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Research Article

ASSESSMENT OF KNOWLEDGE, AWARENESS AND PERCEPTION OF PATIENTS REGARDING ADVERSE DRUG REACTIONS

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ABSTRACT

Adverse drug reactions (ADRs) are one of the major problems associated with medicines. They are often referred to as any harmful, unintended and undesired effects of a drug that occurs at doses normally used in human beings for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function. The primary aim of this study is to assess the knowledge, awareness and perception of the patients regarding adverse drug reactions. The study was carried out using a self-modified questionnaire to analyze demographic information of patients along with ADRs related knowledge, awareness and perception. A total of 140 patients were analyzed out of which 61.42% were males and 38.57% were females. Majority of patients (30%) were uneducated and most of the patients (37.14%) belongs to the age group of 41-50 years. Assessment of knowledge regarding ADRs showed that 30.71% had knowledge about ADRs and 27.14% had knowledge about the outcomes of ADRs. Assessment of awareness on ADRs showed that only 8.57% were experienced an adverse drug reaction. Assessment of perception regarding ADRs showed that all patients (100%) were disagree about adverse drug reaction were normal situation requiring no specific emphasis. This study shows that the most of the patients were unaware about the pharmacovigilance and ADR reporting system. Therefore, it is necessary to create awareness in order to improve ADR reporting. Health care professionals play an important role to aware them and provide knowledge about ADRs reporting.

KEYWORDS: *Adverse drug reactions, knowledge, awareness, perception, reporting*

INTRODUCTION:

Medicines have, beyond any doubt, proved to be a boon for humanity and it fight against the disease and sufferings. However, like most other useful things, medicines come with inherent risks associated with their use, called adverse drug reactions (ADRs). They are often referred to as any harmful and unintended effects of a drug that occurs at doses normally used in human beings for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function [1-3].

Pharmacovigilance is the science related to the identification, detection, assessment, monitoring and management of adverse effects or any other possible drug-related problems. Pharmacovigilance is still in its infancy in India and there exists very limited knowledge about this discipline. The Central Drugs Standard Control Organization (CDSCO), New Delhi, India, under the aegis of Ministry of Health and Family Welfare, Government of India, has initiated a nationwide pharmacovigilance program in July 2010 for monitoring ADR in the country to safeguard public health. All regional pharmacovigilance centers report ADRs to the national center and the final report is sent to the Uppsala Monitoring Centre in Sweden, a center for international service and scientific research toward patient safety [4-6].

Post marketing surveillance of drugs is important because it is impossible to determine all adverse effects of drugs before they are put to use. Hence, knowledge in pharmacovigilance activities and adverse drug reactions reporting become necessary in this regard [7]

METHODOLOGY

This was an observational, questionnaire-based study involving 140 inpatients at Shri Mahant Indiresh Hospital, Dehradun for a period of 6 months. The primary aim of this study was to assess the knowledge, awareness and perception of patients regarding ADRs. The study was approved by Institutional ethical committee

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after issuing ethical clearance certificate. Self-modified questionnaire was designed to obtain the demographic information of patients along with a total of 15 questions to assess knowledge, awareness and perception regarding ADRs. Questionnaire contains 5 questions to assess knowledge, 5 questions for awareness and 5 questions for perception regarding ADRs.

RESULTS AND DISCUSSION

Demographic analysis as per Table 1 showed that out of 140 patients, 61.42% were males and 38.57% were females. Age wise distribution of patients showed that most of the patients were in the age group of 41-50 years (37.14%) followed by 31-40 years (23.57%), 21-30 years (17.86%), 51-60 years (11.43%), 61-70 years (5.71%) and 14-20 years (4.28%). It was further analyzed that majority of patients (30%) were uneducated followed by patients with education upto graduation were 25%, intermediate were 20%, high school were 15% and remaining 10% were postgraduate.

Table 1: Demographic analysis of patients

S.No.	Demographic factors	Number of subjects (%) (n=140)
1	**Gender**	
	Male	86 (61.42)
	Female	54 (38.57)
2	**Age (Years)**	
	14-20	06 (4.28)
	21-30	25 (17.86)
	31-40	33 (23.57)
	41-50	52 (37.14)
	51-60	16 (11.43)
	61-70	08 (5.71)
3	**Education**	
	Uneducated	42 (30.00)
	Up to high school (10th)	21 (15.00)
	Up to intermediate (12th)	28 (20.00)
	Graduated	35 (25.00)
	Post graduated	14 (10.00)

Assessment of knowledge regarding ADRs was analyzed using 5 different questions as shown in Table 2. Out of 140 patients, 30.71% had knowledge about ADRs and 27.14% know about the outcomes of ADRs. 24.28% patients had the knowledge about identifying, reporting and management of ADRs while remaining 75.71% don't know such facts.

