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A Questionnaire Study on the Knowledge, Attitude, and Practice of Pharmacovigilance among the Medical Post Graduates in a Teaching Hospital in West Uttar Pradesh

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ABSTRACT

Background: *Pharmacovigilance aids in early detection of ADRs and as well as identification of various risk factors. Reporting of ADRs is crucial for the success of pharmacovigilance program.* ***Aims/Objective:*** *This questionnaire based study among medical resident's aims at assessing knowledge, attitude & practice towards adverse drug reaction reporting in the teaching hospital attached to a private medical college and design methods to improve existing ADR reporting system in our setup.* ***Methods:*** *This study is a questionnaire based cross-sectional study. It was conducted at Teerthanker Mahaveer Medical College & research Centre, Moradabad, West Uttar Pradesh, among the first year and final year medical post graduates/PGs, by using a pre-validated, modified questionnaire on knowledge, attitude & practice. A total of 90 questionnaires were duly filled out by the post graduates. Data was analyzed by using SPSS V.20. The chi-square test was used to determine statistical significance.* ***Results:*** *Majority (89%) reported to have reasonable knowledge of adverse drug reactions, but reported an average degree of knowledge regarding various aspects of pharmacovigilance. 61% respondents were not aware of presence of an AMC affiliated to this hospital. Final year medical post graduates were found to have poor attitude towards acts of reporting of adverse drug reactions although they pose better knowledge regarding drug safety as well as importance of ADR reporting. Lack of training (90%) on ADR reporting was also recorded.* ***Conclusions:*** *This study recorded average knowledge, positive attitude towards necessity of reporting of ADRs of medical post graduates. Necessity of educational interventions to update knowledge and improve practice of ADR reporting were identified as important measures that need to be taken care of.*

Key words: *Adverse Drug Reaction monitoring; Knowledge, attitude and Practice; Pharmacovigilance.*

INTRODUCTION

Interaction of drugs i.e. either drug-drug interaction or drug-food interaction into the human body generates numerous problems to the individual. Adverse Drug Reactions (ADRs) represents one of several identified classes of 'drug associated complications'. The World Health Organisation defines an adverse drug reaction (ADR) as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function."[1] Adverse effects/toxicities of a drug are generally evaluated during the first three phases of clinical trials. Although it is not possible to come across all the untoward effects pertaining to a drug due to limited exposure to the population. Honest monitoring and prompt reporting is warranted. The incidence of serious ADR's in India is 6.7% as reported in 2014 pharmacovigilance newsletter.[2] However incidence varies among studies, among populations.[3] ADR contribute to drug-related hospital admissions, prolong hospital stay and also increases incidences of emergency medical ward visits.[4] Various studies on ADR related hospital admissions, estimated that around 5–10% of

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hospital admissions were due to adverse drug reactions only.[5,6] Thus ratifies serious adverse drug reactions - a major public health concern.

World Health Organization (WHO) defines pharmacovigilance (Pharmakon= drug; vigilare = to keep watch) 'as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.'[7] WHO's new initiative in health product vigilance has been implicated in many countries through establishing pharmacovigilance programme unlike pharmacovigilance programme of India (PvPi), as was introduced in India in the year 2004 to monitor as well as provide drug safety reports to the WHO-ADR monitoring center in Uppsala (Sweden).[8] The PvPi was initially functioned with only 22 Adverse Drug Monitoring Centers (AMCs) and presently there are around 150 AMCs across the country. Indian Pharmacopoeia Commission, Ghaziabad is the National Coordination Centre for this program. Since its inception more than 80,000 Individual Case Safety Reports have been contributed to Pharmacovigilance Programme of India (PvPI) database. Teerthanker Mahaveer medical college and research center, a premier healthcare institute of Western Uttar Pradesh became one of the AMCs in the year 2016 to promote patient safety. Stakeholders of PvPi programme of India for reporting ADRs are not only the medical and paramedical staff those who prescribe drugs, those who dispense them (pharmacists or pharmacy assistants), those who administer them (nurses), but also the consumers (patients) who can report an ADR by following the standardized, user friendly protocol laid by Central Drug Standard Control Organization (CDSCO).

