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Research Article

EFFECTIVENESS OF STRUCTURED TEACHING PROGRAM ON KNOWLEDGE OF PHARMACOVIGILANCE AMONG THE PATIENTS IN JIPMER, PUDUCHERRY

***Aparna Jacob[1]., Kumari M.J[2] and Sandhiya Selvarajan[3]**

[1]College of Nursing, Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER)
[2]Cum Principal (Ag), College of Nursing, JIPMER
[3]Department of Pharmacology, JIPMER, Puducherry, India

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ABSTRACT

Modern medicine acts to treat symptoms along with the presenting illness which reduces patients discomfort and fastens the process of healing. But these drugs are associated with significant side effects which many patients are unaware of. Hence a study was conducted to assess the effectiveness of teaching program on the same.

Methods: A quantitative research approach with pre-experimental design was used. The samples included were chronically ill patients admitted in medical wards. A pre-test was conducted to assess the knowledge on Pharmacovigilance and then structured teaching program was given to the patients. The main outcomes measured were improvement in knowledge level using two post tests one immediately after the teaching and the second one on the fifth day after teaching program.

Results: There was a significance association of knowledge with age of the patients admitted in JIPMER during pre test. There is improvement in the mean knowledge score from (11.77± 2.566) in the pretest to (24.57 ± 2.455) in the post test. There was also improvement in the mean knowledge score from (11.77± 2.566) in the pretest to (24.96 ± 1.989) in the second post test. The analysis revealed a statistically significant increase in the knowledge score between the pretest, first and second post test knowledge among the patients.

Conclusions: The study concluded that the structured teaching program is effective in improving the knowledge level of patients regarding pharmacovigilance.

INTRODUCTION

According to the World Health Organization (WHO) definition, an adverse drug reaction (ADR) is 'a response to a drug that is noxious and unintended and occurs at doses normally used in human for the prophylaxis, diagnosis and treatment of disease, or for modification of physiological function'. ADR can also be stated as 'an appreciably harmful or unpleasant response, occurring as result of a treatment measure in relation to the use of a medicine, which predicts dangers from administration of specific treatment in future , or a modification of the dosage regimen, or cancellation of the product'(Yadav, 2008)

Adverse drug reactions (ADRs) can be considered as one among the chief reasons for morbidity and mortality. Around 6% hospital admissions occur due to ADRs and about 6-15% of patients experience a serious ADR after hospitalization. Hence, surveillance of the safety profile of all the medications on a regular basis and to review their therapeutic causes in the light of add -on information resulting from adverse drug reaction monitoring activities is very essential (Kumar *et al*., 2011)

During the twentieth- century drug development as an industry rose dramatically. Before this, there were only few drug regulations to ensure its safety. The modern medicines management laws started only after breakthrough progress in the 19th- century science subjects, particularly in chemistry, physiology and pharmacology which laid a firm basis for the modern medicine research and development and started to expand after the second World War. (Rago & Santoso, 2008) Towards the end of 1950's and the beginning of the 1960's evidence that drugs not only cure illness but can also cause disastrous effects was becoming more prominent (Grootheest, 2003). The thalidomide tragedy was an eye opener to look more seriously into the issue of Adverse drug reactions (ADRs) when congenital abnormalities began to be noted in children

Corresponding author:* **Aparna Jacob
College of Nursing, Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER)

whose mothers had used thalidomide during pregnancy (McBride,1961).

Many recent statistics shows the withdrawal of different drugs from the market due to safety reasons. A systematic review done by Igho *et.al* detected that 462 medicinal products were withdrawn from the market during 1953 to 2013 due to improved Pharmacovigilance surveillance systems. The reasons for withdrawal were commercial reasons, lack of pharmacological actions, contamination, lack of information on adverse reactions, lack of licensure for approval of drugs (Onakpoya *et al,* 2016).

The field of drug safety has gained more popularity in the recent times. Spontaneous reporting systems of Pharmacovigilance introduced recently by PvPI serves as a cornerstone for reducing under-reporting of adverse drug reactions. A report of suspected adverse response to a medicinal product by the consumer himself is known as a consumer report. Such a report helps in empowering patients as consumers of medicines with the mechanism to monitor own safety. Reporting is carried out through emails, ADR reporting forms or by using toll- free numbers. (Mukherjee *et al*, 2016) Underreporting is a major threat to as far as Pharmacovigilance program is concerned. Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER) is an institute of National Importance and a tertiary care referral hospital. ADR monitoring program was implemented in JIPMER in 2010. Many health care providers have reported ADR's to the ADR monitoring committee, but there has been no ADR reports from the part of the patients.

