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Research Article

Adverse drug reaction reporting among clinicians in a teaching hospital in South Karnataka

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Abstract: The study was aimed at investigating knowledge, attitude and practice of clinicians towards ADR reporting, to identify the reasons for underreporting and suggestions to improve the ADR reporting system. A questionnaire study involving the clinicians in the teaching hospital of south Karnataka was conducted. A total of 150 questionnaires were distributed to the clinicians with their consent for the participation in the study and completed questionnaire were received back within stipulated time. 120 respondents filled and retuned the questionnaires giving a response rate of 80%. Nearly half of the respondents (48.33%) were aware of the existence of pharmacovigilance (PV) and its programme in India. The ADR reporting form was known to only 12.5% and existence of PV unit in their hospital to 15% of respondents respectively. More than 77% have experienced an episode of ADR but only 15% of them had reported. More than 80% of them commented on inadequacy of ADR reporting in India. Only 2.5% have attended the training programmes in ADR reporting. Commonest factors discouraging ADR reporting were, not knowing where (87.5%), how (82.5%) to report ADR and lack of accessibility of ADR reporting forms (83.3%). The most common suggestions to improve ADR reporting were to make it mandatory, training and bulletins on ADR reporting. This study revealed poor knowledge, practice and underreporting of ADRs among clinicians and the willingness of clinicians to be trained in ADR reporting to contribute the pharmacovigilance efficiently.
Keywords: Adverse drug reaction (ADR), Awareness, PV, Clinicians

INTRODUCTION

The World Health Organization (2000) defines adverse drug reactions (ADRs) as 'a reaction which is noxious and unintended and which occurs at doses normally used in humans for prevention, diagnosis or therapy of disease, or for the modification of physiological functions [1].

Adverse drug reactions (ADRs) are important public health problem and one of the leading causes of morbidity and mortality. ADRs are believed to be the one of the most common leading cause of death among hospitalized patients. ADRs have a major impact on public health by imposing a considerable economic burden on the society and health care systems [1].

The incidence of serious ADRs is 6.7% in India [2]. A study in south India showed that 0.7% of hospital admissions were due to ADRs and a total of 3.7% of the hospitalized patients experienced an ADR, of which 1.3% were fatal [3]. Another study showed that ADRs were responsible for 3.4% of the hospital admissions and 3.7% developed ADRs during their hospital stay [4].

The burden of ADRs may be due to the deficits in the practice of ADR reporting by health care professionals. And these deficits include the factors which influence the under-reporting of ADR like, lack of awareness on reporting, extra work and the lack of time [1].

The deficits can be resolved only if the prescribers are aware of the importance of reporting, the reporting system, and their obligation to report ADRs. With an ADR reporting system in place at the institution, one needs to go a step forward and implement these suggestions for strengthening the existing spontaneous ADR reporting system. Educational interventions, acknowledgment, feedback to reporters about the ADRs reported by them, and professional support offered to the prescribers, by a pharmacologist, in reporting and managing ADRs, would help achieve this [5].

Reporting ADR is of paramount importance for the success of Pharmacovigilance programme (PVP) in the country. Clinicians have immense responsibility in reporting ADR and strengthening PVP. Findings from various studies revealed that ADR reporting is linked to the knowledge, attitude and practice (KAP) of healthcare professionals. It is important for the healthcare professionals to be knowledgeable so as to play key role in ADR reporting programme. There is a need to improve in healthcare professionals KAP so as to improve existing PVP [6].

Our study is aimed at investigating the awareness, attitudes and basic knowledge of clinicians to ADR reporting in a multi-speciality teaching hospital.

Objectives

a. To investigate the knowledge, attitudes and practice of clinicians towards pharmacovigilance and ADR reporting.
b. To identify the reasons for underreporting.
c. To suggest methods for improvement in the current spontaneous ADR reporting system.

METHODS

Study site

This study was conducted at JJM Medical College and hospital in Davangere.

Study design and Study participants

This was a questionnaire based study carried out among the clinicians from all specialties working in the hospital after obtaining approval from institutional ethical committee and informed consent from participants and confidentiality was ensured. Those who were not willing to participate or did not return the questionnaire within the stipulated time of 2 hours were excluded.

