Medical PGs individually thought to have 180 responses. The sample size required for this study would be 360.The inclusion criteria are Medical Interns (MBBS and BDS) and Medical PGs. The exclusion criteria are Health Care Professionals-Physicians, Nurses, Clinical Pharmacists, Community Pharmacists and Unwilling to give informed consent. Data will be collected from the Medical Interns and Medical PGs with their consent by request to them to complete the questionnaire (self-administered). The collected data were analyzed with IBM SPSS statistic software 16.0. By using the categorical variables, descriptive statistics, and percentage analysis were found. To find out significant difference between samples chi- square test was used. In the above statistical tool, the probability value < 0.05 is considered as significant level.

Statistical Inference

The collected data were analysed with IBM SPSS statistic software 16.0. By using the categorical variables, descriptive statistics, and percentage analysis were found. To find out significant difference between samples chi- square test was used. In the above statistical tool, the probability value < 0.05 is considered as significant level.

RESULTS

Demographic details of the participants

A total 360 responses among them 180 were Medical Interns and 180 were Medical PGs in in tertiary care hospital were enrolled into the study. Out of 360 Medical Interns and Medical PGs respondents, 242 (33%) were females and 118 (67%) were males. Regarding educational status, majority of the respondents were Medical PGs 180 (50%), Medical Interns (MBBS) 128 (35.54%) and Medical Interns (BDS) 52 (14.44%). Demographic details of the Medical Interns and Medical PGs is characterized in Tables 1 and 2.

Knowledge wise response

When participants were asked about the definition of pharmacovigilance, among all majority of the Medical Interns 83.88% (*n*=151) and Medical PGs 80.55% (*n*=145) responded correctly to the definition, 77.22% (*n*=139) Medical Interns and 62.77% (*n*=113) would able to specify the primary goal of pharmacovigilance, 84.44% (*n*=152) Medical Interns and 82.2% (*n*=148) Medical PGs know that Post marketing surveillance (PMS) studies is the appropriate comment for the question "Which of the Following Approaches Do Pharmaceutical Companies Usually Use to Follow the Adverse Drug Reactions of New Drugs After They Are Introduced into the Market?", 82.77% (*n*=149) Medical Interns and 71.66% (*n*=129) Medical PGs gave appropriate response to which Indian Regulatory Agency Is in Control of ADR Monitoring, 81.11% (*n*=146) Medical Interns and 76.11% (*n*=137) Medical PGs were aware of the location of the International Centre for Adverse Drug Reaction Monitoring, Only 73.88% (*n*=133) Medical Interns and 67.77% (*n*=122) Medical PGs known that Pharmacovigilance Includes Drug Related Problems, 65.55% (*n*=118) Medical Interns and 37.22% (*n*=67) Medical PGs were known of any drug that has been recently outlawed beacause of ADR and 86.11% (*n*=115) Medical Interns and 81.88% (*n*=146) Medical PGs were known of possible ADR reporting system in India. Knowledge wise response is characterised in Table 3.

Attitude wise response

When praticpants were asked about whether the adverse drug reactions reporting are necessary, Medical Interns 92.77% (*n*=167) and Medical PGs 98.33% (*n*=177) thought it was necessary to report adverse drug reactions, Medical Interns 93.88% (*n*=169) and Medical PGs 97.22% (*n*=175) believed that thorough instruction in pharmacovigilance should be given to Medical Interns and Medical PGs, Most of the Medical Interns 82.77% (*n*=149) and Medical PGs 80.55% (*n*=145) have read articles and seen news on prevention of adverse drug reactions, finally Medical Interns 75% (*n*=135) and Medical PGs 72.22% (*n*=130) gave some opinion about establishing a pharmacovigilance centre in every hospital. Attitude wise response is characterised in Table 4.

