



A survey on knowledge and perception among nursing staffs towards adverse drug reaction reporting in a tertiary care hospital, Kanchipuram

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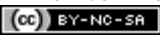
ABSTRACT

Aim: To assess the knowledge and perception of the nursing staffs working in a tertiary care centre towards adverse drug reaction reporting. **Methods:** Nursing staff working in Meenakshi medical college were selected randomly and a KAP (Knowledge, Attitude and Practice) based questionnaire was used to collect the data before and after an educational intervention. **Result:** A total of 47 staff nurses were involved in pre- KAP and post- KAP survey questionnaire. The overall response observed between pre-intervention and post-intervention was found statistically significant proving the effectiveness of educational intervention and improving the knowledge of pharmacovigilance among staff nurses. **Conclusion:** This study reveals that the knowledge, attitude and practice of pharmacovigilance could be improved by educational intervention and the ADR (Adverse Drug Reaction) reporting in day to day practice can also be increased.

Key Words: Pharmacovigilance, Adverse Drug Reaction, Questionnaire

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INTRODUCTION

WHO defines pharmacovigilance as the science and activity relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem [1]. Any drug administered has two actions: desirable or therapeutic effect and undesirable or adverse drug reaction. The third action of the drug is the unknown effect which needs expertise and knowledge to relate as an ADR (Adverse Drug Reaction) in a patient. Adverse drug reaction is encountered in day to day practice by healthcare professionals. ADR (Adverse Drug Reaction) also causes an economic burden on the health care system [2]. These can be alleviated by keeping a close attention to the adverse effects, following any administration of a drug. The science of pharmacovigilance has gained importance over the years and also forms the main stream of phase IV of the clinical trial or post- marketing surveillance which is very important for a drug to sustain in the market and prove its benefits to the patients as well [2]. Therefore an educational intervention about pharmacovigilance is the need of the hour to create awareness about the adverse drug reaction and its reporting.

Hence this study was designed to assess the knowledge and perception of the nursing staffs working in a tertiary care centre towards adverse drug reaction reporting.

MATERIALS AND METHODS

A questionnaire based study was conducted for the staff nurses at Meenakshi Medical College and research institute, Kanchipuram, Tamil Nadu between March 2017 and August 2017. The study was approved by the institutional ethics committee. An educational intervention about pharmacovigilance and reporting was conducted for the staff nurses. A pre-test was conducted before the educational session, followed by a post-test after the session. The study was conducted in two batches with twenty five nurses in the batch conducted in March 2017 and twenty two nurses in the batch conducted in August 2017. Consent was obtained from the participating nurse. Nurses who were not willing to participate were excluded from the study. A total of 47 nurses from various departments in Meenakshi medical college participated in the study

Study tool: A validated KAP- questionnaire was used to assess the knowledge about ADR reporting. There were about ten questions in multiple choice question pattern and each question had only one right answer. The questionnaire was prepared by

the senior staff of pharmacology department who was trained in the field of pharmacovigilance. Out of the ten questions around five questions were knowledge based, three questions were attitude based and two questions were practice based. Any clarification needed in the questionnaire was provided. In order to avoid any potential bias the disclosure of name of the nurses was made optional. The questionnaire evaluated the nurses in their knowledge, attitude and practice skills in pharmacovigilance and ADR reporting. A pre-test was conducted before the start of educational intervention for fifteen minutes and the questionnaires were collected back. The educational intervention started with a presentation for thirty minutes which enumerated the definition of pharmacovigilance, the need for pharmacovigilance, reporting adverse drug reaction and filling the ADR form. The educational intervention was followed by hands on training on filling up the ADR form with a sample case history. The session ended with a post- test with the same questionnaire and was collected after fifteen minutes. The pre-test and post-test was evaluated and subjected to statistical analyses.

Statistical Analysis: Statistical analyses were performed using statistical package for social science version 16 software. Paired- t test was used to evaluate the pre-test and post-test scores of the nurses. A 'p' value <0.05 was considered significant. Collected data was assessed by mean, percentage and standard deviation.

RESULTS

A total of 47 nurses participated in the study. The descriptive statistics indicated that the mean scores improved from 4 to 6 after the educational session and the scores were statistically significant.

Knowledge Analysis towards pharmacovigilance

Question No: 1 was based on the science of pharmacovigilance. The percentage of correct response was 31.9 % in the pre-test and 74.47% in the post-test i.e. after the educational intervention.

