Research Article

Knowledge, attitude and the practice (KAP) of Pharmacovigilance among health care professionals of a tertiary care teaching hospital of South India

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Abstract

Objective: To study the knowledge, attitude and practice among the health care professionals in a tertiary care teaching hospital. **Material and Methods:** A questionnaire based survey was done among the different health care professionals like doctors, interns and nurses. The participants were asked to fill a validated pre designed questionnaire and return it to the department. The questionnaire included the basic knowledge of ADR, attitudes towards the ADR and the voluntary reporting system, practices regarding ADR reporting system, reasons for failures to report, etc. **Results:** A total of 105 health professionals participated in the study. About 51.42% of the doctors, 57.14% of interns and 42.85% of nurses were aware of the national pharmacovigilance programme of India (PvPI). Only 48.5% of participants were aware of the existence of pharmacovigilance center in our institution. A total of 27.6% of them had reported ADR with majority being nurses (42.85%). **Conclusion:** There is a great need to create awareness among the doctors to improve the reporting of ADRs and understand its needs. Timely and adequate awareness campaign should be organized to overcome the underreporting of ADR.

***Keywords*:** ADR, Pharmacovigilance, awareness, knowledge, attitude, practice

Introduction

The World Health Organization defines adverse drug reactions (ADRs) as "any response to a drug which is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or the modification of physiological function" (WHO, 1972). In adverse drug reaction there is causal relationship between the drug and the event (WHO, 2003; WHO, 2004). Pharmacovigilance is the science and the activities which relate to the detection, assessment, understanding and the prevention of adverse effects or any other drug-related problems" (WHO, 2006). It has gained significant importance with increased number of drug molecules entering the market and the increase in the number of drug recalls due to theinvolvement of high health risks. In several high risks profile incidents involving marketed pharmaceuticals have propelled the issues of patient safety and the adverse events to the regulatory attention and increased stay in hospitals.

Drug safety is one of the neglected areas in India. Though pharmacovigilance programme was started in 1982, the awareness about it much lower among the health care professionals (Dhikar et al, 2004). Now only this programme has become sensitive in India and there is a lack of awareness on adverse drug reactions and pharmacovigilance. There is lack of immediate ADR monitoring system as well as lack of voluntary or spontaneous reporting culture among the health care workers (Inman, 1996). In order to improve the reporting rate, it is important to improve the knowledge, attitude and the practices (KAP) of the healthcare professionals with regards to the ADR reporting and the pharmacovigilance. This study is taken step by step at evaluating the baseline KAP of the health care professionals like doctors, interns and nursesat a teaching hospital, regarding the ADR monitoring and pharmacovigilance.

Materials and methods

This cross sectional study was conducted in a tertiary care

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teaching hospital. The health care professionals like doctors, interns and nurses participated in the study. The study was approved by the institutional ethical committee. A predesigned validated questionnaire was prepared which consisted the questions like knowledge of adverse drug reaction, pharmacovigilance, attitude towards reporting of ADR and factors that in practice that could hinder the reporting among health care professionals. The questionnaire included the basic knowledge of ADR, attitudes towards the ADR, attitudes towards the voluntary reporting system, practices regarding ADR reporting system, reasons for failures to report, etc. The health care workers gave consent before participation in the study. They were given the questionnaire to fill and return to the department.

Results

A total of one hundred and five healthcare professionals who completed the questionnaire were included in the study and thirty five in each category. The questionnaires were duly filled and received back. The set of questionnaire were divided into three sections like knowledge, attitude and practice. The answers were divided into the group of doctors, nurses and interns. The data represented in percentage. In the knowledge assessment of the study group, a total of 72.38 % of them knew that pharmacovigilance deals with the safety of the drugs and 53.33% knew the purpose of pharmacovigilance. About 51.42% of the doctors, 57.14% of interns and 42.85% of nurseswere aware of the national pharmacovigilance programme of India (PvPI), but only a total of 40% of them knew the location of national coordinating center of pharmacovigilance programme (Table 1).

Only 48.5% of participants were aware of the existence of pharmacovigilance center in our institution, among which the highest were the interns (60%). About 88.5% knew that Department of Pharmacology deals with the pharmacovigilance program and 81.9% accepts that healthcare professionals are responsible for reporting adverse drug reactions (ADR). The most common practical difficulty which was faced by the doctors in reporting of the ADR's was that a majority of them did not know how and where the ADR's had to be reported. About 64.7% participants felt that ADR reporting is a professional obligation (Table 2).

In practice, about 69.5% of the respondents understood the need for reporting ADR's with majority being doctors. But only a total of 27.6% of them had reported ADR with majority being nurses (42.85%) as shown is table 3. No health care professionals stated that no adequate counseling is being given to patients about identifying and reporting ADR's back to hospital. About 68.5% of the hinder healthcare professionals were they did not know where to report and the priority was patient management.