Practice wise response

When participants were asked about experienced in adverse drug rections during your professional practice, Medical Interns 19.44% (*n*=35) and Medical PGs 29.44% (*n*=53) asnwered that they have not experienced any adverse drug reactions during the professional practice, Medicsl Interns 65% (*n*=117) and Medical PGs 63.33% (*n*=114) have been trained to report adverse drug reactions, Medical Interns 80.55% (*n*=145) and Medical PGs

91.11% (*n*=164) have seen the reporting form and only 16.11% (*n*=29) of Medical Interns and 21.11% (*n*=38) of Medical PGs have reported the adverse drug reactions to the pharmacovigilance centre, Medical Interns 72.77% (*n*=131) and Medical PGs 53.33% (*n*=96) keep their medical records and 92.22% (*n*=166) of Medical Interns and 94.44% (*n*=170) of Medical PGs are willing for ADR reporting. Practice wise response is characterised in Table 5.

DISCUSSION

The current study has focused on the Knowledge, Attitude, and Practice of Medical Interns and Medical PGs working in tertiary care hospitals about Pharmacovigilance.[21] 180 Medical Interns (MBBS, BDS) and 180 Medical PGs students answered KAP questionnaires that were distributed. All of them agreed to participate in our study, and they all answered our questionnaire.[22] The percentage of Medical Interns who took part in the study showed were significantly more female (63.88%) participants than male (36.11%). The results of the investigations done by Rasheed *et al.* could give credibility to this. In our study, females (68.88%) exceed males (31.11%) in the Medical PGs, which is similar to a study by Salman. S *et al.*[23] When respondents answered define pharmacovigilance, 82% of the study participants responded correctly, which is in line with the findings of Rasheed *et al.* and Upadhyaya *et al.*[22,24] The majority of Medical Interns (77%) gave correct responses to the purpose of pharmacovigilance which is similar to the study of Korde RA *et al.*[17] In this study, about 84% of Medical Interns gave correct responses to the methods employed by pharmaceutical companies to monitor ADR; this is concordant with KAP of pharmacovigilance study carried out by Srinivasan *et al.*[25] Gupta *et al.*, conducted a questionnaire study on a KAP of pharmacovigilance which is similar to our study with majority of Medical Interns (82%) responded correctly for regulatory body in India.[26] According to Hussain *et al.*, Medical Interns (81%) gave correct responses to international center for ADR which is similar to our study.[21] When respondents answered pharmacovigilance includes drug related problems, 73% of the study participants responded correctly, which is in line with the findings of Srinivasan *et al.*[25] Srinivasan *et al.*, conducted a questionnaire study on a KAP of pharmacovigilance which is similar to our study with majority of Medical Interns (65%) were aware of recently banned drugs.[25] In this study, about 84% of Medical Interns were aware of suspected ADR reporting system; this is concordant with KAP of adverse drug reaction monitoring study carried out by Gupta *et al.*[26] The majority of Medical Interns (92%) and Medical PGs (98%) agreed that it is important to report adverse drug reactions (ADR) which is similar to the study of Korde RA *et al.* and Upadhyaya *et al.*[17,24] According to Srinivasan *et al.*, Medical Interns (93%) believed that thorough instruction in pharmacovigilance should be given to Medical Interns and Medical PGs which is similar to our study.[25] Gupta *et al.*, conducted a questionnaire study on a KAP of pharmacovigilance which is similar to our study with majority of Medical Interns (82%) embraced reading any articles or watching any news about preventing ADR.[26] In this study, about 75% of Medical Interns gave some opinion about placing ADR monitoring centers in every hospital; this is concordant with KAP of adverse drug reaction monitoring study carried out by Korde *et al.*[17] Similar to Korde RA *et al.*, the majority of Medical Interns (80%) disagreed with the question, "Have you ever experienced ADR during your professional practice."[17] In this study, about (65%) of Medical Interns gave agreed to the question, “Have you been trained on how to report ADR” which is similar to KAP of pharmacovigilance study carried out by Srinivasan *et al.*[25] ADR reporting forms comparable to those used by Wadagbalkar P *et al.* were reported by almost (80%) of Medical Interns in this study.[27] Similar to Wadagbalkar P *et al.*, about (83%) of Medical Interns in this study stated that they have never reported an adverse drug reaction to the pharmacovigilance centre.[27] About (72%) of the Medical Interns in this study agreed to keep an ADR record, which is similar to the KAP of Pharmacovigilance

Table 1: Gender Distribution.