ADR reporting reduce polypharmacy and promote good health. Therefore, ADR reporting through pharmacovigilance program of India (PvPi) can be beneficial in framing policies toward the rational use of drugs. But under reporting becoming a major concern in India. ADR reporting rate in India is merely 1% compared to the global rate of 5%.[9] Lack of awareness is one among the various factor contributing to under reporting. [9] Appropriate sensitization programs to improve ADR reporting is the need of the hour, as many are unaware of the procedure like "to whom or how to report and ADR"? Several studies on knowledge, attitude and perception (KAP) conducted among health care professionals globally as well as in India to assess level of awareness and extent of reporting of adverse drug reactions. But little studies are available among dentists/ medical post graduates. Our study is one of such attempt that study or assess the knowledge, attitude and perception towards pharmacovigilance and ADR reporting among medical post graduates in this region.

METHODS

Study setting

The study was conducted at Teerthanker Mahaveer Medical College and Research Centre, a tertiary care teaching hospital in West Uttar Pradesh, India between months of August and October 2016.

Type of study

It was a cross-sectional questionnaire based study.

Sample size

Convenient sampling method was used in which postgraduate medical post graduates of first year and final year who are pursuing post-graduation in all medical subjects were enrolled in the study.

Before conduction of the study, The KAP questionnaire toward pharmacovigilance and ADRs was developed and verified for suitability. The questionnaire was semi-structured, predesigned, pretested and validated for data collection.[10] Few changes were made as per our study need and the final version of the KAP questionnaire had following number of questions. Knowledge questionnaire comprised of 14 questions, attitude questionnaire had 8 questionnaire and practice component had three (03) questions.

Process

Before administering the questionnaire, consent was obtained from all participants (n=90). All medical post graduates working presently were enrolled in the study. All participants were briefed and explained in detail about the purpose and significance of the study. The questionnaires were then distributed and sufficient time was allotted to fill them and hand it back to the staff in charge. For any clarification in relation to understanding of the questionnaires, additional time was provided.

The details of the questionnaire are as follows.

Knowledge related questions: (14 items), The questions for assessment of participant's knowledge of pharmacovigilance included definition and purpose of pharmacovigilance, responsibility of reporting ADRs, knowledge of National Pharmacovigilance Programme, and regulatory body responsible for monitoring ADRs.

Attitude related questions: (8 items). The questions for assessment of participant's attitude of pharmacovigilance focused on necessity of reporting ADRs, teaching of pharmacovigilance, prevention of ADR, and opinion about ADR monitoring centre.

Practice related questions: (3 items), The questions for assessment of participant's attitude towards pharmacovigilance included experience of ADRs, report to pharmacovigilance centre, ADR reporting form, training to report ADRs, reporting of serious adverse event, identification of rare ADRs, methods to monitor ADRs of new drug, presence of pharmacovigilance centre in the institute.

One question was asked to determine the reasons for underreporting i.e. factors discouraging from reporting ADRs.

From participants' response, a score of 1 and 0 was given for each correct and wrong answer respectively. Five level Likert scale (1= strongly agree, 2 = agree, 3 = neutral, 4 = disagree, 5 = strongly disagree) were used to analyse the attitude and perception of the participants.

Statistical analysis

SPSS version 20 was adopted for database development and analysis. Descriptive analysis, Number and percentage, Chi- square test, Fisher Exact test for determining statistical significance were used for analysis.

