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ADVERSE DRUG REACTIONS REPORTING: ATTITUDES AND PERCEPTIONS OF MEDICAL PRACTITIONERS

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Aim: To assess the attitudes and perceptions of medical practitioners towards adverse drug reaction (ADR) reporting and factors that influence the reporting of ADR.

Method: A suitable self-administered survey questionnaire was designed and randomly circulated to 110 doctors in three different hospitals where local hospital based ADR reporting system exist.

Results: A total of 97 filled questionnaires were returned giving response rate of 88 percent. Ninety percent (n = 87) and 89% (n = 86) of the responders were aware of existence of ADR reporting and monitoring system in India and at their hospital respectively. Forty one percent (n = 40) and 64% (n = 62) of medical practitioners had reported suspected ADR to any of the pharmacovigilance centre located in India and at their hospital respectively. Ninety three percent (n = 90) of the responders opined that the existing ADR centre had created awareness and 98% (n = 95) of responders found the system is useful and benefiting the patients. Factors that encouraged ADR reporting were simple to operate and constant creation of awareness. Factors that discouraged ADR reporting were well-known reactions, mild reactions and immediate management of ADRs. Ninety five percent (n = 92) of responders opined that pharmacist's assistance in detection, reporting, monitoring and management of adverse drug reactions is useful.

Conclusion: Imparting knowledge and awareness of ADR reporting among medical practitioners would bring the reporting culture among medical practitioners and increase the reporting rates of ADR. Pharmacists have a greater role to play in the area of pharmacovigilance.

Keywords : Adverse drug reaction, reporting of adverse drug reaction, pharmacist, questionnaire survey.

INTRODUCTION

The kidneys are endowed with rich innervations of sympathetic nerves extending to the vasculature and tubules. Indeed, the renal sympathetic nerves are increasingly considered as being important in regulating renal hemodynamic and thus blood pressure.[1]

Apart from an important regulatory influence, systemic blood pressure and intravascular volume regulations are also significantly modified by the actions of reninangiotensin system (RAS) in the kidney. Circulating angiotensin II itself then interacts with the SNS at various sites and appears to amplify sympathetic activity. It may act on the brain to increase sympathetic outflow, on the sympathetic ganglia and adrenal medulla to increase catecholamine release, and at presynaptic sympathetic nerve endings to facilitate sympathetic neurotransmission through an enhanced norepinephrine release[2-3] and this will assist the sympathetic influence on the heart and the systemic circulation.[4]

There is a growing concern on the role of renal nerves in the regulation of renal functions and hemodynamics. The renal circulation, tubular reabsorption and release of renin are under multiple controls by the renal nerves, hormones and paracrine active agents.[5]

The interaction between noradrenaline and angiotensin II is particularly relevant as there are several chances for

METHODS

Study setting

This questionnaire study was conducted at three different hospitals where hospital based adverse drug reaction reporting and monitoring system was implemented. The study centres included Jagadguru Sri Shivarathreeshwara Hospital (JSSH), Basappa Memorial Hospital (BMH) and Holdsworth Memorial Hospital (HMH) located at Mysore city, South India. This questionnaire survey was conducted during March 2003 and approval from Institutional Ethical Committee of JSS Medical College, Mysore was obtained prior to administering the questionnaire survey.

Survey recipients

The survey questionnaire was administered to 110 doctors belonged to different specialties practicing across three major hospitals.

Survey questionnaire

A suitable piloted self- administered survey questionnaire was designed and randomly circulated to medical practitioners of all three hospitals where the ADR reporting and monitoring system was implemented. The study questionnaire was designed to assess the attitude and perception of medical practitioners towards adverse drug reaction reporting. Few changes in the order and phrasing

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of the questions were made after discussion with fellow clinical pharmacists and few physicians. The final questionnaire (Appendix I) consisted of twelve questions and were designed specifically to answer the awareness about ADR reporting and monitoring system, its operational procedure, its usefulness, their reporting culture and also to know whether the system needs any further modification and or improvement. After one and a quarter years of implementation of ADR reporting and monitoring system at all study sites the final questionnaire was distributed randomly to 110 medical practitioners across three study sites [JSSH (n=70); BMH (n= 20) and HMH (n=20)]. In order to preclude any potential bias the disclosure of name of the responder was made optional. All participants were briefed about the purpose of the study and asked to submit the filled questionnaire to the identified nursing station of their respective hospital. All participants also were provided with sufficient time of 15 days to fill the two pages questionnaire.

