Research Article

A questionnaire study on the knowledge, attitude, and the practice of pharmacovigilance among medical interns in a tertiary care hospital, Kanchipuram

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ABSTRACT

Objective: The objective of this study was to assess the knowledge, attitude, and the practice (KAP) of the medical interns working in a tertiary care center toward pharmacovigilance and the adverse drug reaction (ADR) reporting. **Materials and Methods:** Medical interns working in Meenakshi Medical College were selected randomly and KAP questionnaire was used to collect the data before and after an educational intervention. **Results:** A total of 53 medical interns were involved in pre-KAP and post-KAP survey questionnaire. The overall scores observed between pre-test and post-test were found to be statistically significant proving the effectiveness of educational intervention and improving the knowledge of pharmacovigilance among medical interns. **Conclusion:** This study proves that KAP of pharmacovigilance and ADR reporting in routine practice can be improved by proper orientation and medical interventions.

KEY WORDS: Adverse drug reaction, Medical interns, Pharmacovigilance, Questionnaire

INTRODUCTION

Pharmacovigilance is defined as the science and activity relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.[1] The number of drugs introduced to the market has substantially increased and so have the adverse drug reactions (ADR). The main reasons for the failure of pharmacovigilance programs are due to the underreporting of ADRs.[2] Any drug administered has two types of actions: Therapeutic effect and ADR. ADR is encountered in day-to-day practice by health-care professionals. ADR also causes an economic burden on the health-care system.[3] These can be decreased by keeping a close attention to the adverse effects, after the administration of drugs. Pharmacovigilance has gained importance over the years and also is an important component of post-marketing surveillance.[3] Therefore, an educational intervention which emphasizes on the importance of pharmacovigilance is the need of the hour to create awareness about ADR and its reporting. Hence, this study was designed to assess the knowledge, attitude, and practice (KAP) of the medical interns posted in a tertiary care center toward ADR reporting.

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MATERIALS AND METHODS

A questionnaire-based study was conducted for the medical interns at Meenakshi Medical College and Research Institute, Kanchipuram, Tamil Nadu, on April 24, 2018. The study was approved by the Institutional Ethics Committee. An educational intervention about pharmacovigilance and ADR reporting was conducted for the medical interns. Before the educational intervention, a pre-test was conducted and the session was followed by a post-test. Consent was obtained from the participating medical interns. Medical interns who were not willing to participate and who were not available in the allotted time were excluded from the study. A total of 53 medical interns posted in various departments in Meenakshi Medical College participated actively in the study.

Study Tool

A validated KAP questionnaire was used to assess KAP about ADR reporting. There were about 16 questions in multiple-choice question patterns which had only

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one right answer. Other four questions enquired the personal opinion and previous exposure of the medical interns toward ADR reporting. Thus, the questionnaire had 20 questions and was prepared by the senior staffs of pharmacology department who was trained in the field of pharmacovigilance. Of the 20 questions, seven questions were knowledge based, seven questions were attitude based, and six questions were practice based. The questionnaire evaluated the medical interns in their KAP skills in pharmacovigilance and ADR reporting. Pre-test was conducted before the educational intervention session began for 30 min and the questionnaires were collected back. The educational intervention started with a presentation for 30 min which enumerated what pharmacovigilance is, its necessity, about proper reporting of ADR and filling the ADR form. The presentation was followed by hands-on training on filling up the ADR form with a case history. At the end of the session, the post-test was conducted with the same questionnaire and was collected after 30 min. The pre-test and post-test were assessed and subjected to statistical analyses.

Statistical Analysis

Statistical analyses were done using the Statistical Package for the Social Sciences version 16 software. Paired *t*-test was used to evaluate the pre- and post-test scores of the medical interns. $P < 0.05$ was considered to be statistically significant. Collected data were assessed by mean, percentage, and standard deviation.

RESULTS

A total of 53 medical interns participated in the study. The descriptive statistics indicated that the mean scores improved from 10.7 to 14.5 after the educational session and the scores were statistically significant.

