

A Descriptive Cross-Sectional Study on Awareness and Perception of Adverse Drug Reaction among Doctors and Nurses, in Tertiary Care Hospital, Belagavi

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Abstract: Adverse Drug Reactions (ADRs) are scantily reported with poor contribution by healthcare professionals worldwide and in particular in developing countries. The aim of this study was to assess the knowledge and awareness of ADRs reporting and pharmacovigilance system among doctors and nurses in KLEs Tertiary care hospital Belagavi. A questionnaire was designed addressing; awareness of ADRs, knowledge of pharmacovigilance system, availability of ADRs reporting system. The questionnaire was distributed to doctors (n=160) and nurses (n=140) working in hospital. Completed questionnaires were collected, data were analyzed and data were expressed in number as well as percentage. Of the 300 questionnaires circulated, a total of 107 doctors and 107 nurses responded. The percent of the respondents who accepted to enroll in the study was 66.8% of doctors and 76.4% of nurses. Most of the respondents were unable to correctly define the pharmacovigilance term, but they were aware of ADRs. The awareness of the national pharmacovigilance system among doctors was 32.5% and nurses were 37.9%. (42.5%) doctors and (54.3%) nurses follow the reporting system to pharmacovigilance center. Our study has demonstrated a lack of knowledge and awareness of pharmacovigilance and ADRs reporting among healthcare professionals in hospitals. The poor knowledge of ADRs reporting emphasized the urgent need to implement the appropriate strategies to improve the awareness of pharmacovigilance practices and ADRs reporting in our hospitals.

Keywords: Adverse drug reaction, Pharmacovigilance, Awareness.

INTRODUCTION

Adverse Drug Reactions (ADRs) are a major problem and are one of the leading causes of mortality and morbidity [1]. ADRs are common causes of hospitalization and death, withdrawals due to safety problems are often based on data from spontaneous reporting systems [2]. Previous studies which were done in both developed and developing countries have shown poor knowledge of healthcare professionals on reporting of ADRs. This is due to the fact that drug safety is not being taken seriously and as it is not one of the top priorities in healthcare programs worldwide. There have been exceptions, of course; for instance, studies which were done in the U.S. and Sweden have shown that healthcare professionals (HCPs) had good knowledge on the rules for reporting ADRs [3]. The reporting of ADRs is a key component for ensuring the safety of the patients and the surveillance of the risk-benefit ratio of medicines during their life cycle. According to WHO definitions, an adverse drug reaction is “a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological

function” and pharmacovigilance is “the science and activity relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine related problems” [4]. ADRs are known as the very important causes for hospitalization. ADRs occur approximately in 30% of hospitalized patients, and patients in the ICU wards are exposed to more danger than the others. ADR can be a threat for patient’s safety and quality of their life and may impose a lot of costs on the health systems. The important point about ADRs is pharmacovigilance or the methods used for their recording, evaluation and prevention [5]. Healthcare professionals’ knowledge, attitudes and perceptions about ADR have central role in improvement of patients’ safety

WHO standards show that the best spontaneous reporting rate is over 200 reports per 1,000,000 populations per year [6].

Objectives

The objectives of the current study were:

- To assess the Awareness and Perception of Doctors and nurses regarding Adverse Drug Reactions.

- To elicit the reporting of Adverse Drug Reactions among nurses.

METHODOLOGY

The study was conducted in KLES' Dr. Prabhakar Kore Hospital, Belagavi. A descriptive cross-sectional approach was adopted for the study. It included collection of information and data directly from the subjects of the study through a pre-designed

and pre-tested structured close-ended questionnaire schedule survey. The population for this study included the One hundred and sixty Doctors and One hundred and forty Nurses working in KLES' Tertiary Care Hospital, Belagavi. Universal sampling technique was adopted.

