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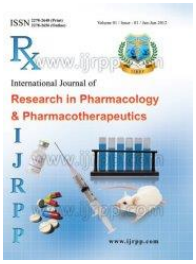

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Comprehensive Study on Assessment of Knowledge, Attitude and Practice of Adverse Drug Reaction Monitoring and Reporting among Nurses in a Tertiary Care Hospital

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ABSTRACT

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. Present pilot study deals with the assessment of ADR monitoring and reporting among nurses in a tertiary care hospital. The results reveal that nurses have sufficient knowledge on ADR monitoring and reporting. Regular teaching and training of the nurses on various aspects of adverse event monitoring and reporting may improve further in good clinical practices and adhere good compliances on patient health care.

Keywords: Pharmacovigilance, Knowledge, Attitude, Practice, nurses, tertiary care hospital, sufficient knowledge.

INTRODUCTION

An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. [1] AEs in patients participating in clinical trials must be reported to the study sponsor and if required could be reported to local ethics committee. Adverse events categorized as serious, results in death, illness requiring hospitalization, events deemed life-threatening, results in persistent or significant disability/incapacity, a congenital anomaly/birth defect or medical important condition) must be reported to the regulatory authorities immediately, whereas non-serious adverse events are merely documented in the annual summary sent to the regulatory authority. [2] The sponsor collects AE reports from the local researchers, and notifies all participating sites of the AEs at the other sites, as well as both the local investigators and the sponsor's judgment of the seriousness of the AEs. This process allows the sponsor and all the local investigators access to a set of data that might suggest potential problems with the study treatment while the study is

still ongoing [3]. In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. An ADR is a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function [4]. The old term side effect has been used in various ways in the past, usually to describe negative (unfavorable) effects, but also positive (favorable) effects. It is recommended that this term no longer be used and particularly should not be regarded as synonymous with adverse event or adverse reaction [5]. In all hospitals doctors/physicians prescribed medicines were administered by the nurses to the patients. Adverse drug reactions may occur for the medicines while administration or after administration. So, the nurses should have sound knowledge on ADR (Adverse Drug Reaction) monitoring, rescuing of the patient and reporting ADR to the particular Pharmacovigilance centre. Hence, our main objective is to assess the nurse's knowledge on ADR monitoring, form filling and reporting, by questionnaire method. This questionnaire will help us to assess the knowledge on the basis of practice and attitude. And our main aim is to asses nurse's knowledge, attitude and practice in monitoring and reporting ADR. The Objectives of the study includes: 1) Questionnaire preparation based on ADR assessment & knowledge, 2) Discussing the ADR and its reporting to the particular Pharmacovigilance centre and 3) Evaluating and interpreting the study result based upon the answers given by the nurses.

MATERIAL AND METHODS

A cross-sectional questionnaire-based survey was conducted from February 2017 to May 2017 under the AMC which is running under PvPI. The study was approved by Institute ethics committee (Human studies, Project number: 17/145). The study was conducted according to Declaration of Helsinki guidelines. It was conducted in different departments of PSG Hospital, Peelamedu, Coimbatore, a tertiary care teaching hospital in South India, Coimbatore involving nurses working in departments of General Medicine, Pulmonary Medicine, Pediatrics, Psychiatry, Cardiology, Neurology, Dermatology & Sexually Transmitted Disease, Endocrinology, Medical Oncology, Clinical Immunology and Nephrology

The questionnaire was prepared based upon the literature survey [6-10] and the suggestions given by the validations. The language was made easy and understandable by the nurses within the prescribed time limit.

Study Instruments

The survey tool used was designed based on pre-designed questionnaires adopted from previous studies [11-15], with minor modification done according to our hospital environment. The modified questionnaire was pretested with doctors, nurses and suitable modifications were done before initiation of the survey. The questionnaire contains totally 34 questions, in which 12 questions in knowledge, 14 questions in attitude and 08 questions in practice individually.

