Original Article

Awareness among tertiary care doctors about Pharmacovigilance Programme of India: Do endocrinologists differ from others?

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ABSTRACT

Background and Objectives: Reporting adverse drug reactions (ADRs) associated with drug use is an important factor in patient safety. Majority of ADRs are preventable through improved prescribing and monitoring. Endocrinologists prescribe drugs with actions on almost all organs and for relatively longer durations. ADR are expected following the use of these drugs. Pharmacovigilance is the study of drug-related adverse effects aimed at protecting patients and public from drug-related harms. The concept of pharmacovigilance is relatively new in India, and this survey is an attempt to explore awareness among doctors of an establishing institution of national importance. **Materials and Methods:** The survey was conducted on faculty and resident doctors by administering a written structured questionnaire in a voluntary manner. The questionnaire contained questions meant to evaluate their awareness, understanding, and misconception about ADR reporting. Identity of the responder was kept confidential. **Results:** A total of 106 (faculty = 56; residents = 50) participated in survey. The most common cause cited for not reporting an ADR was "do not know how to report" by 64.15%. Majority of them (64%) had no information about the Pharmacovigilance Programme of India (PvPI), and only few (8.5%) had actually reported or published an ADR. **Interpretation and Conclusions:** ADRs are major public health problem that needs to be addressed at all levels of health care. High index of clinical suspicion are crucial for their timely detection and management. Various educational interventions have shown to improve medical professionals' awareness, understanding about ADRs and in their reporting behavior. PvPI is an important initiative toward ensuring patient safety.

Key words: Adverse drug reaction, pharmacovigilance, Pharmacovigilance Programme of India

Introduction

Adverse drug reactions (ADRs) accounts for nearly 6.7% of all hospitalizations throughout the world.[1] More than 50% of such ADRs occurred in patients were preventable by careful prescribing and monitoring.[2] Studies have shown that managing ADRs involves huge cost and put a significant burden on health care expenditure.[3] An ADR is "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function."[4] Whereas pharmacovigilance is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems."[5] Pharmacovigilance is the study of drug-related adverse effects aimed at improving patient safety by means of

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issuing a warning to or recommending withdrawal of such products from the market.

The Central Drugs Standard Control Organization, New Delhi, under the aegis of Ministry of Health and Family Welfare, Government of India has initiated a nationwide pharmacovigilance programme in July 2010, for monitoring and reporting ADRs in the country. The program was started with only 22 Adverse Drug Monitoring Centers (AMCs) and currently there are around 150 AMCs across the country. Indian Pharmacopoeia Commission, Ghaziabad is the National Coordination Centre for this program. Since its inception more than 80,000 Individual Case Safety Reports have been contributed to Pharmacovigilance Programme of India (PvPI) database.

All India Institute of Medical Sciences (AIIMS), Jodhpur, Rajasthan is one of the six AIIMS being established under "Pradhan Mantri Swasthya Suraksha Yojna." Our institute decided to join this mission to promote patient safety and was designated the status of "AMC" of PvPI in the year 2014.

After being granted the status of AMC, the major challenge in front of us was to ensure its smooth functioning and regular reporting; by motivating clinician to participate and report any drug-related adverse effects. The concept of pharmacovigilance is relatively new in India, and medical fraternity is also not very much informed about it. Before initiating ADR reporting activity in the institution, we thought that it would be prudent to know the extent of understanding and awareness of the faculty and resident doctors about the concept of pharmacovigilance and ADR reporting.

The results of the present study will also be applicable to endocrinologists, diabetologists, and thyroidologists involved in the management of hormonal disorders and chronic diseases requiring long-term treatment with drugs having widespread actions in the body. Hormonal agonists, partial agonists, and antagonists have different actions in different tissues that can be desirable and undesirable which may take a long time to manifest. A close watch for such undesirable outcomes and awareness regarding reporting of outcomes for use by the peer is of utmost importance for endocrinologists.

Materials and Methods

The survey was conducted in May 2014 on faculty and resident doctors from all existing clinical and nonclinical departments. No formal ethical approval was sought from the Institutional Ethics Committee. However, to maintain the confidentiality of one's identity, participants were not asked to write their name on the questionnaire. For identification and analysis purpose, questionnaire was only marked as resident or faculty (clinical/nonclinical). Nonclinical faculty members were from the departments involved in teaching 1st and 2nd Prof. MBBS students. The questionnaire was circulated to each participant individually. Instruction regarding filling the questionnaire was delivered on the spot. Participation was purely voluntary. However, everybody indirectly provided their implied consent by returning the duly filled questionnaire.