RESULTS

Table-1: Distribution of Doctors and Nurses According to the Profile

Doctors (n = 160)				Nurses (n = 140)			
Sl. No.	Variables	Frequency (f)	Percentage (%)	Sl. No.	Variables	Frequency (f)	Percentage (%)
1	Age (Years)			1	Age (Years)		
	21-30	0	0%		21-30	82	58.60%
	31-40	55	34.40%		31-40	24	17.10%
	41-50	47	29.40%		41-50	1	0.70%
	More than 51	5	3.10%		More than 51	0	0%
No response	53	33.10%	No response	33	23.60%		
2	Gender			2	Gender		
	Male	85	53.10%		Male	43	30.70%
	Female	22	13.80%		Female	64	45.70%
No response	53	33.10%	No response	33	23.60%		
3	Years of experience			3	Years of experience		
	1 – 5	9	5.60%		1 – 5	48	34.30%
	6 – 10	53	33.10%		6 – 10	56	40%
	11 – 15	33	20.70%		11 – 15	3	2.10%
	More than 15	12	7.50%		More than 15	0	0%
No response	53	33.10%	No response	33	23.60%		

From the above table it can be inferred that, majority of doctors responded were male with the age group ranging from 30-40 years and of 6-10 years of experience. Majority of the nurses responded were females with the age group of 20-30 years and with 6-10 years of experience.

From the above table we can infer that, Majority of doctors got knowledge of ADRs from books and they were aware about it. All the doctors respondent that is, 66.8% had knowledge of drugs causing ADRs and they had enough skills to manage or treat the reactions, But majority of the doctors did not follow the reporting system of ADRs and were unaware about the pharmacovigilance program started by the government and many of them had not undergone any

reporting training. All the doctors who responded to the study were aware about all type of adverse drug reactions.

Majority of the nurses also got the knowledge of ADRs from books but only 30.70% had knowledge of drug causing ADRs and only 2.1% nurses had enough skill to manage ADRs. Majority of the nurses that is, 76 follow the reporting system of ADRs to pharmacovigilance center and many of them had undergone reporting training. Half of the nurses responded were aware about the pharmacovigilance program started by the government. All the nurses who responded were not aware about the different type of adverse drug reactions.

Tabl-2: Distribution of respondents according to their Awareness and Personal experience on Adverse Drug Reactions and Pharmacovigilance.

Items	Responses	Doctors (n = 160)		Nurses (n = 140)	
		Frequency	Percentage	Frequency	Percentage
Source of knowledge about ADRs	Books	96	60%	106	75.70%
	Reference	0	0%	0	0%
	Seminar	5	3.10%	0	0%
	Symposium	0	0%	0	0%
	Others	6	3.80%	1	0.70%
	No response	53	33.10%	33	23.60%
Knowledge about the drugs causing ADR	Yes	107	66.90%	43	30.70%
	No	0	0%	40	28.60%
	Uncertain	0	0%	24	17.10%
	No response	53	33.10%	33	23.60%
Existing knowledge of ADR is sufficient to treat	Yes	95	59.40%	3	2.10%
	No	0	0%	92	65.70%
	Uncertain	12	7.50%	12	8.60%
	No response	53	33.10%	33	23.60%
Existing skills/knowledge is sufficient to manage reactions	Yes	107	66.90%	12	8.60%
	No	0	0%	55	39.30%
	Uncertain	0	0%	40	28.60%
	No response	53	33.10%	33	23.60%
Reporting of ADRs to monitoring centre and pharmacovigilance centre	Yes	68	42.50%	76	54.30%
	No	39	24.40%	17	12.10%
	Uncertain	0	0%	14	10%
	No response	53	33.10%	33	23.60%
Type of patients found with ADRs	Inpatients	16	10%	41	29.30%
	Outpatients	0	0%	0	0%
	Both	91	56.90%	66	47.10%
	No response	53	33.10%	33	23.60%
Action taken for patients found with ADRs:					
Give another drug	Yes	68	42.50%	53	37.80%
	No	0	0%	10	7.10%
	Uncertain	0	0%	44	31.40%
	No response	92	57.50%	33	23.60%
Drug withdrawal	Yes	90	56.30%	105	75%
	No	0	0%	1	0.70%
	Uncertain	17	10.60%	1	0.70%
	No response	53	33.10%	33	23.60%
Refer to another Doctor	Yes	35	21.90%	2	1.40%
	No	60	37.50%	52	37.10%
	Uncertain	12	7.50%	53	37.90%
	No response	53	33.10%	33	23.60%
Explain the ADR to the patient	Yes	107	66.90%	56	40%
	No	0	0%	0	0%
	Uncertain	0	0%	51	36.40%
	No response	53	33.10%	33	23.60%
PHARMACOVIGILANCE					
Awareness regarding pharmacovigilance program started by Govt. of India.	Yes	52	32.50%	53	37.90%
	No	55	34.40%	52	37.10%
	Uncertain	0	0%	2	1.40%
	No response	53	33.10%	33	23.60%
If yes how do you feel about pharmacovigilance program	Good	52	32.50%	53	37.90%
	Complicated	0	0%	0	0%
	Unnecessary	0	0%	0	0%
	Others	0	0%	0	0%
	No response	108	67.50%	87	62.10%