Sampling Procedure

A total of 150 questionnaires were distributed to all the clinicians in the hospital. Among them 120 filled questionnaire forms were returned. Thus the response rate was good.

Study questionnaire

A self administered study questionnaire was the data collection to assess the awareness about ADRs reporting among clinicians. The questionnaire was structured to obtain demographic data, the information about their knowledge of ADR reporting, attitudes to reporting, factors that may influence reporting, and their training and measures to improve ADR reporting. The questionnaire after its preparation was reviewed by subject experts in the field of Clinical Pharmacology.

Data analysis

Collected data was analyzed by frequency, percentage, mean and standard deviation. Statistical software used was Graph Pad.

RESULTS

Out of 150 questionnaires distributed among clinicians of teaching hospital, 120 were returned within stipulated time with an overall response rate of 80%.

Demographic characters

Out of 120 clinicians more than 60% were male and more than 32% were female clinicians. Among the respondents, more than 37% were in the age group of 41 to 50 years and 35% were in 30-40 years. 25% of clinicians had the experience of 6-10years and more than 22% had 21-30years of experience. The detailed demographic characters of the respondents are shown in table 1.

Table 1: Demographic characters

Sl. No.	Category	Sub-category	Number (%)	Mean ± SD
1	**Gender**	Male	81 (67.5%)	
		Female	39 (32.5%)	
2	**Age (in years)**	30-40	42 (35**%**)	37.14±2.93
		41-50	45 (37.5**%**)	47.53±2.83
		51 and above	33 (27.5**%**)	58.18±4.06
3	**Work experience (in years)**	1-5	15 (12.5**%**)	4.2±0.77
		6-10	30 (25**%**)	9.2±1.35
		11-15	24 (20**%**)	13.88±1.30
		16-20	12 (10**%**)	18.5±1.68
		21-30	27 (22.5**%**)	24.67±3.22
		31 and above	12 (10**%**)	33.75±1.36

Assessment of knowledge

In our study, 48.33% (58) of clinicians were aware of existence of pharmacovigilance and its programme in India; only 20% (24) were aware of national and zonal centre for ADR reporting. 12% & 15% of respondents were aware of ADR reporting form and existence of pharmacovigilance in working hospital respectively (Table 2).

Table 2: Clinician's knowledge of Pharmacovigilance and ADR Reporting Scheme

Sl. No.	Category	Yes	No	Not responded
1	Awareness Pharmacovigilance and Pharmacovigilance programme in India	58 (48.33%)	62 (51.66%)	-
2	Base of national and south zonal Pharmacovigilance centre	24 (20%)	96 (80%)	-
3	Awareness of ADR reporting form	15 (12.5%)	100 (83.75%)	05 (3.75%)
4	Presence of Pharmacovigilance in your hospital	18 (15%)	72 (60%)	20 (25%)

Assessment of attitude and practice

It is interesting to note that, more than 77% (93) of the respondents had observed at least an episode of ADR and 15% of them had ever reported it. Almost 100% of respondents felt that ADR reporting is a professional obligation and should be made compulsory in the hospital setting. More than 82% of respondents felt that ADR reporting is not adequate in India. More than 32% of respondents say that, nursing and paramedical staff are aware of ADR and its reporting. 92.5% of respondents have not attended the CME/Workshop/Seminars (Table 3).

Table 3: Attitudes and practice of ADR reporting

Sl. No.	Category	Yes	No	Not responded
1	Seen any patients experiencing an ADR	93 (77.5%)	27 (22.5%)	-
2	Where to report ADRs	15 (12.5%)	105 (87.5%)	-
3	How to report ADRs	15 (12.5%)	99 (82.5%)	06 (5%)
4	Necessity of ADR reporting	120 (100%)	-	-
5	Adequacy of ADR reporting in India	6 (5%)	99 (82.5%)	15 (12.5%)
6	Compulsion of ADR reporting	117 (97.5%)	03 (2.5%)	-
7	Do you feel nursing and other paramedical staff aware of ADR and its reporting	39 (32.5%)	75 (62.5%)	06 (5%)
8	Attended CME/Workshops/Seminars	03 (2.5%)	111 (92.5%)	06 (5%)

Discouraging factors for ADR reporting

The commonest factors that discourage the ADR reporting were not knowing where (87.5%), how (82.5%) to report ADRs and lack of accessibility to ADR reporting forms (83.3%) (Table 4).