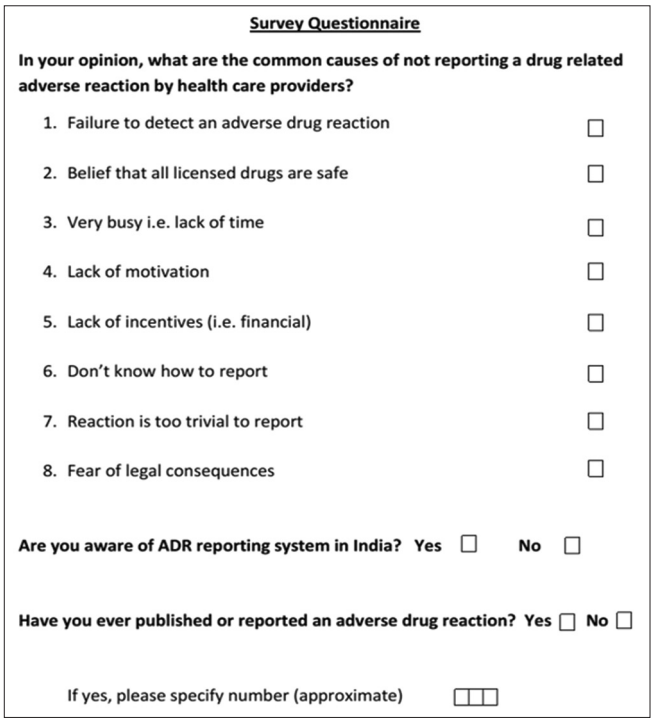
The survey questionnaire included three pertinent questions [Figure 1]:

1. Whether the study population is aware that an ADR reporting system exists in country?
2. Do they have any experience of reporting/publishing an ADR?
3. What are common causes of underreporting of ADRs by health care professionals?

In response to question (iii) the participants were allowed to select more than one response.

Results

A total of 106 (faculty = 56; residents = 50) filled questionnaire were collected. Out of which 58 were from the clinical department and 48 from nonclinical departments.



Survey Questionnaire

In your opinion, what are the common causes of not reporting a drug related adverse reaction by health care providers?

1. Failure to detect an adverse drug reaction ☐
2. Belief that all licensed drugs are safe ☐
3. Very busy i.e. lack of time ☐
4. Lack of motivation ☐
5. Lack of incentives (i.e. financial) ☐
6. Don't know how to report ☐
7. Reaction is too trivial to report ☐
8. Fear of legal consequences ☐

Are you aware of ADR reporting system in India? Yes ☐ **No** ☐

Have you ever published or reported an adverse drug reaction? Yes ☐ **No** ☐

If yes, please specify number (approximate) ☐☐☐

Figure 1: Survey questionnaire

With regard to the reasons for not reporting an ADR, major reason cited was "do not know how to report" by 64.15% followed by "lack of motivation" (48.11%); "reaction is too trivial to report" (45.28%); "failure to detect" (40.57%); "fear of legal consequences"(39.62%) and so on [Table 1].

Among all respondents, 64.15% have no idea about the PvPI. The unawareness about PvPI was more among clinicians (68.97%) than nonclinical doctors [Figure 2]. The percentage of unawareness was more among residents (74%) than among faculty members (55.36%) [Figure 2].

In response to the third question, out of 106 participants, only nine had an experience of reporting or publishing an ADR. The number of ADR reported or published varied from 1 to 10.

Discussion

AIIMS, Jodhpur is an upcoming medical institute of national repute. Results of the survey were surprising to us as almost two-third (64.15%) of the participants were unaware that a nationwide system for ADR reporting under PvPI exists in India. We understand that it could be due to several reasons, i.e., less than adequate publicity about PvPI; participation by institution or hospitals is voluntary; less importance is given to drug safety than efficacy in patient care in India; ADR reporting is not a binding on a physician and lack of sensitization about ADR reporting and its outcomes during medical training. However, they can still be sensitized about the importance of pharmacovigilance by delivering regular small lectures and insisting them to report drug-related problems. To deal with such a situation in future, we have already started teaching undergraduate students about the importance of pharmacovigilance; how to suspect, fill ADR form and report an ADR?

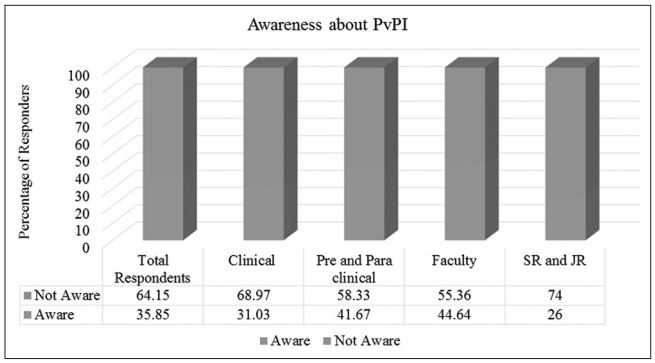


Figure 2: Awareness about Pharmacovigilance Programme of India

One or the other reasons have been cited by participants for nonreporting of ADRs by health care professionals. The most important reason for nonreporting was "do not know how to report." However, this issue can be tackled by delivering them a short and frequent hand on a training session with special emphasis on how to fill a standard ADR reporting form in a structured format available under PvPI. This will probably help in improving frequency as well as the quality of ADR reporting. Not only that, frequent exposure to such training session would dispel misconception, such as fear of litigation surrounding ADR reporting.