Question No: 2 was the abbreviation of ADR. According to the data, 95.74% of nurses chose the right answers in the pre-test and the same percentage i.e. 95.74% selected the right answer in the post-test. Hence response rate was not statistically significant. **Question No: 3** asked whether any minor unfavourable effect of a proven drug should be reported or not and was a true or false question. In this 44.67% of nurses answered correctly in the pre-test which increased to 51.06% in the post-test and the response rate was statistically significant i.e. $p < 0.05$. **Question No: 4** sought information about the aim of

pharmacovigilance. In the pre-test 36.17% opted for the right answer which increased to 44.67% after the post-test. The response was significant at $p < 0.05$. **Question No: 5** was the abbreviation for IPC. Around 12.77% answered correctly and 63.88% answered rightly in the post-test. The response rate between the pre-test and post-test was significant.(Table 1).

Attitude Analysis towards pharmacovigilance

Question No: 6 what they would do if someone contacts them to complain about a drug. The response was 59.57% and 89.36% for pre-test and post-test respectively. The results were statistical significant between pre-test and post-test where $p < 0.05$. **Question No: 7** sought information about the identity of the patient and was a true or false question. The pre-test score was 63.83% and the post-test score was 85.11% where $p < 0.05$ and was significant. **Question No: 8** asked whether reporting source and the patient can be the same. The pre-test and post-test scores were 74.47% and 70.21% respectively and was not statistically significant (Table 2).

Practice based Analysis towards pharmacovigilance

Question No: 9 was based on a case history which was answered by 19.15% correctly in the pre-test but the correct answers percentage fell to 17.02% in post-test and was not statistically significant. **Question No: 10** were also based on a case history where 44.68% of nurses answered it right in the pre-test and 63.83% answered it right in the post test. The p value was not significant (Table 3)

The comparison between pre-test and post-test scores for attitude analysis and knowledge analysis towards pharmacovigilance are 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 reflects that the educational awareness has increased the level of understanding about pharmacovigilance.

DISCUSSION

The field of pharmacovigilance have been evolving over the last 30 years under the aegis of the World Health Organization (WHO). In the recent years pharmacovigilance is based on scientific principles and has become a major arm of effective clinical practice. Pharmacovigilance needs to develop further to meet the demands of the modern public

health. In recent years there has been a substantial increase in the number of clinical trials in our country. There has been a growing alliance between academics and the pharmaceutical industries. This has given rise to many issues in which poor reporting and management of adverse event is a serious issue [3]. During the drug discovery it is now generally accepted that a part of evaluating drug safety needs to happen in the post-marketing (approval phase). If the new innovative drugs are not to be lost then a strong national system of pharmacovigilance and ADR (Adverse Drug Reaction) reporting is mandatory. Spontaneous reporting remains the corner stone of pharmacovigilance and is indispensable for signal detection. Hence an active surveillance is the need of the hour. Without clear information on utilization and extent of consumption, spontaneous reports do not help us to determine the frequency of ADR to a drug or its safety [4]. The only way to meet this emerging demand is to educate and create awareness among the healthcare professionals at all levels about the science of pharmacovigilance and ADR reporting.

Murariah et al [5] suggested that the reporting rate of ADRs could be increased by improving facilities and giving the health care professionals an educational intervention. Studies [6-8] have shown that the awareness about pharmacovigilance is very low among health care professionals. The main reason behind under reporting is lack of knowledge and expertise. Hence to improve this scenario, a questionnaire based study along with an educational intervention was planned. After an educational session there was a significant difference between the pre-test and post-test scores. The post-test scores were significantly greater than the pre-test score.

In the post-test around 74.47 % of nurses have answered correctly about the science of pharmacovigilance and 44.67% have understood that pharmacovigilance will not lead to any legal implications. Although the knowledge and attitude based questionnaire scores improved in the post-test, the scores of the practice based questions was not encouraging. The case history of question no. 9 was answered rightly by 17.02% of nurses only. Though the post-test of the second case history had comparatively better scores of 63.83% compared to 44.68% in the pre-test, statistically it was not significant. This result reflects on the need of practice based training on reporting adverse drug reaction in day to day practice. Although pharmacovigilance is taught to an extent in theory, the practical application skill is lacking [9]. Hence the need of a regular educational and awareness session is the key for the nurses to increase their

reporting [10]. The results of this study suggest a half yearly repetition of pharmacovigilance sessions not only to nurses but also to undergraduate medical students, postgraduate doctors, consultants, paramedical staffs to improve the reporting.

Such education sessions must also highlight certain adverse effects of the most prescribed drugs to be monitored thereby educating them about drugs also so that they can co-relate the effect with the administered drug. Hence this study suggest that an educational intervention on pharmacovigilance improves the knowledge of the nurses towards ADR but the expertise in drug-effect co-relation can be attained only by repeated re-enforcement of the subject among the nurses from the academic level.

CONCLUSION

Concluding this study an educational interventional session exposed that awareness of knowledge, attitude and practice about pharmacovigilance among nurses could be improved only by an educational intervention and ensure their

incorporation of knowledge in their day to day practice. Half-yearly educational intervention with hands on training and practice based information are needed to re-enforce pharmacovigilance among the nurses. Hence several studies of the same kind should be carried out among the health care professionals to develop and improve strategies and make the national pharmacovigilance in India a great success.