Analysis

The survey questionnaire was analysed questionwise and their percentage value was calculated. In the analysis of all questions total number of responders to questionnaire survey were considered rather total number of responders to each question. In case of unanswered questions, the number of responders unanswered to each question were categorized under 'non responded' category, and percentage value, questionwise, was calculated.

RESULTS

Of the 110 survey questionnaires circulated, 97 filled questionnaires were returned giving overall response rate of 88 percent. The response rate from each study site was 89%, 85% and 90% for JSS hospital, BMH and HMH respectively.

Our survey results revealed that 90% [n = 87/97] of the responders were aware of existence of ADR reporting and monitoring system in India and 41% [n = 40/97] of them had reported suspected ADR to any of the pharmacovigilance centre located in India. Eighty nine percent of responders were aware of existence of ADR reporting and monitoring system at their hospital. Sixty four percent of responders had reported suspected ADR, while implemented ADR reporting and monitoring system had created awareness in 93% of the responders. The implemented ADR reporting and monitoring system has been found to be useful by 98% of responders, and 98% of the responders opined that the implemented ADR reporting and monitoring system had been benefiting the patient. Majority (95%) of responders expressed that the existing system had encouraged them to report further. Seventy three percent [n = 71/97] of responders found that operating procedure of existing ADR reporting and monitoring system is simple. Majority [(77%) n = 75/97] of responders reported to have had received proper feedback to reported reactions. Ninety five percent [n =

TABLE 1: Table Shows attitudes and perception of doctors towards and reporting.

QUESTIONS	PERCENTAGE (n=97)		
	YES	NO	*NR
Are you aware of existence of adverse drug reactions (ADRs) reporting and monitoring system (National Pharmacovigilance Centre) in India?	90	10	Nil
Have you reported any suspected adverse drug reactions to any of the ADR reporting and monitoring centres?	41	56	03
Are you aware of existence of adverse drug reactions (ADRs) reporting and monitoring system at your hospital?	89	11	Nil
Did you report any suspected adverse drug reactions to ADR reporting and monitoring system existing at your hospital?	64	36	Nil
Has this system created an awareness of ADR reporting in you?	93	06	01
Is the ADR reporting and monitoring system exists at your hospital useful for your practice?	98	01	01
Do you think that existing ADR reporting and monitoring system would benefit the patient or improve the patient care?	98	02	Nil
Does the ADR reporting and monitoring system exist at your hospital encourage you to report further?	95	01	04
Are you getting proper feedback to your reported reaction?	77	08	15
Is pharmacists' assistance in detection, reporting and management of adverse drug reaction useful?	95	02	03

*** NR – Not responded**

92/97] of responders opined that pharmacist's assistance in detection, reporting, monitoring and management of adverse drug reactions is useful. The details of attitudes and perceptions of doctors towards ADR reporting are summarised in Table-1.

Our study findings revealed several factors that influenced the doctors from reporting ADRs. Factors that encouraged ADR reporting included awareness creation, system was simple to operate, acknowledging the receipt of report, provision of feedback to the reported ADRs and constant encouragement. Factors that were considered as contributing factors for not reporting suspected ADRs included lack of time, well-known reactions, mild adverse reactions and immediate management of ADRs. Factors that were considered to be encouraging or discouraging the doctors in reporting ADR are presented in Table-2. Some of the suggestions provided by the survey participants are presented in Table-3.

TABLE 2: Table shows factors that encouraged of discouraged doctors from reporting an ADR.

FACTORS INFLUENCED	PERCENTAGE RESPONDERS
Encouraging: (n=92)	
Creation of awareness amongst doctors	93
Provision of feedback on reported ADR	75
System is simple to operate	73
Acknowledging the receipt of the report	29
Discouraging: (n= 35)	
Time consuming	11
Tedious	05
Well-known reactions	03
Mild adverse reactions	03
Immediate management of ADRs	03