What is to be done if one fails to detect an adverse effect? In our study, more than 40% of the participant thinks that "failure to detect" an ADR is also an important reason for nonreporting. The undergraduate and postgraduate training focuses more on clinical uses and effectiveness rather than detection, assessment and reporting of drug-related adverse effects. In our opinion, the knowledge of a drug safety profile is to be considered before taking the decision to prescribe. Reasons for not being able to detect ADR should be explored further.

Further, out of 38 who had awareness regarding ADR reporting, only 9 (23.7%) actually have experience of reporting adverse drug incident. A major question in front of us is that how this percentage can be improved? Motivating doctors to report ADRs is not easy. Many attempts have been made to encourage ADR reporting with

Table 1: Number and percentages of responders to common causes of not reporting an adverse drug reaction

Responses to questions	*n* (%)				
	All respondents (*n*=106)	Clinical (*n*=58)	Nonclinical (*n*=48)	Faculty (*n*=56)	Residents (*n*=50)
In your opinion, what are the common causes of not reporting a drug-related adverse reaction by health care providers					
Failure to detect	43 (40.57)	17 (29.31)	26 (54.17)	25 (44.64)	18 (36)
Belief that all licensed drugs are safe	20 (18.87)	7 (12.07)	13 (27.08)	12 (21.43)	8 (16)
Lack of time	35 (33)	19 (32.76)	16 (33.33)	18 (32.14)	17 (34)
Lack of motivation	51 (48.11)	26 (44.83)	25 (52.08)	33 (58.93)	18 (36)
Lack of incentives	14 (13.21)	6 (10.34)	8 (16.67)	8 (14.29)	6 (12)
Do not know how to report	68 (64.15)	38 (65.51)	30 (62.5)	40 (71.43)	28 (56)
Reaction is too trivial to report	48 (45.28)	24 (41.38)	24 (50)	28 (50)	20 (40)
Fear of legal consequences	42 (39.62)	13 (22.41)	29 (60.42)	24 (42.86)	18 (36)

various success rates. Hyperlinking the electronic patient records to an ADR reporting form, automated ADR reports, giving financial incentive, arranging workshops or implying an educational program of lectures, periodic text message or E-mail reminders are some of them.[6-12] In our institution, we have adopted the policy of sending E-mail reminders, distributing a newsletter and sticking posters in OPDs and patient wards. E-mails were sent initially at least once in a month and now at increased frequency to once every week, which we feel is enough to encourage reporting. Many of the doctors now report anything they suspect, and many after witnessing our sincere efforts feel uncomfortable if they are not reporting. Our institute is in growing phase with shortage of clinical faculty. Lack of time may also be an important constraint in reporting ADRs for those who actually want to report. We expect that with an increase in manpower the reporting number will also go up.

Endocrinologists are specialists dealing with management of chronic disorders requiring long-term therapy. They are among the few specialties who are in a position to identify delayed ADR. The classical example is the case study of use of thiazolidinediones in the management of type 2 diabetes mellitus. With the ball swaying from one end to the other end regarding the issues related to bladder carcinoma and cardiovascular mortality to the incidence of fractures, role of endocrinologists in identification, management and reporting of such ADR becomes vital and indispensable. Hormones and their antagonists are likely to demonstrate adverse effects after prolonged use only. Detection and reporting of such ADR by endocrinologists is required for safe use of these medicines. Although, this study did not cover endocrinologists since there is none at the organization but the results are likely to be applicable to them also.

Major challenge ahead is to develop awareness among healthcare providers of the potential risks of medicines while also understanding the extent of their benefits. Often neglected, is the ongoing and routine monitoring of patients for adverse effects. In some cases, this includes more than just asking patients about adverse effects. In fact, patients should be encouraged to actively report any intolerance or adverse effect to a drug throughout the course of therapy. Endocrinologists can make a major contribution toward making medicines safer for all patients by reporting their suspicions of ADRs. Ultimately, these interventions are intended to make medicines safer to use. Health professionals who care for patients' drug therapy are taught to consider as well the benefit as the risk when making therapeutic choices. To recognize and properly manage ADRs, careful observation and high index of clinical suspicion are of crucial importance. Moreover, it is also possible to detect an unusual adverse reaction associated with an old drug that is widely used and with known side effects profile. All such efforts will lead to better ADR management and increased patients' safety.

Conclusion

Medical professional need to be more informed and vigilant to appreciate the potential benefits and problems associated with the use of drugs they prescribe for their patients. PvPI is an important step toward ensuring patient safety in our country, and its success is entirely based on detection and spontaneous reporting of ADRs by medical professionals. Endocrinologists play an important role in the detection of chronic ADR, which can be detrimental in many patients.

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Conflicts of interest

There are no conflicts of interest.

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