Limitations: The important limitation is that the study was applied to only nurses and could have been applied to a wider medical community at Meenakshi medical college hospital and research institute, Kanchipuram

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Table 1: Knowledge Analysis towards Pharmacovigilance

KAP – Questions KNOWLEDGE	Pre-test response (%) N=47	Post-test response (%) N=47	Z-Value	P-Value
1. The science of pharmacovigilance includes				
a. Detection	3 (6.38%)	1(2.13%)		
b. Assessment	3(6.38%)	0		
c. Understanding& Prevention	26(55.3%)	11(23.40%)		
d. All of the above.*	15(31.9%)	35(74.47%)	± 4.13341	p < 0.05
2. Abbreviation for ADR				
a. Adverse Drug Reaction*	45(95.74%)	45(95.74%)	0	Not significant
b. Adverse Drug Reporting	2(4.25%)	1(2.13%)		
c. Any Drug Reaction	0	1(2.13%)		
d. Any of the above	0	0		
3.Any minor unfavorable effect of a proven drug should not be reported				
a. True	26(55.3%)	23(48.94%)		
b. False*	21(44.67%)	24(51.06%)	±0.6194	P <0.05
4.Aim of pharmacovigilance includes all EXCEPT				
a. Patient call	5(10.64%)	6(12.76%)		
b. Public health	25(53.19%)	20(42.55%)		

c. Patient benefit assessment	0	0		
d. Legal action on health care programs*	17(36.17%)	21(44.67%)	±0.8407	p<0.05
5.IPC in Pharmacovigilance stands for				
a. Indian Penal Code	15(31.9%)	6(12.76%)		
b. Indian Pharmacopoeia commission*	6(12.77%)	30(63.83%)	±5.0923	p<0.05
c. Indian Pharmacological Community	18(38.30%)	7(14.89%)		
d. International Pharmacopoeia Commission	8(17.02%)	4(8.51%)		

*- Correct answers

Table 2: Attitude Analysis towards Pharmacovigilance

KAP- QUESTIONS ATTITUDE	Pre-test response (%) N=47	Post-test response (%) N=47	Z-Value	P-Value
6. What do you do if someone contacts you to complain about a drug?				
a. Get the name and contact number of the patient and send him.	11(23.40%)	3(6.38%)		
b. Advice the patient it's all normal.	2(4.25%)	0		
c. Ask the patient to contact pharmacy and get an alternate drug.	6(12.77%)	2(4.25%)		
d. Get the name and drug details of the patient and inform the respective doctor & Pharmacology department.*	28(59.57%)	42(89.36%)	±3.3116	p<0.05
7. The identity of the patient and reporter is important to avoid duplicate cases, detection of fraudulent ones and follow up.				
a. True*	30(63.83%)	40(85.11%)	±2.3654	p<0.05
b. False	17(36.17%)	7(14.89%)		
8 .The reporting source and the patient can be the same.				
a) True	35(74.47%)	33(70.21%)	±0.4012	Not significant
b) False.	12(25.53%)	14(29.79%)		

*- Correct answers

Table 3: Practice based Analysis towards Pharmacovigilance

KAP- QUESTIONS PRACTICE- BASED	Pre-test response (%) N=47	Post-test response (%) N=47	Z- Value	P-Value
9. An Orthopaedician prescribed tablet Diclofenac Sodium for a 60/M Suffering from Osteoarthritic pain. 3 days after intake of the medicine pt. complained of Epigastric pain & Vomiting. O/E the Pt. had Epigastric tenderness & diagnosed as Acute Gastritis.				
a. Serious/ case reportable	26(55.31%)	19(40.43%)		
b. Serious / Case reportable *	9(19.15%)	8(17.02%)	±0.268	Not significant
c. Serious/ Case not reportable	7(14.89%)	10(21.28%)		

d. Non serious/ Case not reportable	5(10.64%)	10(21.28%)		
10. A Patient on enalapril for 2 years, on routine follow up was found to have his BP to be 160/100 mm Hg. The physician added 5 mg of amlodipine twice daily, after 10 days the pt. complained anorexia, constipation, dysphagia and dysuria. The physician reduced the dose to 5mg once daily. The symptoms resolved thereafter. What would you do?				
a. Report the case.*	21(44.68%)	30(63.83%)	±1.863	Not significant
b. Advice the patient it's all normal.	15(31.91%)	9(19.15%)		
c. Ignore the patient.	3(6.38%)	3(6.38%)		
d. Suggest him a different doctor.	8(17.02%)	5(10.64%)		

*- Correct answers

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