Table 4: Factors that may discourage doctors from reporting adverse drug reaction

Sl. No.	Category	Frequency	Percentage
1	Did not know about Pharmacovigilance and Pharmacovigilance programme	62	51.6%
2	Did not know where to report	105	87.5%
3	How to report ADRs	99	82.5%
4	Lack of access to ADR reporting forms	100	83.3%

Suggestions to improve ADR reporting:

Some of the measures suggested by the study participants to improve ADR reporting were to make it mandatory, training in reporting, availability of ADR reporting information sheets and to conduct monthly meetings on rare ADRs (Table 5).

Table 5: Suggestions to improving ADRs reporting

Sl. No.	Category	Frequency	Percentage
1	ADR reporting made mandatory	117	97.5%
2	Workshops and seminars	111	92.5%
3	Pharmacovigilance teaching programmes for undergraduates, internees and postgraduates	108	90%
4	Educate nursing and paramedical staff	111	92.5%
5	Monthly meetings of rare ADRs	99	82.5
6	Bring out bulletins on ADRs	108	90%

DISCUSSION

The main intention of Pharmacovigilance program by the WHO is to ensure safe and rational use of medications after their approved for use among the general population (WHO, 2002). Spontaneous reporting of ADRs is the widely practiced method of detection of ADRs and withdrawal of drugs that can result in serious and life threatening among patients [1]. Under-reporting of ADRs is a universal phenomenon that exists as an inherent weakness of current voluntary reporting schemes [7].

This questionnaire based study included the clinicians of a tertiary care teaching hospital. The percentage of completed response (80%) was found to be almost similar to the previous studies [1, 8, 9].

Compared to the results of previous surveys which have acceptable knowledge, attitude and poor practice [7, 10], our findings suggest that there is inadequate knowledge (25%) and practice (8%) but favourable attitude (49%) among the respondents towards ADR reporting.

In our study, 92.5% of respondents have never attended any CME or workshops or seminars on ADR reporting. However, it was shown that an educational intervention can improve clinician's awareness of ADRs, and enable them to incorporate the knowledge into their daily clinical practice [11].

Ninety three (77.5%) had seen patient experiencing an ADR. However only 15 (12.5%) of them had reported to the pharmacovigilance unit in hospital. But in countries where ADR monitoring system is well established, ADR reporting rates among clinicians estimates 40-70% [12-16]. The main reasons for not reporting ADRs in this study were clinicians did not know about the pharmacovigilance unit in the working hospital, how and where to report and lack of access to ADR reporting forms. This suggests that, there is a greater need of awareness and various programmes among clinicians to report ADRs promptly.

The suggestions given by the respondents in our study to improve ADR reporting are compulsory ADR reporting, workshops, seminars, teaching programmes to medical students, nursing and paramedical staff, monthly meetings and bulletins on ADR. And these suggestions correspond to those observed in other studies [5, 8-10].

Limitations of study

- Small sample size
- Conducted only in a single hospital with self administered study questionnaire which might have lead to recall and personal bias
- Nurses and pharmacists who play an important role in pharmacovigilance were not included.

CONCLUSION

The present study shown that, the respondents had inadequate knowledge and poor practice of ADR reporting but showed favourable attitude towards ADR reporting. The deficits in the practice of ADR reporting can be resolved only if the clinicians are aware of the importance of reporting and reporting system and their professional obligation to report ADRs. Therefore, there is a need to increase the awareness regarding the importance ADR reporting through medical education programmes at regular intervals, training the doctors on how to report an ADR and also including the pharmacovigilance awareness programmes to undergraduates and other healthcare professionals. All these steps would further help the clinicians to contribute the pharmacovigilance efficiently.

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