1. The participants were given 30 minutes to answer the questionnaire.
2. Each correct answer was awarded 1 mark, 0.5 marks for the questions which had more one correct answer and the wrong answer was awarded as 0 marks.
3. A total scoring of 75% was the highest, graded as A, 65% was as Grade B, 55% was Grade C and less than 55% was Grade D.

RESULTS AND DISCUSSION

The questionnaire was given to 100 participants of which 80% were females (n=80) and 20% of the participants were males (n=20). The number of participants were in emergency and critical care 10, general medicine 16, followed by dermatology 14, psychiatric 10, pediatrics 13, cardiology 5, neurology, nephrology 8, pulmonary medicine 7, medical oncology 7, Clinical Immunology 3, endocrinology 3, medical gastroenterology 2 and pediatric neonatology 2. The participants were given 30minutes to answer the questionnaire and were not allowed to consult anyone during this time. They could maintain anonymity with regard to their names but had to write their designation. Regarding knowledge about ADRs and ADR monitoring as per the WHO definitions, only few nurses were answered

correctly. The responses to the questions on KAP were shown in the figures. ADR reporting can be further improved by educating the medical & para-medical staff & fresher courses by conducting CME's on Pharmacovigilance. Other measures which can be included are:- 1. Knowledge on Pharmacovigilance programme of India (PvPI). 2. The knowledge of ADRs. 3. Educate to fill up the ADR form. 4. Encourage the health care providers to report all suspected ADRs. 5. Encourage to report ADRs by interventional substances like tubing etc. 6. To take away the prospects from the professionals that ADR are occurring due to the drug, the prescriber is not responsible for the drug.

Adverse drug reactions contribute to excessive healthcare costs through increased patient morbidity and mortality. Several studies identify ADRs as important factors leading to hospital admission. Therefore, monitoring of ADRs should be an integral component of patient care. Most of the participants felt that ADR monitoring should be performed routinely for better patient care. It is essential that ADRs are to be reported and their significance is communicated effectively to the audience for which knowledge and attitude of health care professionals exert a strong influence [16]. The lack of knowledge and negative perceptions about pharmacovigilance and ADR reporting would lead to ADR under-reporting. Overall, the final year dental students had better knowledge that pre-final year students [17]. Fortunately, in the present study, the attitude of the students were positive, however their knowledge has to be increased in some of the aspects of ADR reporting. Creating awareness through educational intervention or training among these health care profession students would help these students to gain knowledge which is very essential for their future practice. This survey will also serve as a preparative measures among these students if they have realized that they are unaware of the answers.