Undergone training to report ADR	Yes	21	13.10%	73	52.10%
	No	86	53.80%	34	24.30%
	No response	53	33.10%	33	23.60%
Aware about the ADR reporting form by CDSCO	Yes	48	30%	11	7.80%
	No	59	36.90%	96	68.60%
	No response	53	33.10%	33	23.60%
Reporting of ADRs to pharmacovigilance centre on a regular basis	Gladly accept	103	64.40%	88	62.80%
	Do it just like that	4	2.50%	0	0%
	Just Ignore it	0	0%	0	0%
	Others	0	0%	19	13.60%
	No response	53	33.10%	33	23.60%
Number of ADR patients encountered weekly during practice	0-1	90	56.20%	86	61.40%
	2-Jan	17	10.60%	21	15%
	4-Mar	0	0%	0	0%
	6-May	0	0%	0	0%
	>6	0	0%	0	0%
	No response	53	33.10%	33	23.60%
Communication with pharmacovigilance centre when patients arrive with ADR	Fill ADR reporting forms	72	45%	52	37.10%
	Inform telephonically	0	0%	52	37.10%
	Discuss with HoD	31	19.40%	0	0%
	Contact Dept. of Pharmacology	0	0%	0	0%
	Get help of pharmacovigilance centre	4	2.50%	3	2.10%
	No response	53	33.10%	33	23.70%
Familiar with the types of ADR	Yes	107	76.40%	5	3.60%
	No	0	0%	51	36.40%
	Uncertain	0	0%	0	0%
	No response	53	33.10%	84	60%
Awareness about the types of Adverse Effects					
Type A Adverse Effects (Pharmacological Adverse effects)	Yes	107	76.40%	5	3.60%
	No	0	0%	52	37.10%
	Uncertain	0	0%	0	0%
	No response	53	33.10%	83	59.30%
Type B Adverse Effects (Immunoallergic reactions)	Yes	107	76.40%	5	3.60%
	No	0	0%	52	37.10%
	Uncertain	0	0%	0	0%
	No response	53	33.10%	83	59.30%
Type C Adverse Effects (Spontaneous Disease)	Yes	107	76.40%	6	4.30%
	No	0	0%	51	36.40%
	Uncertain	0	0%	0	0%
	No response	53	33.10%	83	59.30%
Occuring in special situations	Yes	0	0%	5	3.60%
	No	0	0%	1	0.70%
	Uncertain	41	25.60%	51	36.40%
	No response	119	74.40%	83	59.30%
Alternative medicine do not cause ADR	Strongly Disagree	31	19.40%	51	36.40%
	Disagree	37	23.10%	4	2.90%
	Uncertain	39	24.40%	51	36.40%
	Agree	0	0%	1	0.70%
	Strongly Agree	0	0%	0	0%
	No response	53	33.10%	33	23.60%
Which is the safest medicine?	Allopathic	20	12.50%	51	36.40%
	Homeopathic	0	0%	1	0.70%
	Ayurvedic	0	0%	0	0%

	Unani	0	0%	0	0%
	Chinese	0	0%	0	0%
	None	87	54.40%	55	39.30%
	No response	53	33.10%	33	23.60%
Discussion on adverse effects of medicines prescribed by them to the patients	Yes	20	12.50%	0	0%
	No	48	30%	52	37.10%
	Uncertain	0	0%	55	39.30%
	No response	92	57.50%	33	23.60%