Sl. No.	Gender	Number of responses (N)	Percentage (%)
1.	Male	118	67
2.	Female	242	33

Note: Out of 360 Medical Interns and Medical PGs respondents, 242 (33%) were females and 118 (67%) were males.

Table 2: Educational status.

Sl. No.	Educational status	No of response (N)	
		Male (*n*=118) (%)	Female (*n*=242) (%)
1.	Medical Interns (MBBS)	50 (13.88)	78 (21.66)
2.	Medical Interns (BDS)	13 (3.61)	39 (10.83)
3.	Medical PGs	55 (15.27)	125 (34.72)

Note: MBBS: Bachelor of Medicine and Bachelor of Surgery; BDS: Bachelor of Dental Surgery; PGs: Post Graduates.

Table 3: Knowledge Related Response Among Medical Interns and Medical PGs.

Questions	Category				*p* value
	Medical Interns		Medical PGs		
	Appropriate comment n (%)	Inappropriate Comment n (%)	Appropriate comment n (%)	Inappropriate Comment n (%)	
K_1: Pharmacovigilance is defined as?	151(83.88)	29(16.11)	145(80.55)	35(19.44)	0.408
K_2: What Is Pharmacovigilance's Primary Goal?	139(77.22)	41(22.77)	113(62.77)	67(37.22)	0.003
K_3: Which of the Following Approaches Do Pharmaceutical Companies Usually Use to Follow the Adverse Drug Reactions of New Drugs After They Are Introduced into the Market?	152(84.44)	28(15.55)	148(82.2)	32(17.77)	0.572
K_4: Which Indian Regulatory Agency is in Control of ADR Monitoring?	149(82.77)	31(17.22)	129(71.66)	51(28.33)	0.012
K_5: The Location of the International Centre for Adverse Drug Reaction Monitoring Is	146(81.11)	34(18.88)	137(76.11)	43(23.88)	0.247
K_6: Pharmacovigilance Includes Drug Related Problems	133(73.88)	47(26.11)	122(67.77)	58(32.22)	0.202
K_7: Do You Know of Any Drugs That Have Recently Been Outlawed Because of ADR?	118(65.55)	62(34.44)	67(37.22)	113(62.77)	0.000
K_8: Do you know the possible ADR Reporting System in India?	146(81.88)	34(18.88)	115(86.11)	25(13.88)	0.200

Note: PGs: Post Graduates; ADR: Adverse Drug Reaction. The probability value <0.05 is considered as significant level. In above table, there are some responses are not statistically significant.

Table 4: Attitude Related Response Among Medical Interns and Medical PGs.

Questions	Category				*p* value
	Medical Interns		Medical PGs		
	Appropriate comment n (%)	Inappropriate Comment n (%)	Appropriate comment n (%)	Inappropriate Comment n (%)	
A_1: Any suggestions about Reporting Adverse Drug Reactions Is Necessary?	167(92.77)	13(7.22)	177(98.33)	3(1.66)	0.011
A_2: Do You believe that thorough instruction in pharmacovigilance should be given to Medical Interns and Post Graduates?	169(93.88)	11(6.11)	175(97.22)	5(2.77)	0.125
A_3: Have You Ever Read Any Article or Seen Any News on Prevention of Adverse Drug Reactions?	149(82.77)	31(17.22)	145(80.55)	35(19.44)	0.586
A_4: What Do You Think About ADR Monitoring Centres Being Placed in Every Hospital?	135(75)	45(25)	130(72.22)	50(27.77)	0.550

Note: PGs: Post Graduates; ADR: Adverse Drug Reaction. The probability value <0.05 is considered as significant level. Out of four questions, only one is statistically significant and remaining three are not statistically significant ($p<0.05$).

Table 5: Practice Related Response Among Medical Interns and Medical PGs.