DISCUSSION

The overall results of the questionnaire survey was encouraging and revealed that the doctors are aware of not only the local hospital based ADR reporting and monitoring system exists at their respective hospitals but also the national pharmacovigilance centres. Although there are several factors that either encouraged or discouraged them to report an ADR, majority (64%) of doctors have reported the suspected ADRs. Interestingly, 23% of them reported ADRs for the first time. This result suggests that ADR reporting rate may be enhanced through appropriate campaigning and overcoming the existing barriers. Of the remaining 36% who have not reported an ADR, 26% of them reported that they have not come across with any ADR. However, it is possible that there may be unnoticed adverse drug reactions. Unless the clinicians are trained to have a high index of suspicion, it is difficult to consider it as a part of differential diagnosis. Other reasons quoted for not reporting an ADR included no serious reactions observed, well-known reactions and reactions were managed immediately. Similar reasons for not to report an ADR was reported in one of the attitudinal survey study.[18] This highlights the need for the encouraging medical practitioners to report suspected ADRs and therefore there is a greater potential for the pharmacists to increase the reporting rate of ADRs through creating awareness and educating the medical practitioners about the importance of reporting of ADRs.

TABLE 3: Table Shows common Suggestions provided by the respondents.

IMPORTANT SUGGESTIONS	PERCENTAGE RESPONDERS (n = 41)
Continue the same system	27
Need more feedback on reported reactions	12
Educate the nursing staff	10
Discuss the rare ADRs in monthly meeting	10
Provide information on ADRs to newer drugs	07
Bring out monthly/ quarterly bulletin on ADRs	07

Majority (95%) of responders had opined that the existing ADR reporting and monitoring system had encouraged them to report further. This was evident from the opinion expressed by the medical practitioners that approximately half of them had mentioned that they were encouraged through more than single mode including provision of information on ADR, personal meeting, acknowledging the report and provision of thank you note. To substantiate the same we compared a year reports of ADRs reported by the medical practitioners before and after we created awareness [Jan to Dec 2002 Vs. Jan to Dec. 2001]. We observed 63 % increase in the reporting of ADRs [649 ADRs in 2002 Vs. 412 ADRs in 2001] after the launch of appropriate continuous campaigning. Majority of responders found that the ADR reporting system exist at their hospitals is simple. Perhaps these could be the major

reasons for doctors reporting considerable number of adverse drug reactions. Studies have shown that enhancing knowledge and improving awareness can increase the number of ADR reports.[19-21] Almost all the responders appreciated the ADR reporting and monitoring system as they found that the system is simple and very useful. Many doctors suggested that the system should continue as it would enhance patient care. But few responders opined that the existing system is time consuming (11%) and tedious (5%).

It was also evident from our study that medical practitioners are in need of information in managing ADRs especially information on ADRs to newer drugs. We observed that medical practitioners of our study sites were enthusiastic and encouraging as considerable number of responders of questionnaire survey expressed that they were in need of more feedback either in terms of discussing on ADRs during monthly academic meeting and publishing bulletin on ADRs. Few of the responders suggested that pharmacists should educate nursing staff in reporting and managing ADRs. Doctors opined that adopting the ADR reporting system which is simple to operate, monitoring the newer drugs, creating wider publicity among medical staff and pharmacists involvement would enhance ADR reporting rates. Several studies have shown that not only improving knowledge and awareness of ADR reporting can increase the reporting rates but also the convenient ADR reporting system.[19-21] In addition, doctors felt that providing more information to them on reported ADRs may assist them in better management of patient. Providing assistance therefore may likely to encourage doctors to report more often than ever.

In our survey, majority (98%) of responders not only reported that ADR reporting and monitoring system is benefiting the paients but also opined (95%) that pharmacist's involvement in the detection, reporting, monitoring and management of adverse drug reactions is very useful. This suggests that trained and skilled pharmacists could be of value to medical practitioners in detecting, reporting and managing ADRs.

The major limitation of our study is that the study findings could not be applied to the wider medical community as the study was restricted to physicians practicing in hospital setup where already a reporting system was existing. Therefore we recommend that several studies of similar kind especially in community setup scattered throughout the nation need to be conducted to know the attitudes of community doctors and other healthcare professionals towards ADR reporting so as to develop strategies to improve the ADR reporting system in India.

Our study strongly suggests that there is greater need to create awareness and to promote the reporting of ADR among healthcare professionals of the country. Only such approach can greatly influence in bringing reporting culture among healthcare professionals and may improve the reporting rates of ADR in our country. Pharmacists, as doctors opined that their involvement may increase the reporting rate, have a greater role to play in the area of pharmacovigilance.

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