Knowledge Analysis toward Pharmacovigilance

Question No: 1 was based on definition of pharmacovigilance. The percentage of correct response was 75.47% in the pre-test and 84.90% in the post-test, i.e., after the educational intervention which was not statistically significant. Question No: 2 was regarding the domains that pharmacovigilance covers. According to the data, 86.79% of medical interns chose the right answers in the pre-test which increased to 96.22% in the post-test even though it was not statistically significant. Question No: 3 asked the location of the WHO Collaborating Centre for international drug monitoring. Only 11.32% of the medical interns answered correctly in the pre-test which increased significantly to 81.13% in the post-test. Question No: 4 assessed their knowledge regarding the domains which a serious adverse event covers. In the pre-test, 66.04% opted for the right answer which increased significantly to 94.33% after the post-test. Question No: 5 was based on the method by which the company monitors ADR once the drug is launched into market. Around 41.50% answered correctly and 77.35% answered rightly in the post-test. The response rate between the pre-test and post-test was statistically significant. Question No: 6 asked them to define CDSCO. Only 52.83% answered it right in pre-test, whereas 81.13% of the candidates answered it right in post-test. Question No: 7 asked them the location of National Coordinating Centre of Indian Pharmacopoeia Commission. Pre-test percentage of the right answers was just 13.20 which increased significantly to 73.58% in the post-test [Table 1].

Attitude Analysis toward Pharmacovigilance

Question No: 8 asked them whether reporting an ADR is a medical obligation. The pre-test and the post-test responses as "yes" were 84.90% and 100%. Question No: 9 was regarding training all the medical professionals toward proper pharmacovigilance. In pre-test, 77.35% of the medical interns said that all the medical professionals should be trained toward pharmacovigilance, whereas it significantly increased to 98.11% in the post-test. Question No: 10 asked them whether the reporting of serious adverse effect is only essential. In the pre-test, 86.79% said no and was right while in post-test, the numbers increased to 98.11% which was statistically significant. Question No: 11 asked the interns whether the doctor and patient are benefitted from reporting an ADR. 84.90% of them answered yes in pre-test which increased to 100% in the post-test. Question No: 12 asked them whether they have the opinion that medical students have a key role in reporting an ADR. Yes was the answer by 86.79% in pre-test while it became 98.11% in post-test. Question No: 13 asked them the necessity if including ADR reporting under pharmacology practical for undergraduate students. In pre-test, 86.79% of the interns felt that it was required while in post-test, it increased to 94.33% even though not statistically significant. Question No: 14 asked them the necessity of keeping an ADR collecting box at all clinical department. Only 66.03% of them said yes in pre-test which significantly increased to 98.11% during post-test [Table 2].

Practice-based Analysis toward Pharmacovigilance

Question No: 15 asked them whether they had reported ADR that they had come across. Only 13.21% said yes while the rest 86.79% said no. Question No: 16 asked them whether they had been trained in reporting ADR in the past. Only 15.09% of the interns said yes, whereas the majority (84.90%) said no. Question No: 17 asked them what means they prefer to send ADR information to ADR monitoring center. 28.30% of the medical interns prefer direct contact, 30.18% through telephone, and the majority (rest

Table 1: Knowledge analysis toward pharmacovigilance

KAP - questions knowledge	Pre-test response (%) *n*=53	Post-test response (%) *n*=57	*Z*-value	*P*-value
Define pharmacovigilance				
Monitoring ADRs	6 (11.32)	5 (9.43)		
Process improving the drug quality	7 (13.21)	3 (5.66)		
Science and activities relating to detection, assessment, understanding, and prevention of adverse events*	40 (75.47)	45 (84.90)	1.1	0.25
Process carried out by pharmacist to improve benefits of the drug	0	0		
Process of pharmacovigilance covers				
Vaccines and medical devices	3 (5.66)	0		
Problems related to drugs	4 (7.54)	2 (3.77)		
Blood and its products	0	0		
All of the above*	46 (86.79)	51 (96.22)	1.8	0.07
The WHO Collaborating Centre for international drug monitoring				
Moscow, Russia	7 (13.20)	4 (7.54)		
New Delhi, India	21 (39.62)	2 (3.77)		
Uppsala, Sweden*	6 (11.32)	43 (81.13)	7.2	0.0001#
Geneva, Switzerland	19 (35.84)	4 (7.54)		
Serious adverse event includes				
Death due to medication	16 (30.18)	2 (3.77)		
Hospitalization or prolongation of hospitalization	1 (1.88)	0		
Congenital anomalies due to a medicine	3 (5.66)	1 (1.88)		
All of the above*	33 (66.04)	50 (94.33)	3.6	0.0003#
Once a drug is launched into the market which of the following methods is used to monitor ADRs?				
Progression analysis	9 (16.98)	5 (9.43)		
Regression analysis	6 (11.32)	0		
Paired *t*-test	16 (30.18)	7 (13.20)		
Periodic safety update reports*	22 (41.50)	41 (77.35)	3.8	0.0003#
Expansion of CDSCO				
Central drugs systemic control organism	5 (9.43)	3 (5.66)		
Central drugs standard control organization*	28 (52.83)	43 (81.13&)	3.2	0.0016#
Centrifuged drug systematic controllable organism	9 (16.98)	22 (3.77)		
Central dose standard control organization	11 (20.75)	5 (9.43)		
Location of National Coordination Centre of Indian Pharmacopoeia Commission				
Ghaziabad, UP*	7 (13.20)	39 (73.58)	6.2	0.0001#
Kochi, Kerala	13 (24.52)	2 (3.77)		
Chennai, Tamil Nadu	12 (22.64)	4 (7.54)		
New Delhi	21 (39.62)	8 (15.09)		