Questions	Category				*p* value
	Medical Interns		Medical PGs		
	Appropriate comment n (%)	Inappropriate Comment n (%)	Appropriate comment n (%)	Inappropriate Comment n (%)	
P_1: In the course of your professional practice, have you ever seen adverse drug reactions in a patient?	35(19.44)	145(80.55)	53(29.44)	127(70.55)	0.027
P_2: Have You Ever Been Trained on How to Report Adverse Drug Reactions?	117(65)	63(35)	114(63.33)	66(36.66)	0.742
P_3: Have You Ever Reviewed the Form for ADR Reporting?	145(80.55)	35(19.44)	164(91.11)	16(8.88)	0.004
P_4: Have You Ever Informed the Pharmacovigilance Centre of an Adverse Drug Reaction (ADR)?	29(16.11)	151(83.88)	38(21.11)	142(78.88)	0.223
P_5: Do You Keep Records Of ADR?	131(72.77)	49(27.22)	96(53.33)	84(46.66)	0.000
P_6: Are You Willing for ADR Reporting?	166(92.22)	14(7.77)	170(94.44)	10(5.55)	0.398

Note: PGs: Post Graduates; ADR: Adverse Drug Reaction. The probability value <0.05 is considered as significant level. Out of six questions, three are statistically significant and remaining three are not statistically significant ($p<0.05$).

Hussain *et al.*[21] Comparable to Srinivasan *et al.*, 92% of Medical Interns in this survey indicated that they would be willing to reporting ADRs.[25] In the current study, which sought to evaluate participants' understanding of pharmacovigilance, the majority of Medical Interns and Medical PGs students correctly comprehended the study's objectives (72.22% and 62.77%, respectively), India's regulatory body (82.77% and 71.66%), and the newly banned medications (65.55% and 37.22%). They are statistically significant ($p<0.05$) as a result. Some of the responses such as definition, methods, International Monitoring centre and suspected ADR system are not statistically significant ($p<0.05$).[21] In the current survey, which was intended to assess the Attitude of individuals on pharmacovigilance, the majority of Medical Interns (92.77%) and Medical PGs (98.33%) agreed that it is important to report Adverse Drug Reactions (ADR). Thus, they have a statistical significance level of less than 0.05. Out of four questions, only one is statistically significant and remaining three are not statistically significant ($p<0.05$).[21] According to the practice of pharmacovigilance, the majority of Medical Interns and Medical PGs agreed to experience adverse drug reactions in patients (19.44% and 29.44%), see the ADR Reporting Form (80.55% and 91.11%), and keep records of adverse drug reactions (72.77% and 53.33%), making them statistically significant ($p<0.05$). A few responses, like training on reporting ADR and being willing to report ADR are not statistically significant ($p<0.05$).[21] Hence, we consider it as a fair knowledge among Medical Interns and Medical PGs.

CONCLUSION

This study determined the Assessment of Knowledge, Attitude and practice of Pharmacovigilance among Medical Interns and Medical Post Graduates in a tertiary care hospital. According to the current study, the majority of Medical Interns and Medical Post Graduates were knowledgeable and supportive of pharmacovigilance, however they are not as effective in practice. In view of the previously stated, actions are required to instruct, empower, and train Medical Interns and Medical Post Graduates in the field of pharmacovigilance. Developing an individual ambulatory pharmacovigilance department with an ADR specialist in every clinical department and at the hospital level, a system of practical training and workshops for handling ADR events must be implemented are some suggestions for Pharmacovigilance.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

EU: European Commission; **ADRs:** Adverse Drug Reactions; **ASA:** Acetyl Salicylic Acid; **US:** United States; **EC:** European Commission; **WHO:** World Health Organization; **UMC:** Uppsala Monitoring Centre; **KAP:** Knowledge, Attitude and Practice; **MBBS:** Bachelor of Medicine and Bachelor of Surgery; **BDS:** Bachelor of Dental Surgery; **PGs:** Post Graduates; **PMS:** Post marketing surveillance; **CDSCO:** Central Drugs Standard Control Organisation.

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