Discussion

Pharmacovigilance depends on spontaneous reporting by health care professionals which leads to signal detection of ADRs. Under-reporting of ADRs is a major problem of

Table 1. Knowledge of health care professionals about ADR and Pharmacovigilance programme

Questions	Doctors		Interns		Nurses		Total	
	Right answer N (%)	Wrong answer N (%)	Right answer N (%)	Wrong answer N (%)	Right answer N (%)	Wrong answer N (%)	Right answer N (%)	Wrong answer N (%)
Pharmacovigilance deals with	20 (57.14)	15 (42.85)	31 (88.57)	04 (11.42)	25 (71.42)	10 (28.57)	76 (72.38)	29 (27.61)
The most important purpose of Pharmacovigilance is	21 (60)	14 (40)	23 (65.71)	12 (34.28)	12 (34.28)	23 (65.71)	56 (53.33)	49 (46.66)
Are you aware of Pharmacovigilance Program of India (PvPI)?	18 (51.42)	17 (48.57)	20 (57.14)	15 (42.85)	15 (42.85)	20 (57.14)	53 (50.47)	52 (49.52)
Where is the NCC (National Coordinating Center of PvPI) present?	22 (62.85)	13 (37.14)	04 (44.42)	31 (88.57)	16 (45.71)	19 (54.28)	42 (40)	63 (60)
Are you aware of the existence of pharmacovigilance program in your Institute?	16 (45.71)	19 (54.28)	21 (60)	14 (40)	14 (40)	21 (60)	51 (48.57)	54 (33.2)
Which department in your college deals with the program?	35 (100)	0 (0)	32 (91.42)	3 (8.57)	26 (74.28)	9 (25.71)	93 (88.57)	12 (11.42)
The healthcare professionals responsible for reporting ADRs in a hospital is/are	31 (88.57)	04 (44.42)	25 (71.42)	10 (28.57)	30 (85.71)	05 (14.28)	86 (81.90)	19 (18.09)
Where the international center for Adverse Drug Reaction monitoring is located?	19 (54.28)	16 (45.71)	24 (68.57)	11 (31.42)	05 (14.28)	30 (85.71)	48 (43.04)	57 (27.28)

Table 2. Attitude of health care professionals about ADR and Pharmacovigilance

Questions	Doctors		Interns		Nurses		Total	
	Right answer N (%)	Wrong answer N (%)	Right answer N (%)	Wrong answer N (%)	Right answer N (%)	Wrong answer N (%)	Right answer N (%)	Wrong answer N (%)
Pharmacovigilance report should be made mandatory	28(80)	07 (20)	25 (71.42)	10 (28.57)	20 (57.14)	15 (42.85)	73 (69.52)	32 (30.47)
If you come across an ADR in your hospital, what should you do	30 (85.71)	05 (14.28)	30 (85.71)	05 (14.28)	13 (37.14)	22 (62.85)	73 (69.52)	32 (30.47)
Do you think ADR reporting is a professional obligation?	33 (94.28)	02 (5.71)	22 (62.85)	13 (37.14)	13 (37.14)	22 (62.85)	68 (64.76)	37 (35.23)
Have you ever been trained on how to report an ADR?	22 (62.85)	13 (37.14)	15 (42.85)	20 (57.14)	18 (51.42)	17 (48.57)	55 (52.38)	50 (47.61)
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	32 (91.42)	03 (8.57)	32 (91.42)	03 (8.57)	27 (77.14)	08 (22.85)	91 (86.66)	14 (13.33)

Table 3. Practice of health care professionals about ADR and Pharmacovigilance

Questions	Doctors		Interns		Nurses		Total	
	Right answer N (%)	Wrong answer N (%)	Right answer N (%)	Wrong answer N (%)	Right answer N (%)	Wrong answer N (%)	Right answer N (%)	Wrong answer N (%)
Have you ever reported an ADR?	07(20)	28(80)	07(20)	28(80)	15(42.85)	20(57.14)	29(27.61)	76(72.38)
What are the factors, which hinder you from reporting an ADR?	17(48.57)	18(51.42)	11(31.42)	24(68.57)	16(45.71)	19(54.28)	44(41.90)	61(58.09)

spontaneous reporting which would delay signal detection leading to high economic burden on the community. Though pharmacovigilance is still in its infancy in India, this is likely to expand in the time to come which requires more awareness among doctors & nurses. The determinants of under reporting are not well evaluated in India. Therefore this study was conducted to mainly assess the knowledge, attitude and practices regarding reporting of adverse drug reactions and awareness in a tertiary care teaching hospital. Though few studies from India have evaluated the same objective (Gupta et al, 2011). This was in agreement with the results of Hardeep et al. (2013). Therefore, it seems necessary to hold awareness programmes to improve the ADR reporting. The para-medical staffs should also be encouraged and inform the importance of ADRs reporting, since they are well connected with the patients from admission to discharge and they can play an important role in making the pharmacovigilance programs more efficacious. A majority of the doctors (94.2%) felt that the ADR reporting should be compulsory, which again matched with the results which were obtained by Qing et al, 2004 and Belton et al,1995, but not with those which were obtained by Bateman et al. (1992). In the clinical practice, the factors that discourage the doctors from a spontaneous reporting are a lack of knowledge about the reporting procedure (52.3%) and other practical issues such as the patient management (45.7%) and the patient confidentiality issues (31.4%). A majority of the doctors opined that the ADR reporting should be done voluntarily. To improve the spontaneity in the reporting rates, the doctors suggested the organization of training programmes and an uncomplicated reporting system with a quick feedback regarding their specific reports. A similar study demonstrated that an educational intervention could increase the physicians' awareness on ADRs and that the physicians would be able to incorporate the knowledge that they gained from their training into their everyday clinical practice (Tabali et al., 2009). This had to be reinforced by

holding regular seminars and workshops.

Conclusion

Our study strongly suggested that there was a great need to create awareness among the doctors to improve the reporting of ADRs and understand its needs. The training sessions must clarify the roles of the various healthcare professionals in pharmacovigilance. There should be closer relationship between the doctors and the pharmacovigilance centers. So, educational intervention and improvement of facilities in coordinating with the healthcare professionals would definitely bring on a difference in adverse drug reactions.

Author's Contribution

All the authors have the same contribution in this research (carried out the research, collected the data, analyzed the data, and formatted the manuscript).

Conflicts of interest

The authors declare that they have no conflicts of interests in this research.

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