A study conducted by Hughes *et.al* in the United Kingdom reported insufficient knowledge regarding potential side effects of their medications. The primary purpose of monitoring for ADRs is to provide information that can be utilized to establish the benefit-risk ratio due to the usage of the medicines by the patient. The overall aim of any such analyses should be to safeguard patients. The ongoing assessment of risk versus benefit balance should be made mandatory to improvise the field of Pharmacovigilance (Hughes *et al*, 2002)

Medicines are vital in maintaining health of individual patients as well as the health of the public. Medicinal products undergo many pre-clinical and clinical studies inorder to establish its quality, safety and efficacy before receiving the market authorization. But the product can only be tested only on a restricted group of patients and that too for a limited time and strict protocols. Pregnant patients, children, elderly and patients with certain illnesses are vulnerable categories and so have been excluded in such studies. These situations make it unfeasible to detect rare Adverse Drug Reactions (ADRs), long-term effects, drug interactions and particular patient risk groups or risk factors (Sanvidhan *et al*, 2015)

ADR reporting is something, which is to be carried out on a regular basis by all healthcare professionals and should be handled seriously by the regulatory authorities. If reporting of ADRs should take place on regular basis sufficient information should be shared with the reporters. The incidence of the adverse drug reactions in India is likely to be same as that of the West, or more. Despite the presence of five well- organised centers for drug monitoring in the country, the number of reports sent annually is very less. There is an urgent need to reinforce the monitoring of adverse reactions to drugs; public education against self-medication, systems for reaction surveillance and an introduction to drug-safety in the curriculum of undergraduates, and systemic and periodic continuing medical education of health care professionals is required. (Dhikav *et al*, 2004)

MATERIALS AND METHODS

The research design adopted for the present study was pre-experimental one. Data collection was carried out at five different medical wards, JIPMER hospital, Puducherry for six weeks.

The study was done in Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), a National importance Institute under the Ministry of Health and Family Welfare, Government of India. Target Population included all the admitted patients in JIPMER and the accessible population includes all the admitted patients in medical wards of JIPMER Exclusion Criteria consisted of patients who were too weak or critically ill to take part in study and those unable to understand Tamil or English. All the categorical data were presented by frequencies and percentages. The comparison of knowledge scores between pre and post-test was performed by using paired t- test. Chi- square was used find out the association between the pre- test knowledge score with the selected demographic variables of the patients. All statistical analysis had been carried out at 5% level of significance and p- value <0.05 was considered significant.

Study Instruments and Data Collection Approach

Description of Instruments

The researcher constructed the instrument with the help of extensive literature review and by eliciting opinions from experts in the field of Nursing and Department of Pharmacovigilance. Interview method was used for data collection. The tool was translated into Tamil and the validity and reliability was established. Section A consisted of Socio-Demographic variables *like* age, sex, education, occupation, marital status and *Section B* dealt with clinical variables like duration of illness, duration on medication, current diagnosis, form of medication and past history of side-effects. Section C consists of Structured questionnaire on knowledge on Pharmacovigilance with 25 multiple choice questions. Patients were asked to choose the response among the given options. After pretest, structured teaching program on Pharmacovigilance was provided. Soon after the teaching program, a post test was done on the same day immediately after the pre-test to evaluate the increase in the knowledge level of the patients. Each correct answer was given one point and incorrect answers zero points. The total scoring was out of 32. A second post- test was carried out on the fifth day of hospitalization of the patient.

The teaching program consists of Basic information on Pharmacovigilance and Adverse Drug Reactions its causes, reporting methods if ADR's occur, side effects of commonly used drugs and patients role in preventing Adverse Drug Reactions.

The teaching was provided using power point slides. The slides consisted of information regarding Adverse drug reactions

using pictures and captions in patients native language (Tamil). The slides were prepared in simple and easily understandable. The Structured Teaching Program lasted for 45 minutes. Hand outs with necessary information was given to the participants before discharge

Ethical considerations

Permission was obtained from the Institute (JIPMER) ethical committee, Human studies. Informed consent was obtained from every participant after a brief explanation regarding the study by the researchers. Confidentiality was maintained during the data collection.

RESULTS

Distribution of socio-demographic variables of the patients show that majority of them were under the age of 60years, n=75 (75%). The sample constituted mainly of male patients, n=51 (51%) and most of them had education only up to primary schooling, n=59 (59%). A large portion of them were from rural areas, n=85 (85%) and most of them were engaged in unskilled works, n=69 (69%). 87% (n=87) of the participants were married. Distribution of clinical variables of patients show that 56 out of 100 patients had illness less than or equal to one year and the rest had more than one year.55 % (n=55) of the patients have been taking medicines for about one year and 45 % (n=45) has been taking for more than a year. Only 18% (n=18) of the clients have past history of Adverse Drug Reaction and the rest had no past history. The study results show that there was a significance association, (P = 0.036*, significant) of age of the patients with the knowledge level during pre test.