RESULTS

Knowledge analysis

The results for knowledge on pharmacovigilance and ADRs reporting based questions are presented in Table 1. Out of the 90 participants, about 51% of participants correctly defined pharmacovigilance. Of which 72% were final year post graduates. 58% correctly stated the important purpose of pharmacovigilance. Correct response for this question was recorded more by final year respondents (69.7% vs 46.8%). This finding was found statistically significant with a p value 0.03. 'Predictable, undesirable effect occurring at usual therapeutic doses' as 'best describe adverse drug reaction' was answered correctly by 89% respondents. Majority who described adverse drug reactions to the best belonged to final year postgraduates (95.35%) than the first-year postgraduates (82.98%). However, the finding was not statistically significant (P>0.05). 16.7% of participants correctly identified the phase in clinical trial where the rare ADRs can be identified. No significant difference among knowledge in this regard was found among first and final years of postgraduates (p>0.05). Half of the participants (54.4%, n=49) answered correctly for the question on the location of the international center for adverse drug reaction monitoring. 58.14% of the participants from final year answered correctly for this question. However, 48.94% of participants answered correctly among the first-year post graduates. No statistical significance was found among them for this question. More than half of the participants (67.78%) answered correctly -'Vigibase" as the 'WHO online database' for reporting ADR. Final year post graduates were found to answer correctly than the first-year postgraduates (83.7% vs 53.2%) in this regard with a p value of 0.003. About 94.4% of the participants answered correctly for the method employed by pharmaceutical companies to monitor ADR of new drugs after launching them into the market. No significant difference towards correct knowledge on methods to monitor ADR reaction of new drug was found among final year (97.6%) and first year (91.49%) post graduates. For the question regarding 'most commonly used scales to establish the causality of an ADR', 64.44% (n=58) stated the correct response. Knowledge regarding 'Naranjo algorithm scales' to establish causality of ADR was found more by final year (79.07%) than the first year (51.1%) post graduates. This was found statistically significant with a p value of 0.008. Half of the respondents (57.8%, n=52) correctly answered 'CDSCO' as the regulatory body that regulates ADR reporting in India. However, 46.67% correctly knew that the pharmacovigilance center in India was established under CDSCO. Correct response on regulatory body for ADR reporting in India was reported more by final year (74.42%, 32 of 52) post graduates than the first years. It was found statistically significant with a p value of 0.003. While asking regarding 'major risk factor for occurrence of maximum ADR', 96.67% participants answered correctly i.e. 'renal failure' among the choices. In this study, less than half of the participants (35 of 90, 38.89%) were found to know that their own college is the zonal pharmacovigilance center. Knowledge regarding zonal center was found lacking among first year post graduates (n = 12, 8.5%) than the final year post graduates (n= 23, 53.4%). This was found statistically significant with a p value 0f 0.009. In our study 77 of 90, 85.6% participants correctly identified all the important health care professionals responsible for reporting ADR. Majority who reported correct answer belonged to final year post graduates (93%).

Attitude Analysis

The results on the attitude towards pharmacovigilance and adverse drug reaction reporting among the first and final year medical students are presented in Table 2-5. Table 2 depicts responses of attitude towards reporting ADR. 87 (96.66 %) participants totally agreed (agree plus strongly agree) with the view that ADR reporting is necessary. Final year post graduates attitude (97.67 %) was more positive than first year post graduates (95.67 %). 'Reporting of ADR should be considered as professional obligation' was supported by 72 (80 %) participants (final vs first year; 81.39 % vs 78.72%). ADR reporting should be made voluntary was totally agreed by 85 (94.44%) participants. Final year participants were more positive to this view compared to the first year participants (76.74 % vs 74.46 %). ADR reporting should be made compulsory was the view of 73 (81.11 %) participants. 50 (55.55 %) participants were of the view that reporting of known ADR will make no significant contribution to the reporting system. Over all a positive attitude was seen among participants towards reporting ADR. The difference between attitude of final year and first year participants towards reporting ADR was found to be statistically insignificant (P value > 0.05).

Table 3 depicted responses of attitude towards technical aspects of ADR reporting. 79 (87.77 %) participants agreed with the view that it is necessary to confirm that an ADR is related to particular drug. First year participants had more positive attitude in this context than final year participants (89.36 % vs 86.04 %). Total 53 (58.88 %) participants were of the opinion that only serious and unexpected reactions should be reported. It was noted that both final year as well as first year participants had positive attitude towards technical aspects of ADR reporting. The difference in their attitude towards technical aspect of ADR reporting was not found to be statistically significant (P value > 0.05). Both lack of time to report ADR (n=57, 63.3 %) as well as non-remuneration for reporting (n= 33, 36.7 %) were reported as important contributing factor to cause ADR underreporting (Table 4).