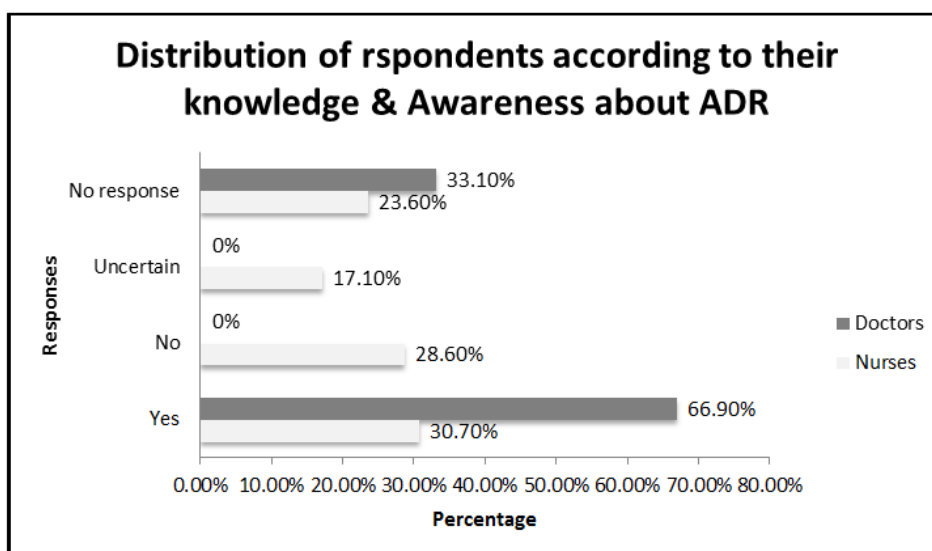


Fig-1: Distribution of respondents according to their Knowledge & Awareness about ADR

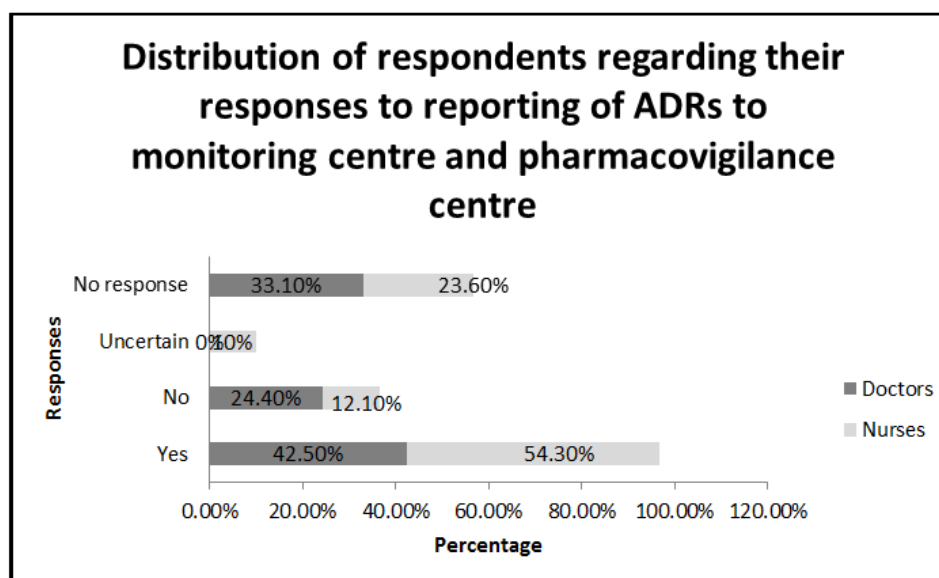


Fig-2: Distribution of respondents regarding their responses to reporting of ADRs to monitoring center and pharmacovigilance center

DISCUSSION

In spite of good pharmacovigilance centers there are lack of studies that address the knowledge and awareness of health profession about the pharmacovigilance system and ADR reporting in this country. In our study it was found that among doctors the awareness was 66.8% and among nurses it was 43%

which is similar to the study conducted in Sweden where nurses awareness was 58%.

Majority of the doctors 53.1% who responded were males and 34.4% were between age group of 31-40 years. 66.9% were postgraduates and 33.1% with the experience of 6-10 years. Majority of the respondents

were from surgery and medicine department. Of 160 doctors 33.1% did not respond to the study as they were busy and some of them were on leave.

Majority of the nurses responded were females that is, 45.7%. 58.6% were between the age group of 21-30 years. 67.8% were staff nurses and 40% with the experience range of 6-10 years. Majority of the nurses respondents were from medicine ward. Of 140 nurses 23.6% did not respond to the study as they had heavy workload and some were on leave.