*Correct answer #$P<0.05$

41.50%) preferred mail or through website. Question No: 18 enquired the response to a serious adverse effect. In pre-test, only 60.38% of the interns were correct, whereas it increased to 77.35% in post-test which was not statistically significant. Question No: 19 asked them the factor that discourages them from reporting ADR. 15.09% of them claimed that they did not know how to report, 9.43% did not know where to report, and 33.96% of them were concerned with the legal liability issues, whereas majority said that managing the patient is more important than reporting ADR. Question No: 20 was a case scenario which was made correct by 67.92% of the medical interns in pre-test and increased significantly to 88.68% at the time of post-test [Table 3].

The comparison between pre-test and post-test scores for attitude analysis and knowledge analysis toward pharmacovigilance is statistically significant, whereas the practice-based analysis scores are not significant which clearly projects that though the nurses have understood the science of pharmacovigilance to an extent but are not able to bridge the gap between the knowledge and its practical application. The overall results are significant between pre-test and post-test in nurses which clearly reflect that the educational awareness has increased the level of understanding about pharmacovigilance.

DISCUSSION

The spontaneous reporting of ADR, especially by the medical interns who come across the patient initially, is very much vital for the success of the pharmacovigilance program. In our study, only 13.21% of the interns said that they have reported ADR that they have come across. Underreporting of ADRs is mainly due to the shortcoming in knowledge and attitude of health-care professionals.[4] The awareness about pharmacovigilance is very low

Table 2: Attitude analysis toward pharmacovigilance

KAP - questions attitude	Pre-test response (%) *n*=53	Post-test response (%) *n*=53	*Z* Value	*P* value
According to you is the reporting of an ADR, a medical obligation				
Yes	45 (84.90)	53 (100)	2.9	0.0034#
No	8 (15.10)	0		
Do you feel that proper training in pharmacovigilance should be given to all the medical professionals				
Yes	28 (59.57)	42 (89.36)	3.5	0.0004 #
No	41 (77.35)	52 (98.11)		
Is it necessary only to report serious adverse events?				
Yes	7 (13.20)	1 (1.88)		
No*	46 (86.79)	52 (98.11)	2.3	0.022#
Are the doctors and patients benefitted from reporting ADR?				
Yes*	45 (84.90)	53 (100)	3	0.0024#
No	8 (15.09)	0		
Are you of the opinion that medical students like you could play a major role in reporting ADR?				
Yes*	46 (86.79)	52 (98.11)	2.3	0.022#
No	7 (13.20)	1 (1.88)		
Should ADR reporting be included under pharmacology practical for undergraduate students?				
Yes*	46 (86.79)	50 (94.33)	1.4	0.16
No	7 (13.20)	3 (5.66)		
Do you think ADR collecting box at all departments is helpful for proper reporting?				
Yes*	35 (66.03)	52 (98.11)	4.3	0.0001#
No	18 (33.96)	1 (1.89)		

*Correct answer #$P<0.05$

among health-care professionals.[5-7] Reporting rate of ADRs could be increased by improving facilities and giving the health-care professionals an educational intervention.[8] Only 15.09% of the interns said that they have been trained in the past to report ADR. This showed the need for medical interventions and proper orientation programs toward pharmacovigilance and ADR reporting. Here, we planned a questionnaire-based study (pre-test and post-test) and a medical intervention. It was seen that there has been significant improvement of the scores of the medical interns in the post-test which was conducted after the medical intervention, compared to the pre-test.