Table 5 depicts responses of attitude towards role of pharmacovigilance in teaching curriculum. Most of the participants totally agreed with the views that

pharmacovigilance should be taught in their curriculum, information on reporting ADR should be taught to all health care students in their curriculum and information on reporting ADR shall be better learnt during internship training /clinical posting, their percentage being 63.2 %, 83.33 % & 83.33 % respectively. Only 8.9 % participants totally agreed that with their present knowledge they are well prepared to report any ADR noticed in their future practice and 66.7 % participants do not had any idea on how to report ADR to the relevant authorities in India. The difference of attitude towards role of pharmacovigilance in teaching curriculum between final and first year post graduates was found to be statistically insignificant (P value > 0.05).

Attitude towards practice

Most of the post graduates response towards practice related questions were negative. 73.33 % post graduates replied that they have not read any article on prevention of ADR (Q-28), 90.00 % answered that have not come across with an ADR patient during their professional practice /training /ward posting(Q-29), 100.00 % responded that they have not been trained on how to report ADR and 72.22 % had never seen ADR reporting form (Q-31). The statistical difference between the two group of post graduates attitude towards practice was noted to be insignificant (P value > 0.05) (Table 6).

DISCUSSION

The current study investigates the knowledge, attitude and practices/perceptions associated with adverse drug reaction (ADR) reporting among participants of a medical teaching hospital of West Uttar Pradesh. Studies specific to north Indian states are necessary to identify the knowledge/skill acquired, perception developed and practice adopted regarding ADR reporting among medical participants through education/ medical teaching curriculum. To our knowledge there are limited systematic studies / published articles available from northern India representing monitoring of spontaneous adverse drug reactions to assess the safety of drugs in hospital setting.[11] The responses to the knowledge based questions in this study indicated an average to poor degree of knowledge regarding various aspects of pharmacovigilance. About half of the respondents were found to possess knowledge regarding definition and purpose of pharmacovigilance correctly. But in contrast it was noted that majority (80, 89%) of the respondents had reasonable knowledge of adverse drug reactions, its major risk factors (96.7%, 87). Therefore it can be concluded that a gap exists in generating awareness and importance of ADR reporting through pharmacovigilance practice among resident dentists. There was a significant correlation between first year and final year resident dentists and number of correct responses. Final year medical participants were found to be acquainted with both the subjective aspects of adverse drug reactions such as drug safety, risk factors for severe adverse drug reactions, technical aspects of ADR reporting such as reporting of suspected adverse drug reactions through ADR reporting form only in India and regulatory body of ADR reporting in India. ($p<0.05$). Our findings regarding overall knowledge of the respondents towards pharmacovigilance was found similar with the findings of a study done by Akshaya et al.[12] Less than the half of the respondents (35 of 90) were aware of their zonal pharmacovigilance centre, where suspected adverse effects of drugs need to be reported. Majority of them belongs to final year medical participants ($p=0.009$). Current study also recorded respondent's attitude towards reporting of ADR, technical aspects of ADR reporting and role pharmacovigilance in teaching curriculum. A vast majority of the respondents expressed that the reporting of ADR's is necessary (96.6%, n=87) and considered it to be a professional commitment (80%, n-72). Whereas a smaller percentage of respondents (28.9%, n= 26) strongly agrees with the fact that reporting of ADR should be made compulsory and three fourth of the respondents (75.6%, n = 68) agrees to voluntarily reporting of ADR. It is an indication of a positive attitude towards the need to report, but a relative lack of commitment to do so. The overall findings of this study regarding attitude towards reporting of adverse drug reactions was found similar to another study by Datta S et al, in which 97% of respondents considered reporting is necessary and is a professional obligation.[13] While comparing the attitude among first and final years participants, towards reporting of adverse drug reactions, it was observed that final year participants lacks in attitude towards acts of reporting of adverse drug reactions although they poses better knowledge regarding drug safety and also knows the importance of reporting of it ($p>0.05$). 36.7%(n=33) respondents quoted the lack of remuneration for reporting as a discouraging factor, which is much higher than that seen in Datta S et al study (17%), Pimpal khute et al studies.[13,14] In contrast, there are several studies indicating financial incentives as an important stimulus to enhance ADR reporting.[15] This however does not appear to be a sustainable solution, as this increases the possibility of doubtful over reporting. Findings of a study done by Reddy et al matches with our findings (63%, lack of time to report ADR) regarding major reason for ADR under reporting.[16] In our study only 10% of the respondents agreed that they had come across an ADR during three year post graduation period, which clearly indicates that lack of ADR's is a major contributing factor to under reporting in our existing clinical setup. Determining a possible causal relationship between an adverse drug reaction and a drug by using causality assessment tools such as Naranjo algorithm, reporting of only serious and unexpected adverse drug reactions were acknowledged as major approach towards technical aspects of ADR reporting by both the first and final year medical participants who agrees with the necessity and compulsory reporting of adverse drug reactions ($p<0.005$). Our findings towards the need to meticulously establish causality for ADRs to improvise the fundamental aspect of drug safety matches with similar findings by Khan LM et al study.[17] Average knowledge and awareness regarding reporting of adverse drug

