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"A QUESTIONNAIRE BASED STUDY ON KNOWLEDGE, ATTITUDE AND PRACTICE OF ADR REPORTING AND PHARMACOVIGILANCE AMONG HEALTH CARE WORKERS IN A TERTIARY CARE CENTER."

Pharmacology

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ABSTRACT

Aims & Objectives: The objective of this study was to analyze the knowledge of awareness, attitude and practice regarding the ADRs reporting and Pharmacovigilance activity in the healthcare workers of a tertiary care centre.

Design: A cross-sectional questionnaire based study.

Material and Methods: Questionnaire was prepared to assess the KAP of the ADRs reporting and Pharmacovigilance activity. A total of 20 questions were prepared and divided in three groups ie questions regarding knowledge (10 in number, from 1 to 10), attitude (6 in number, from 11 to 16) and practice (4 in number, from 17 to 20) of health care workers about pharmacovigilance. A validated questionnaire was given to the 100 health care workers ie. 67 Doctors, 27 nurses and 6 pharmacists present on that day. They were given half an hour time to answer the questions. Then the questionnaire was collected from them and the data was analyzed statistically. Data was expressed in number as well as percentage.

Results: The study involved total 100 healthcare workers. Among the 67 doctors participated, 50% questions related to knowledge, 100% questions related with attitude and 100% practice related questions were attended by them. Only the knowledge related questions were not attended fully by doctors, this shows their lack of awareness in knowledge in ADR reporting and Pharmacovigilance. It means, we need to conduct continuous education programs to improve their knowledge. In 27 nurses, 50% questions related with knowledge, 83% questions related to attitude and 100% related questions were attended by them. In 6 pharmacists, attended 40% questions related to knowledge, 83% attitude related questions and 100% practice related questions. In nurses and pharmacists also knowledge related questions were less attended.

Conclusions: The knowledge regarding ADRs reporting and Pharmacovigilance need the urgent attention on priority basis, not only for the success of the Pharmacovigilance program, but for the better clinical management of the patients in general. There should be a continuous teaching intervention is required to obtain the 100% practice of ADR reporting.

KEYWORDS

Pharmacovigilance, ADR, Doctors, Nurses, Pharmacists.

INTRODUCTION

Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems." Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce risks and increase benefits from medicines.[1] ADR can be defined as any noxious change which is suspected to be due to a drug, occurs at doses normally used in man, requires treatment or decrease in dose or indicates caution in the future use of the same drug[2]

The history of ADR & PVG started with thalidomide. It can be argued that the history of pharmacovigilance goes back even further but, for practical purposes, the story of modern pharmacovigilance begins there. In the late 1950s there was little, regulation of medicines outside the USA (where thalidomide was not marketed), and their testing and development was almost entirely in the hands of pharmaceutical companies. In the case of thalidomide, unjustified claims of safety in pregnancy were made and its use as a sedative was targeted at pregnant women. The drug turned out to be a teratogen, producing a variety of birth defects but particularly limb defects known as phocomelia . Worldwide, about 10,000 fetuses were affected, particularly in Germany where the drug was first marketed. Since phocomelia was otherwise a very rare congenital abnormality, the existence of a major increase in its incidence did not go unnoticed in Germany but the cause was initially thought to be environmental. In 1961 a series of just three cases associated with thalidomide was reported in *The Lancet*, the problem was finally recognised and the drug withdrawn from sale. At the beginning of the 1960s, publication of possible adverse effects of drugs in the medical literature was effectively the only mechanism for drawing attention to them. Thalidomide produced a non-lethal but visible and shocking adverse effect, leading people to ask why so many damaged babies had been born before anything had been done? This question is central to subsequent developments. It is unlikely that we will ever be able to predict and prevent all the harms which may be caused by medicines but limiting the damage to much smaller numbers is now achievable[3]

Pharmacovigilance has constantly grown importance in last 15 years, relating to absolute amount of adverse drug reactions (ADRs) and to the fact that several hospital admissions are due to ADRs. Good pharmacovigilance programs will identify the risks and the risk factors in the shortest possible time so that harm can be avoided or minimized[4,5,6] .They affect both children and adults with varying magnitudes, causing both morbidity and mortality[7-10]. Doctors, Nurses and pharmacists are in a position to play a major key role in pharmacovigilance programs[11,12] but underreporting is very common, with an estimated median underreporting rate (defined as percentage of ADRs detected from intensive data collection that were not reported to relevant spontaneous reporting systems) of 94%,[13] and occurs frequently for serious and unlabeled reactions.[14,15]

Studies from different settings indicate inadequate knowledge about pharmacovigilance among healthcare workers as well as attitudes that are associated with a high degree of underreporting.[16-21]

Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. However, The Indian national pharmacovigilance programme lacks continuity due to lack of awareness and inadequate training about drug safety monitoring among healthcare professionals in India.[22] Assessment of awareness of pharmacovigilance among the healthcare professionals is very important due to under reporting of adverse drug reactions.