Table 2: Knowledge based questions regarding ADRs

Q.No.	Questions	Yes (%)	No (%)
1	Do you know what are adverse drug reactions (ADRs)?	43 (30.71)	97 (69.28)
2	Do you know the outcomes of ADRs?	38 (27.14)	102 (72.85)
3	Do you know how to identify the ADRs?	34 (24.28)	106 (75.71)
4	Do you know how to report ADRs?	34 (24.28)	106 (75.71)
5	Do you know how to manage ADRs?	34 (24.28)	106 (75.71)

Assessment of awareness on ADRs was analyzed using 5 different questions and the respective assessment was shown from Figure 1 to 5. Out of 140 patients, only 8.57% were experienced an adverse drug reaction and aware of them. 44.28% thought of reporting ADRs at certain point of time while remaining 55.71% never thought of reporting ADRs. Most of the patients (88.28%) thought that it is important to report adverse drug reactions but only few of them (15.71%) don't think so because of less knowledge. Majority of patients (87.14%) were never felt any unwanted effects during the treatment. 43.57% patients talked to the doctors, 30% talked to the nurses, 22.14% talked to the pharmacist and 4.28% talked to any other person about any side effects during the treatment.

Figure 1: Awareness of patients regarding ADR experience

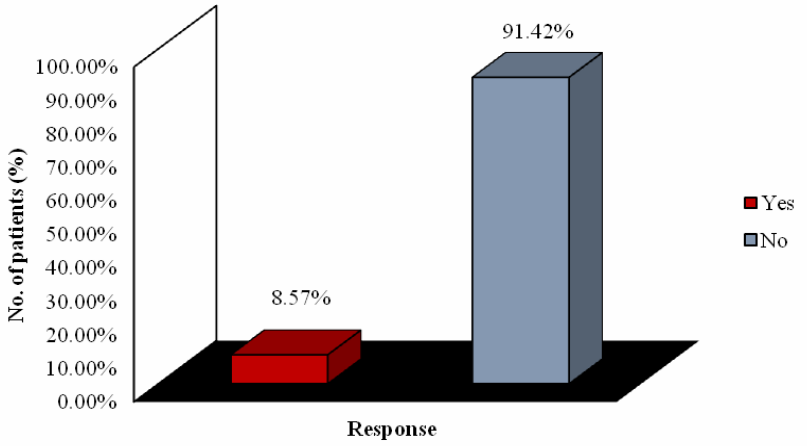

Fig 1: Awareness of patients regarding ADR experience

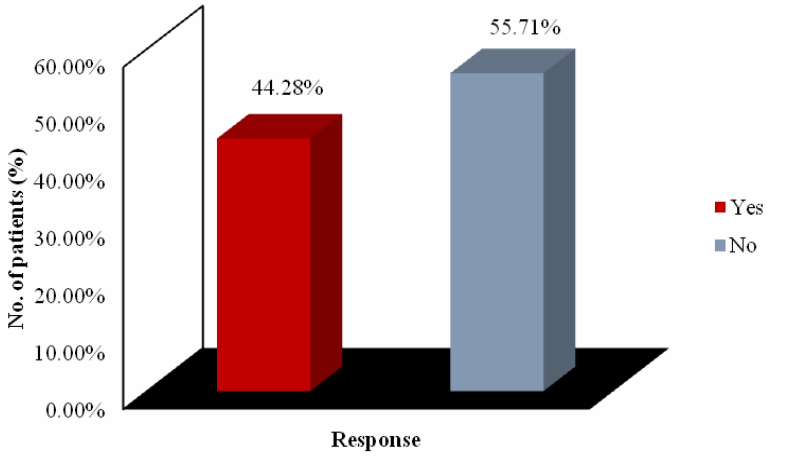

Fig 2: Awareness of patients regarding thought of reporting ADRs

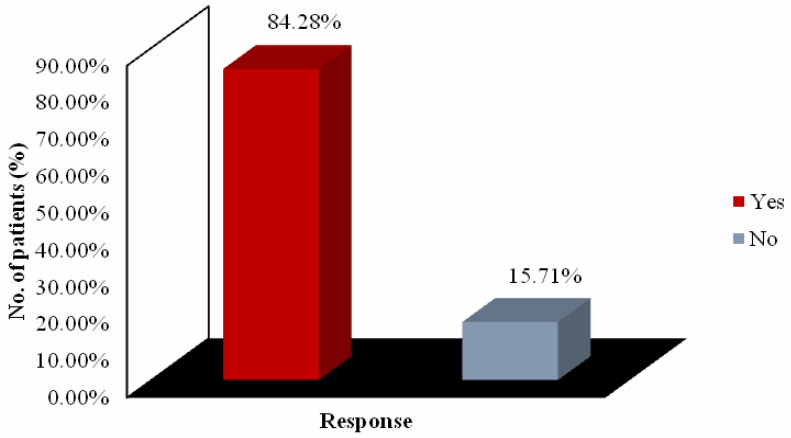

Fig 3: Awareness of patients regarding importance to report ADRs

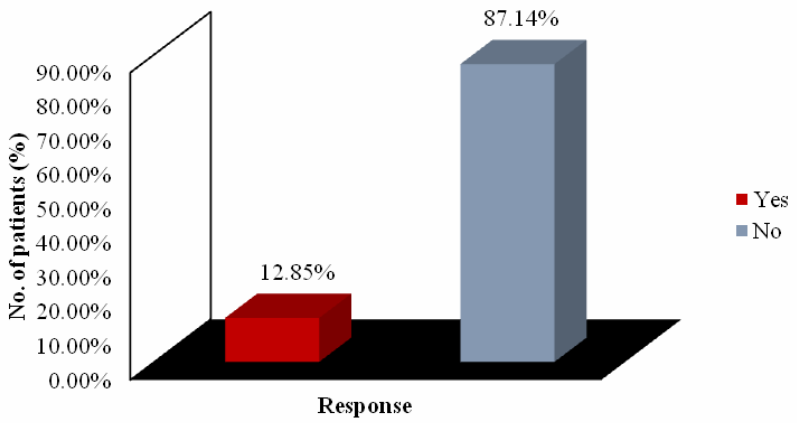

Fig 4: Awareness of patients regarding feeling of unwanted effect during treatment

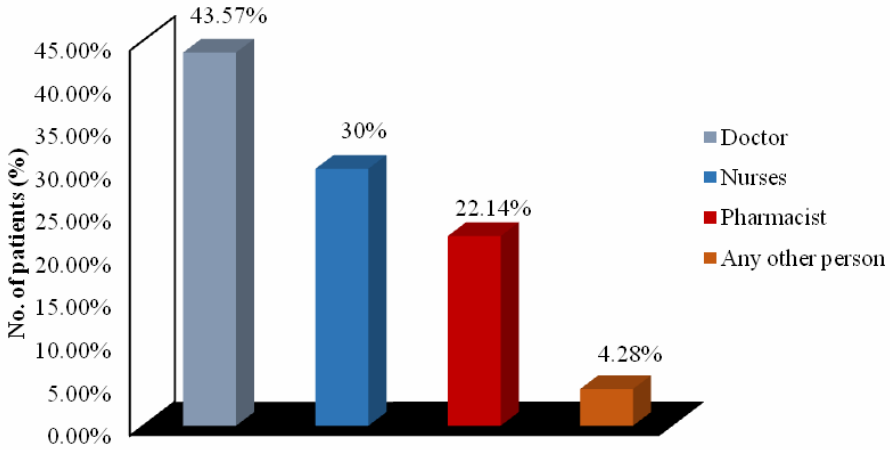

Fig 5: Awareness of patients regarding the person to talk about any side effects during the treatment