In our study 60% of the doctors got knowledge of ADR from books, which is similar to a study conducted by A. K. Choudhary where books remained the main source knowledge of ADRs among health care professionals. This was followed by seminar among doctors. In our study 106 nurses got knowledge from books, seminars, practical experience and discussion with doctors and 0.7% from practical knowledge while in other study nurses came to know about ADR from somebody.

The total 107 doctors respondents have knowledge of drugs causing ADRs which correspond to the study conducted in Indore by Sarfraz Alam Khan *et al.*, where major proportion 85.3% of the doctors were aware of all ADRs caused by different drugs & among 107 nurses and 30.7% nurses respondents have knowledge of drugs causing ADRs.

Majority of the doctors had sufficient knowledge to treat ADRs and had enough skills to manage ADRs which is similar to the study conducted in Southern Romania where all doctors are well versed with the ADR knowledge.

In our study 34.4% doctor respondents were unaware about the pharmacovigilance program started by the government as no special awareness was created regarding pharmacovigilance program in the hospital. 32.5% respondents were aware about the program of which majority of them were of 30-40 years of age group which means they are exposed to advance knowledge of pharmacovigilance program.

53 (37.9%) nurse respondents were aware about the pharmacovigilance program started by government as they had undergone pharmacovigilance training.

Despite the Saudi National pharmacovigilance center that regularly publishes an ADR bulletin information pertaining to ADRs is stored in the National ADRs database, there is a lack of studies that address the knowledge and awareness of healthcare professionals about the pharmacovigilance system and ADRs reporting in Saudi Arabia.

In our study 68 (42.5%) doctors follow the reporting system to pharmacovigilance center and 76 (54.3%) nurses report to pharmacovigilance center.

Majority of doctors that is, 86 (53.8%) had not undergone any reporting training of ADRs while majority of nurses that is, 73 (52.1%) had undergone reporting training, this is one of the reason for which the doctors lack in reporting of ADRs to pharmacovigilance centre.

Some of the nurses even after undergoing training lack in reporting of ADRs, study conducted in Sweden by Elisabeth Ekman *et al.* it is likely that nurses with a longer experience are more independent and have sufficient self-confidence to make this decision by themselves. In contrast to this study number of nurses with higher experience was found less. One of the causes for it was work overload and lack of time which corresponds to the study conducted in European countries, where the main cause of under-reporting was attributed to the time and lack of time and workload. All the doctors who responded to the study (107) were familiar with different adverse drug reactions and have knowledge of different types (i.e Type A, Type B, & Type C) of adverse effects. In spite of this they lacked in reporting about it due to lack of knowledge about pharmacovigilance which is similar to the study in Saudi Arabia by Mohamed M. *et al.* where the main reason for under-reporting of ADRs are lack of time, poor knowledge on the reporting mechanisms, unfamiliarity with the existence of national pharmacovigilance system, belief that ADR was already well known, doubt about the importance of the ADRs reporting and fear to report ADRs.

In our study 90 (56.2%) doctors encounter 0-1 number of ADR patients weekly in their practice. This shows that the incidence of adverse drug reaction is very less in our hospital which is again one of the factors because of which doctors lack in reporting of ADRs in our hospital

CONCLUSION

In our study majority of doctors were aware about the adverse drug reactions and have sufficient knowledge to treat the adverse reactions caused by drugs while nurses are aware about the adverse drug reactions, but they don't have enough knowledge and skills to manage adverse drug reactions. Majority of the doctors did not follow the reporting system to pharmacovigilance center and had not undergone any training program to report ADR while majority of the nurses follow the reporting system and had undergone training program.

LIMITATIONS

- Many doctors and nurses did not respond to the questionnaire.

- Doctors & nurses on leave were excluded from the study.
- Biased responses from the nurses.
- Some of the questions were unanswered in the questionnaire by few respondents.
- The study is confined to KLES' Tertiary Care Hospital, Belagavi.

Despite these limitations, this study attempted to identify the awareness & perception of adverse drug reactions among doctors & nurses working in the hospital, and the findings and recommendations should be viewed against these limitations.

Ethics committee

The research project was cleared by the JNMC Institutional Ethics Committee on Human Subjects Research as ethical and justifiable.

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