Table 1: Responses of Knowledge questionnaire

Questions	Correct response	Total sample (90)	First year (47)	Final year (43)	P- value (Fisher exact test)	Statistically significant at P<0.05
		N (%)	N (%)	N (%)		
Define pharmacovigilance	Activities relating to the detection, assessment, understanding and prevention of adverse effect	46 (51%)	15(31.91%)	31(72.09%)	0.002	**P<0.05**
Important purpose of pharmacovigilance	Safety, monitoring of medicinal products	52(58%)	22(46.81%)	30(69.77%)	0.03	**P<0.05**
Best describes ADR	Predictable, undesirable effect occurring at usual therapeutic doses	80(89%)	39(82.98)	41(95.35)	0.09	
Rare ADR identified in which phase of clinical trial	Phase IV	15(16.7%)	06(12.76)	09(20.93)	0.39	
International centre for ADR monitoring	Sweden	49(54.4%)	23(48.94%)	26(58.14)	0.29	
WHO online database	Vigibase	61 (67.8)	25(53.20%)	36(83.72)	0.003	**P<0.05**
Method to monitor ADR reaction of new drug	PMS studies	85(94.4)	43(91.49)	42(97.67)	0.36	
Scale for causality of ADR	Naranjn algorithm	58(64.4)	24(51.06)	34(79.07)	0.008	**P<0.05**
Regulatory body for ADR reporting in India	CDSCO	52(57.8)	20(42.55)	32(74.42)	0.003	**P<0.05**
PvPI established under	CDSCO	42(46.7)	20(42.55)	22(51.16)	0.52	
ADR reporting system in India is	ADR reporting form	85(94.4)	45(45.74)	40(93.02)	0.66	
Major risk factor for occurrence of maximum ADR	Renal failure	87(96.7)	44(93.62)	43(100)	0.24	
Zonal pharmacovigilance centre is	TMMC & RC, Moradabad	35(38.9)	12(08.51)	23(53.49)	0.009	**P<0.05**
Important healthcare professional responsible for reporting ADR	All	77(85.6)	37(78.72)	40(93.02)	0.07	

Table 2: Overall Attitude towards reporting of ADR

S no	Variables	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
		N (%)	N (%)	N (%)	N (%)	N (%)
1	Do you think ADR reporting is necessary?	0(0)	3(3.3)	0(0)	58(64.4)	29(32.2)
2	Do you think reporting is a professional obligation?	6(6.7)	7(7.8)	5(5.6)	67(74.4)	5(5.6)
3	Do u think pharmacovigilance reporting should be voluntary?	0(0)	5(5.6)	17(18.9)	68(75.6)	0(0)
4	Do u think reporting should be compulsory?	0(0)	7(7.8)	10(11.1)	47(52.2)	26(28.9)
5	Do you think reporting of known ADR will make no significant contribution to the reporting system?	8(8.9)	17(18.9)	15(16.7)	41(45.6)	9(10.0)