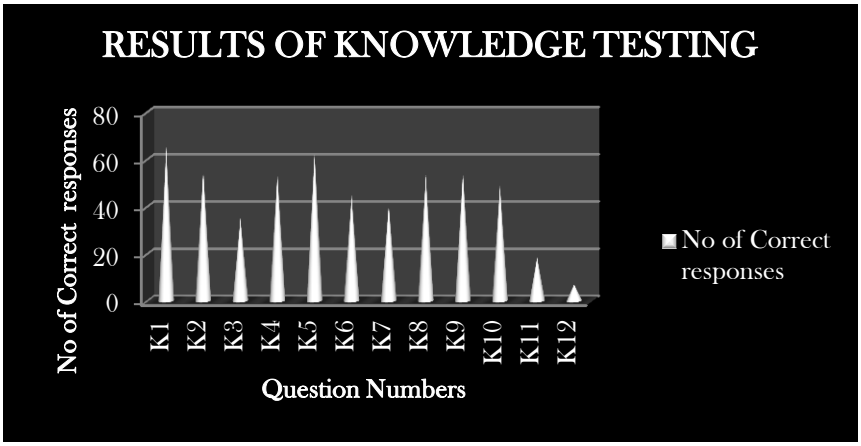

Fig.No.01: Results of Knowledge Testing

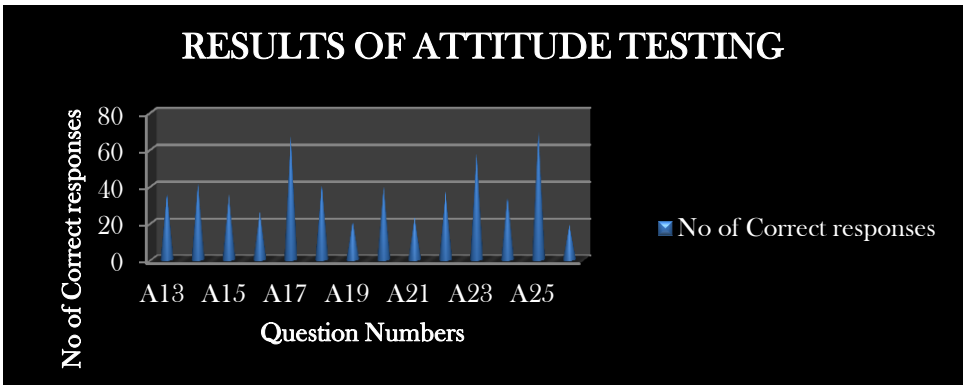

Fig.No.02: Results of Attitude Testing

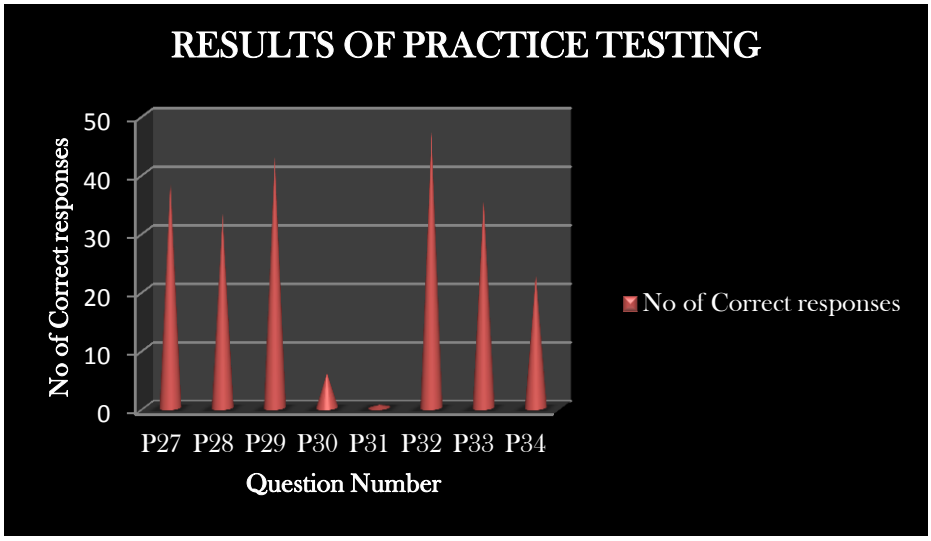

Fig.No.03: Results of Practice Testing

SUMMARY AND CONCLUSION

The present study indicates that majority of participants have good knowledge about local hospital based ADR monitoring and national level pharmacovigilance programme. However, the transition from knowledge to practice is not adequate. This may be due to the attitude of the health care professionals towards ADR reporting. ADR reporting can be further increased by improving access to ADR reporting forms, using user-friendly methods such as electronic reporting and by educational interventions targeting especially the junior healthcare professionals. Effect of awareness program on improvement in knowledge, attitude and practice of pharmacovigilance will be studied to see if there is an impact on ADR reporting.

In conclusion, the present study has shown that though the level of knowledge about ADR reporting and attitude towards it was adequate, yet doctors showed average practice of ADR reporting. Therefore, there is a need to increase the awareness regarding the importance of ADR reporting through Continuous Medical Education at regular intervals, training the doctors on how to report an ADR and also including pharmacovigilance awareness program for undergraduates. All these steps would further help the doctors to contribute to pharmacovigilance efficiently. The fact that majority of respondents agreed that reporting of ADR is necessary and awareness that pharmacovigilance should be taught in detail to healthcare professionals emphasize that they have started to understand the importance of pharmacovigilance.

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