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Original Article

An observational study to assess the possibility of patient participation in implementing pharmacovigilance in a busy tertiary care hospital

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ABSTRACT

Background: Adverse drug reactions are an important cause of morbidity and mortality worldwide. Monitoring adverse drug reaction is the primary function of Pharmacovigilance Programme of India (PvPI). The national program at the inception allowed only physicians, nurses, and pharmacists to report adverse drug reactions but has recently permitted even the consumers or patients to report. The knowledge, attitude, and practice of patients toward such a program have not been studied, and hence, the present study was conducted to assess the same.

Methods: A questionnaire was prepared based on the review of literature and was filled up by the interviewer based on inputs from patients attending various outpatient departments and dispensary of a tertiary care center after obtaining informed consent. Descriptive statistical analysis was carried out, and the results are expressed in terms of means and proportions for continuous and categorical data, respectively.

Results: Majority of the patients were male (58.3%) and were using smart phones (63.9%). Most of the participants (91.6%) felt reporting adverse drug reaction is important, but only 37.7% thought of reporting the same. A very low percentage of participants (10%) were aware about the PvPI and the helpline number.

Conclusion: The Indian health consumer is highly unaware about the existence of the PvPI and various tools available to report adverse drug reactions. It is the need of the hour to create awareness of the same by using the positive attitude toward the program.

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Introduction

Adverse drug reactions (ADRs) are defined by the World Health Organization as “a response to a drug that is noxious and unintended and occurs at doses normally used in men for the prophylaxis, diagnosis, or therapy of disease or for modification of physiological functions.”^{1–3} ADRs are an important cause of morbidity and mortality worldwide.^{4,5} The monitoring of the ADR database is important to improve patient safety.⁴ The system of ADR reporting is based on voluntary reporting by healthcare professionals and may lead to underreporting.⁶ An estimate suggests that only 5–10% of ADRs are reported.⁷

To enhance the ADR database, many countries (e.g., Australia, United Kingdom, Canada, Denmark, Netherlands, Sweden) have included patients to be a part of the ADR reporting system.^{3,8} In line with this trend, the Pharmacovigilance Programme of India (PvPI) has permitted even the consumers or patients to report ADRs.⁸ Inclusion of patients to report ADRs will provide different perspectives for pharmacovigilance (e.g., quality of life, psychiatric feelings of patients, etc.) and also covers ADRs due to use of over-the-counter drugs, self-medication, and herbal remedies not generally covered by healthcare professionals.^{3,4,8}

Many studies have been undertaken to assess the level of knowledge of pharmacovigilance among healthcare professionals. Studies suggest that although the knowledge level of healthcare professionals on ADR monitoring is adequate, the practice of the same is inadequate.^{6,9} The awareness of Indian healthcare consumer regarding ADR monitoring and pharmacovigilance is questionable.⁸ In view of this, the present study has been undertaken to assess the knowledge, attitude, and practice of patients attending a tertiary care medical college hospital in North India in respect of the current ADR reporting system.

Material and methods

The present study was undertaken as a cross-sectional questionnaire-based survey among patients attending a tertiary care hospital and medical college in Delhi. The hospital caters to serving personnel of the Armed Forces, their dependent family members, and veterans, who belonged to various parts of the country with different cultural and demographic backgrounds, were included. Based on a detailed review of literature, a questionnaire was designed which included three parts, including demographic details of patients, knowledge regarding pharmacovigilance, and finally their attitude and practice toward pharmacovigilance in the third part.^{9–15}

After obtaining due clearance from the institutional ethics committee, the questionnaire was pretested on 20 randomly selected patients and was finalized after eliminating and modifying inappropriate questions based on the result of the pretest. Patients visiting or attending various outpatient departments and dispensary of the hospital were approached and explained in detail about the importance of the conduct of the study, and an informed written consent was obtained from those who agreed to participate in the survey.

The study was carried out during the period of Nov 2016 to Feb 2018. The interview was conducted in patients' own language, and the responses were marked by the interviewer. The interviewers were medical undergraduate students who were initially explained and trained about interviewing patients. The minimum required sample size was calculated using the formula Z^2PQ/d^2 , assuming that 30% of the population attending the hospital had knowledge about ADRs and the Pharmacovigilance Programme of India (PvPI). Considering an absolute precision of 4%, the sample size required was derived at 520. Accordingly, a total of 523 patients were interviewed and questionnaires filled up.

Study participants were selected based on the simple random sampling technique using the hospital outpatient department (OPD) patient registers. Every 10th patient registered in the OPD for consultation irrespective of illness was selected and interviewed from different OPDs on selected days by the interviewers. The sampling was continued until the required sample size was achieved. In case when a patient was not willing to participate in the study, the next patient in the sampling frame was approached and included. Operational definition of good attitude toward support to pharmacovigilance is to have a positive response by the participants for at least 4 of the 5 following: (a) importance of reporting ADRs; (b) ever thought of reporting ADRs; (c) do you think consumers should be involved in reporting ADR; (d) willingness to participate in future training programs; (e) if you are provided with an option would you like to participate. Data were entered and analyzed using the statistical software SPSS 23.0. Descriptive statistical analysis was carried out, and the results are expressed in terms of means and proportions for continuous and categorical data, respectively. The Chi-square test was applied to test for statistical difference in proportions, and a *p* value < 0.05 was considered statistically significant.

Results

The results of our study are presented in [Tables 1–4](#).

Table 1 – Distribution of study participants based on baseline demographic characteristics (n = 523).