Table 3: Overall Attitude towards technical aspects of ADR reporting

Sl no	Variables	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
		N (%)	N (%)	N (%)	N (%)	N (%)
1	Do u think it is necessary to confirm that an ADR is related to particular drug before reporting it?	0(0)	3(3.3)	8(8.9)	74(82.2)	5(5.6)
2	Do u think it is necessary to report only serious and unexpected reactions?	5(5.6)	17(18.9)	15(16.7)	44(48.9)	9(10)

Table 4: Overall Responses of attitude questionnaire:

Questions	Responses	N (%)	First year	Final year	P-value
Factor to cause ADR underreporting	1. lack of time to report ADR	57(63.3)	34	23	P=0.08
	2. Non-remuneration for reporting	33(36.7)	13	20	

reactions among first year participants than the final year participants as observed in this study, need to be improved by approaches like inclusion of pharmacovigilance topic in their teaching curriculum, as because majority of they deny with the fact that is well covered in their curriculum. Need of educational interventions to update knowledge and subsequently generate a greater degree of awareness to pharmacovigilance is also supported in several studies.[18,19] More than half of the respondents in this study (66.7%) did not have any idea about how to report ADR to the relevant authorities of India.

Table 5: Over all Attitude towards role pharmacovigilance in teaching curriculum.

Sl no	Variables	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
		N (%)	N (%)	N (%)	N (%)	N (%)
1	Pharmacovigilance should be taught to all healthcare students during their curriculum?	3(3.3)	0(0)	31(34.4)	44(48.9)	12(13.3)
2	I believe that topic of pharmacovigilance is well covered in my curriculum?	12(13.3)	17(18.9)	41(45.6)	15(16.7)	5(5.6)
3	Information on reporting ADR should be taught to all health care students in their curriculum	0(0)	2(2.2)	13(14.4)	57(63.3)	18(20.0)
4	Information on reporting ADR shall be better learnt during internship/training/clinical posting?	0(0)	0(0)	15(16.7)	64(71.1)	11(12.2)
5	With my present knowledge, I am very well prepared to report any ADRs notice in my future practice	55(61.1)	15(16.7)	12(13.3)	8(8.9)	0(0)
6	I do not have any idea on how to report ADR to the relevant authorities in India?	0(0)	5(5.6)	25(27.8)	55(61.1)	5(5.6)

Table 6: Responses of Practice questionnaire.

Variable	Responses	Total sample (N=90)	First year (N =47)		Second year (N=43)		P- value	Significance
		(N, %)	N	%	N	%		
Have you anytime read any article on prevention of adverse drug reactions?	Yes	24(26.6)	16		08		0.15	p>0.05 Not significant statistically
	No	66 (73.3)	31		35			
Have you ever come across with an ADR in your patient during your professional practice/Training/ Ward posting?	Yes	9 (10)	05		04		1.0000	
	No	81 (900)	42		39			
Have you ever been trained on how to report Adverse Drug Reaction (ADR)?	Yes	0 (0)	0		0		1.0000	
	No	90 (100)	47		43			
Have you ever seen ADR reporting form?	Yes	25 (27.7)	12		13		0.64	
	No	65 (72.2)	35		30			

Therefore it can be concluded that education as well as training on ADR reporting, both are important factor for the success of pharmacovigilance programme.

The improper reporting practice is evident from the fact that majority (73%) had never read any article on prevention of adverse drug reactions, belongs to the final year participants who were not aware of the presence of an AMC in this institute ($p<0.05$) and did not know about the suspected ADR form (72%). These contributes towards lack of awareness towards pharmacovigilance.

CONCLUSION

Therefore basic steps need to be imposed beginning from first year of the medical participants teaching curriculum to impart more knowledge of adverse drug reactions reporting, to generate awareness and practice through organized training programs.

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