The knowledge of the medical interns about what pharmacovigilance is and about the various coordinating centers significantly improved following the medical intervention, which is evident from the post-test scores. 100% of the interns agreed that reporting ADR is a medical obligation in post-test while only 84.90% only agreed it during the pre-test.

The preferred method by majority of the interns to report an ADR was through mail or website (41.50%). About 30% preferred to communicate through telephone while nearly 28% opted for direct contact. None of the interns preferred the traditional way of sending post to the regional center. The clinical scenario was better answered by the medical interns in the post-test (88.68%) compared to the pre-test (67.68%). This result reflects that practice-based training on reporting ADR will definitely improve the rates of ADRs being reported. Even though pharmacovigilance is being taught for medical students as a part of curriculum, the practical application skill is lacking.[6] This calls for the need of regular education and awareness sessions to increase their reporting.[9] Hence, we would suggest a half-yearly repetition of pharmacovigilance sessions not only to medical interns but also to all other medical professionals to improve the reporting.

This study would also help us to devise future strategies as it gives an account of the factors responsible for underreporting. Furthermore, making the process of ADR reporting less cumbersome and giving proper feedback to the one who reports ADR, etc., are the various steps that can be taken in this regard. The successful reporting of ADR will benefit both the reporter and the patient and also help in limiting the resources spent on health care and at the same time decrease the morbidity and mortality rates.[10]

CONCLUSION

An educational interventional session can increase the knowledge about pharmacovigilance and better the attitude and practice of it among the medical interns. Half-yearly awareness and orientation programs with hands-on training and practice-based information are needed to reenforce pharmacovigilance among the medical interns. Similar studies should be regularly

Table 3: Practice-based analysis toward pharmacovigilance

KAP - questions practice based	Pre-test response (%) *n*=53	Post-test response (%) *n*=53	*Z* value	*P* value
Have you ever reported ADR that you came across?				
Yes	7 (13.20)			
No	46 (86.79)			
Have you ever been trained to report ADR in the past?				
Yes	8 (15.09)			
No	45 (84.90)			
Which method do you prefer to send ADR information to ADR monitoring center?				
By direct contact	15 (28.30)			
Telephone	16 (30.18)			
By post	0			
Mail/website	22 (41.50)			
Upon occurrence of a serious ADR, what needs to be done with the suspected drug?				
Dose reduced	1 (1.88)	0		
Stopped immediately*	32 (60.33)	41 (77.35)	1.9	0.0596
Dose tapered and stopped	4 (7.54)	2 (3.77)		
Depending on the drug and ADR	16 (30.18)	10 (18.86)		
Which of the following factors discourage you from reporting ADR?				
Did not know how to report	8 (15.09)			
Not knowing where to report	5 (9.43)			
Managing patient was more important than reporting the ADR	22 (41.50)			
Legal liability issues	18 (33.96)			
Others	0			
Case scenario: A patient who is a known case of chronic renal disease was admitted to your hospital with severe anemia. Blood transfusion was advised by the department of nephrology. During the transfusion, patient developed chills, rigors, and fever. Transfusion was stopped at once and the patient was managed with antipyretics, antihistamines, and steroids. What will you do in this case?				
Report this case*	36 (67.92)	47 (88.68)	2.6	0.0096#
Ignore the case as it was not life-threatening	17 (32.08)	6 (11.32)		

*Correct answer #*P*<0.05

carried out among various health-care professionals to improve strategies and make the National Pharmacovigilance Program of India a great success.

STRENGTHS AND LIMITATIONS

To the best of our knowledge, only a very few studies have been done to assess KAP of pharmacovigilance among the medical interns in Tamil Nadu. Furthermore, comparing the scores in the pre-test and the post-test is the definite proof that a medical intervention can be very much helpful in the betterment of KAP of pharmacovigilance. The major limitation of our study was essentially the small sample size and it could have been applied to a wider medical community.

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