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The first objective was to assess the knowledge regarding Pharmacovigilance among patients in JIPMER, Puducherry

The level of knowledge was further classified into 4 categories as poor knowledge (< or equal to 12 out of the total score), adequate knowledge (13 – 21 out of the total knowledge score), good (22-27) and excellent (>27). Among 100 samples majority of them (65%) were having poor knowledge and 35% had adequate knowledge .None of the samples fall in the group of patients with good or excellent knowledge. Hence it can be interpreted that the knowledge regarding Pharmacovigilance among patients is very low. After the structured teaching program among the 100 patients, 89 of them gained good knowledge. A sum of six of them had adequate knowledge and five patients had excellent knowledge. Hence it can be interpreted that the knowledge of patients can be increased after structured teaching programme.

Inadequate knowledge may be because of ignorance and lack of awareness programs among the patients. Hence it was necessary for the investigator to improve the knowledge by giving specific teaching programme on Pharmacovigilance.

These findings are supported by the study conducted by Joshi *et al*. 23 who carried out an observational study at a tertiary-care teaching hospital regarding knowledge and perception among 150 patients toward adverse drug reactions who were

Table 1 Distribution of level of knowledge of patients regarding Pharmacovigilance in the pre test, immediate and second post -tests.

N=100

Knowledge level	Frequency (pre test)	Percentage(%)	Frequency (immediate post test)	Percentage (%)	Frequency (second post test)	Percentage (%)
Poor (<12)	65	65%	0	0%	0	0 %
Adequate(13– 21)	35	35%	6	6%	2	2 %
Good (22-27)	0	0%	89	89%	86	86 %
Excellent (>27)	0	0%	5	5%	12	12 %

Effectiveness of the structured teaching programme on knowledge of Pharmacovigilance among the patients

Table 2 Mean and standard deviation of knowledge of patients in pretest, first post test and second post test

ASSESSMENT	MEAN	T VALUE	SD	P VALUE
PRE TEST	11.77	- 39.341	2.566	
POST TEST 1	24.57		2.455	0.000*
POST TEST 2	24.96	- 42.638	1.989	

P<0.001***

DISCUSSION

The focus of the study is to assess the effect of structured teaching programme on knowledge regarding Pharmacovigilance among patients in JIPMER, Puducherry.

The details on the distribution of patients according to socio-demographic variables were given in table 1. A majority of patients were under the age of 60years, n=75 (75%). The

selected randomly. Totally, 78.6% patients were aware about the potential of drugs to cause ADR's of the drugs and 33% had experienced side effects in the past. None of the respondents were aware of ADR reporting center. Regarding perceptions toward ADR, 86.7% agreed to report ADR in future and 56% respondents believed ADR reporting may strengthen the patient safety. The study concluded that educational interventions are needed to improve awareness among patients regarding importance of ADR reporting.

The second objective was to assess the effectiveness of structured teaching programme on knowledge regarding Pharmacovigilance among the patients in JIPMER, Puducherry

The hypothesis of the study was that Structured teaching programme was effective in improving the knowledge on Pharmacovigilance among the patients.

The present study shows the improvement in the mean knowledge score from (11.77± 2.566) in the pretest to (24.57 ±

2.455) in the post test (P=0.000*) the analysis revealed a statistically significant difference in the knowledge score between the pretest and post test knowledge among the patients.

There was significant improvement in the knowledge score in posttest of the present study, so the hypothesis was accepted. The results are verified by the study of Pamela *et al*.22 who conducted a prospective study on 285 adult male patients in 1986 attending outpatient clinics at Veterans Administration Medical Centre taking thiazide diuretics. They were given patient information leaflets regarding its usage. The patients were followed up through phone calls which showed that 81.9% read the Patient Medication Information (PMI), 72.5% felt their knowledge improved after reading it and 20.9% felt that more information need to be provided about their diuretics .This study suggests that patient information sheet can bring about positive impact on patient education and can be effectively used by HCP's to have better understanding of the prescribed drugs.

The third objective was to find out the association of mean pre-test knowledge scores on Pharmacovigilance among the patients with selected demographic variables

This study reveal the significant association of knowledge among the patients with age, but other socio demographic variables like gender, education, domicile, occupation and marital status did not show any significant association.

CONCLUSION

This study assessed the knowledge of the patients on Pharmacovigilance and found that they had insufficient knowledge regarding drug safety. There was significant improvement in knowledge of patients after structured teaching programme. Thus, the investigator concludes that structured teaching programme was effective in improving the knowledge of patients regarding Pharmacovigilance. This study shows that there is significant association between age of the patients with the knowledge score.

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