Therefore this study was conducted to assess awareness of pharmacovigilance among the healthcare workers and to plan on an educational intervention for improving awareness of pharma covigilance among doctors, nurses and pharmacists in a tertiary care teaching hospital. In our college, we wanted to know the KAP of health care workers and wanted to introduce more knowledge of PVG and about PvPI to them that's why we conducted this study.

MATERIALS & METHODS

This is a cross sectional, observational, questionnaire based study.

The study was approved by the Institutional ethics committee before it was done.

A Questionnaire was prepared to assess the KAP of the ADRs reporting and Pharmacovigilance activity. A total of 20 validated questions were prepared and divided in three groups ie questions regarding knowledge (10 in number, 1 to 10), attitude (6 in number. 11 to 16) and practice (4

in number, 17 to 20) of health care workers about pharmacovigilance. The validated questionnaire was given to the health care workers ie. Doctors, nurses and pharmacists available on that day. They were given half an hour time to answer the questions. Then the questionnaire was collected from them and the data was analyzed statistically. Data was expressed in number as well as in percentage.

RESULTS

The study was conducted in a tertiary care center. The validated questionnaire with 20 questions were given to the healthcare workers who were present on that particular day. Among the 103 available persons 100 were accepted to answer the questionnaire. Among the 100, 67 were doctors, 27 were nurses and 6 were pharmacists. Half an hour time was given them to answer the questionnaire. Among the 20 questions, the percentage of questions answered by the healthcare workers is given in Table 1.

Table:1, Assessment of Questionnaire

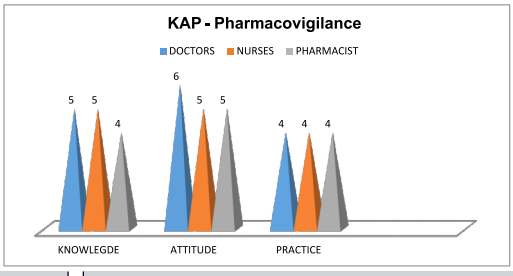
Questions	Attempted	% of candidates who attempted	Not Attempted	% of candidates who did not attempted
Q1	60	60%	40	40%
Q2	80	80%	20	20%
Q3	61	61%	39	39%
Q4	30	30%	70	70%
Q5	74	74%	26	26%
Q6	18	18%	82	82%
Q7	30	30%	70	70%
Q8	35	35%	65	65%
Q9	54	54%	46	46%
Q10	68	68%	32	32%
Q11	78	78%	22	22%
Q12	92	92%	8	8%
Q13	100	100%	0	0%
Q14	100	100%	0	0%
Q15	100	100%	0	0%
Q16	100	100%	0	0%
Q17	100	100%	0	0%
Q18	100	100%	0	0%
Q19	100	100%	0	0%
Q20	100	100%	0	0%

Knowledge based questions were not answered by the healthcare workers in 100%. Attitude based questions were answered by doctors 100% and nurses and pharmacists in less percentage. Practice based questions were answered 100% by all the doctors, nurses and pharmacists. It is given in Table 2 and Fig 1.

Table 2. Comparison of awareness of pharmacovigilance among doctors, Nurses & pharmacist.

Group	Number Attended out of 100	%	Response in average		Practice Out of 4 ques &%
			Knowledge Out of 10 ques & %	Attitude Out of 6 ques &%	
Doctors	67	67	5 (50%)	6 (100%)	4 (100%)
Nurses	27	27	5 (50%)	5 (83%)	4 (100%)
Pharmacist	6	6	4 (40%)	5 (83%)	
					4 (100%)

Figure: 1, KAP- Pharmacovigilance



DISCUSSION

Pharmacovigilance deals with detection, assessment, understanding and prevention of adverse effects or any other drug related problems. The ultimate aim of pharmacovigilance is to ensure patient safety and rational use of medicines, once a new medicine is released for general use in the society. This is the study assessing the Knowledge, attitude, practice of pharmacovigilance among the healthcare workers who was working in an educational institution. In all the medical colleges, pharmacovigilance and ADR reporting and monitoring system exist. The present study shows the amount of knowledge, attitude and practice that healthcare workers has in ADR reporting and Pharmacovigilance.

There were 67 doctors, 27 nurses and 6 pharmacists participated. There was totally 20 questions were given to them. There was 10 questions related with knowledge about ADR reporting and Pharmacovigilance. In the first question, the definition of Pharmacovigilance were attended by 60% of total participants which shows many of them doesn't know the exact definition of pharmacovigilance. In the second question, 80% of the people attended and it showed that their knowledge is better about post marketing surveillance. In all the questions related with knowledge, 4,6,7,8 & 9 were not attempted by many, it shows their unawareness in this areas even doctors. Rest of the questions like 3,5 &10 were attended by many people.

There were 6 (From 11 to 16) questions for attitude related to ADR reporting and Pharmacovigilance. Among the 6 questions 11th , 12th were answered by many. And rest of the 4 questions were answered by 100% of the people, it shows all the health care workers are aware of the attitude of ADR reporting and Pharmacovigilance. In attitude related questions, 3 questions were yes/No type of questions. In that, 14th question which was asking whether ADR reporting is necessary or not, answer Yes was given by 92% of people. Only 8% doesn't know the correct response. In 15 th question, whether health care professionals need education in this regard, 87% people responded with Yes. In 16 th question, it was asked whether anyone read any article related with ADR, 38% people responded with the answer Yes (As in Table 1). It means the healthcare workers needs awareness in improving their knowledge in ADR reporting and Pharmacovigilance.