Assessment of perception regarding ADRs was analyzed using 5 different questions as shown in Table 3. Majority of the patients (100%) were disagree about adverse drug reaction were normal situation requiring no specific emphasis under which 40% were strongly disagree and 60% were normally disagree. Further, 58.57% were strongly agree and 41.42% were normally agree that ADRs upon exposure requires immediate reporting to concerned authority. 70% patients were agreed that some drug/ patients required special ADR monitoring but 30% patients were disagreed to the fact. All patients were agreed that general public/patient should be practiced with ADR related educational/ awareness information. At last, all patients (100%) were agreed that every ADR requires either therapeutic/ preventive management.

Table 3: Perception of patients towards ADRs

Q.No.	Questions	Strongly agree (%)	Agree (%)	Strongly disagree (%)	Disagree (%)
1	Adverse drug reactions are normal situations requiring no specific emphasis?	00	00	56 (40)	84 (60)
2	ADRs upon exposure requires immediate reporting to concerned authority?	82 (58.57)	58 (41.42)	00	00
3	Some drug/ patient requires special ADR monitoring?	00	98 (70)	00	42 (30)
4	General public/ patient should be practiced with ADR related educational/ awareness information?	94 (67.14)	45 (32.14)	00	00
5	Every ADR requires either therapeutic/ preventive management?	62 (44.28)	78 (55.71)	00	00

CONCLUSION

This study shows that the most of the patients were unaware about the pharmacovigilance and ADR reporting system and don't have knowledge about the term of ADRs. The major cause for under reporting was poor clinical knowledge on ADRs. Therefore, it is necessary to create awareness in order to improve ADR reporting. Health care professionals play an important role to aware them and give knowledge about ADRs reporting. It is very important that general public/ patient should be practiced with ADR related educational/ awareness information.

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