In the 4 questions (From 17 to 20) related with practice of ADR reporting there was 100% response. In 17 th question, whether they have come across any ADR, 75% people have given response as Yes. Only 25% doesn't expose to any ADR. In 18 th question, whether they have undergone any training on ADR reporting, only 26% responded as Yes. 74% people were not undergone any training in reporting ADR. In 19 th question, whether anyone follows any preventive measures to reduce the ADR, 65% has said Yes. In 20th question, whether they have prevented any ADR, only 28% said Yes. 72% of participants said No to prevention of ADR.

Among the 67% doctors participated, 50% questions related with knowledge, 100% questions related with attitude and 100% practice were attended by them. Only the knowledge related questions were not attended fully by doctors, this shows their lack of awareness in knowledge in ADR reporting and Pharmacovigilance. It means, we need to conduct continuous education programs to improve their knowledge. In 27 nurses, 50% knowledge related questions, 83% attitude related questions and 100% practice related questions were attended by them. In 6 pharmacists, 40% knowledge related questions, 83% attitude related questions and 100% practice related questions were attended by them (As in Table 2 & Figure 1). In nurses and pharmacists also knowledge related questions were less attended. So the health care workers need to be educated for ADR reporting and Pharmacovigilance.

This data suggests that continuing educational intervention is an important tool for increasing doctors, pharmacist and nurse's awareness to pharmacovigilance. Based on our study results and the finding of Cosentino et al [23] and Figueras et al[24] recommend including "Pharmacovigilance" as a topic in continuing education programmes and would also recommend a yearly repetition of such educational interventional program.

Our study strongly suggests that nurses are in need of information regarding the adverse effects of drugs especially information on occurrence of common and rare adverse drug reactions. It was also evident from our study that pharmacist were found to be more aware

regarding attitude, practice of pharmacovigilance, this is because they were taught about detection, assessment, understanding and prevention of adverse drug reaction to a certain extent in their syllabus during graduation.

In the literature, a lack of time and knowledge about ADRs is often considered to be a cause of underreporting [25- 27]. The results of the present study show that the factor discourage doctors from reporting ADRs was lack of time and types of reaction to be preferentially reported. This was supported by the study conducted by Chatterjee et.al[28] which stated that a main reason for under reporting of ADRs was the clinical negligibility of the adverse reaction due to lack of time and little knowledge about the types of reactions to be preferentially reported.

However, in a similar educational interventional program in pharmacovigilance study of Li Q, Zhang et al[29] showed that educational intervention improved awareness of knowledge, attitudes, practice of healthcare workers towards practice of pharmacovigilance. This study has two important limitations. Firstly, the study period was too short. Secondly, the study findings could not be applied to the wider community pharmacist as well as to medical community as the study was restricted to nurses, pharmacist and to doctors practicing at this tertiary care center. Therefore we recommend that several such studies of similar kind should be conducted among community pharmacist as well as to all types of medical practitioners so as to develop strategies to improve the knowledge, attitudes, practice of pharmacovigilance in India.

A study from Italy reported that doctors had little information concerning ADRs and ADR reporting systems [30]. A recent study from India also identified that the awareness about Pharmacovigilance program and the knowledge of ADR reporting were very low among the doctors [31,32]. The most important outcome of pharmacovigilance is the prevention of patients being affected unnecessary negative consequences of pharmacotherapy.[33] Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market. However, under-reporting of ADRs is one of the major problems associated with pharmacovigilance programs.[34-36] It is known that spontaneous reporting programs (one of the most widely used methods of pharmacovigilance) are associated with relatively low levels of reporting. The scheme operates on the basis of reporting all ADRs despite uncertainty about a causal relationship. Even in countries like the United Kingdom, where pharmacovigilance programs are well established, a high level of under-reporting is documented.[37]

The major reasons for under-reporting of ADRs are lack of knowledge about the reporting procedure, unavailability of the reporting center mailing address, unavailability of the ADR report form, lack of knowledge of the existence of a national ADR reporting system, and belief that the ADR in question was already well known, ADR is not serious, uncertainty concerning the causal relationship between the ADR and the drug, forgetting to report the ADR and lack of time and ignorance of reporting procedure.[38-42]

CONCLUSION

The healthcare workers had a relatively better attitude and practice but limited knowledge towards ADRs and pharmacovigilance. The majority of the healthcare workers felt ADR monitoring is important, but only a few had ever reported an ADR to the pharmacovigilance center. The reasons for under-reporting were either they did not come across an ADR or a few may unaware of the existence of a pharmacovigilance center at the hospital. The findings of the study suggest a huge scope for improving the ongoing pharmacovigilance activities in the hospital. There is a need for continuous educational initiatives for the doctors, nurses and the pharmacists.

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