Characteristic	Frequency	Percentage
Age (mean ± SD) in years	36.8 ± 15.4	
Gender		
Male	305	58.3
Female	218	41.7
Educational status		
Up to high school	144	27.6
Higher secondary	229	43.8
Graduate	110	21.0
Postgraduate	40	7.6
Nativity		
Urban	291	55.6
Rural	232	44.4
Mobile phone being used		
None	36	6.9
GSM/CDMA phone	153	29.3
Smart phone	334	63.9
Total	523	100.0

SD, standard deviation; GSM, Global System for Mobile Communication; CDMA, Code Division Multiple Access.

Table 2 – Distribution of study participants based on knowledge and practices of ADRs (n = 523).

Parameter	Frequency	Percentage
Knowledge about ADRs		
Yes	346	66.2
No	177	33.8
Experienced ADRs		
Yes	216	41.3
No	307	58.7
It is important to report ADRs		
Yes	479	91.6
No	44	8.4
Ever thought of reporting ADRs		
Yes	197	37.7
No	326	62.3
Right person to report ADRs		
Doctor	302	57.7
Nurse	11	2.1
Patient/consumer	85	16.3
Pharmacist	125	23.9
Consumers should be involved in reporting ADRs		
Yes	495	94.6
No	28	5.4
Total	523	100.0
ADRs, adverse drug reactions.		

The mean age of the study participants was 36.8 ± 15.4 years. Majority of the study participants were male (58.3%), educated up to higher secondary schooling (43.8%), and none of the study patient was an illiterate. Most of the study

Table 3 – Distribution of study participants based on knowledge of the PvPI and their perceptions (n = 523).

Parameter	Frequency	Percentage
Heard about pharmacovigilance program		
Yes	50	9.6
No	473	90.4
Aware about PvPI helpline		
Yes	9	1.7
No	514	98.3
Knowledge about mobile app^a		
Yes	4	1.2
No	330	98.8
Knowledge about ADR monitoring centers		
Yes	2	0.4
No	521	99.6
Have you seen medicine safety promotional material?		
Yes	1	0.2
No	522	99.8
Consumers should be involved in reporting ADRs		
Yes	498	95.2
No	25	4.8
Wish to participate in reporting ADRs		
Yes	420	80.3
No	103	19.7
Willingness to participate in PvPI training program		
Yes	342	65.4
Maybe	92	17.6
No	89	17.0
Total	523	100.0

^a n = 334, among those who were using smart phones.

participants belonged to urban regions (55.6%), and majority were using a smart phone (63.9%) (Table 1).

Although most of the participants felt it is important to report ADRs (91.6%), only 37.7% had ever thought of reporting ADRs. Most of the participants felt consumers should be involved in reporting ADRs (37.7%), while 57.7% stated it is appropriate to report to doctors (Table 2).

Less than 10% of the participants stated that they are aware about the PvPI, and less than 2% were aware about the PvPI helpline phone numbers. Most of the study participants felt that consumers should be involved in reporting ADRs (95.2%), and 80.3% of the participants wish to participate in reporting ADRs (Table 3). None of the study participants have ever interacted with any PvPI-related personnel.

A good and positive attitude toward support to pharmacovigilance program was noted among the elderly age group (>60 years) and among those who did not use mobile phones followed by smart phone users. Both these associations were found to be statistically significant. No significant association was observed between educational qualification of the participants and attitude toward pharmacovigilance (Table 4).

Discussion

Pharmacovigilance is the science of detecting, assessing, evaluating, and preventing various ADRs.¹⁶ It plays a key role in the healthcare system and must become an integral part of practice of medicine.¹⁶ Patient participation is vital to the success of any therapeutic intervention.¹⁷ The objective of our study was to assess possibilities and extent of patient participation in implementing pharmacovigilance in a busy tertiary care hospital. It is an initial assessment of the Indian health facility consumer in respect of the PvPI.

Although there are various research works undertaken in India among healthcare workers including nurses/para-medical staff, medical undergraduates, and doctors, the same among the patients were least explored. Patients being a source of firsthand information and considering the increasing level of health literacy in India, the vital role of patients in reporting ADRs and their perceptions regarding the same need to be evaluated. The results of the present study may help medical professional and healthcare workers to encourage and to further enhance the involvement of patients in reporting ADRs. Furthermore, a good positive attitude toward supporting pharmacovigilance services was noted among majority of the study participants (63.1%), which in turn reflects the desire to aid the services from the clientele also.

In our study, most of the participants (91.6%) felt it is important to report ADRs, which correlates with other studies by healthcare professionals.¹⁸ Desai et al.¹⁸ reported that in their study, 97.3% of the prescribers (consultants, resident doctors) felt reporting ADRs is important.

Although majority of the participants considered reporting ADRs important, only 37.7% of them ever thought of reporting an ADR, which is in line with other studies carried out on healthcare professionals. Upadhyaya et al.¹⁹ in their study observed that only 7.92% of residents who participated in a similar questionnaire-based study had reported ADRs. This clearly indicates the gross mismatch between the knowledge

Table 4 – Association between baseline characteristics and positive attitude toward reporting adverse drug reactions (n = 523).

Factor	Attitude toward ADR reporting		Total n (%)	Odds ratio (95% CI)	p value
	Good n (%)	Acceptable n (%)			
Age (in years)					
18–45	240 (63.5)	138 (36.5)	378 (100.0)	1 (ref)	0.007
46–60	55 (53.9)	47 (46.1)	102 (100.0)	2.52 (1.1–5.6)	
>60	35 (81.4)	8 (18.6)	43 (100.0)	3.73 (1.6–8.8)	
Gender					
Male	188 (61.6)	117 (38.4)	305 (100.0)	0.86 (0.6–1.2)	0.414
Female	142 (65.1)	76 (34.9)	218 (100.0)		
Educational Qualification					
Up to high school	91 (63.2)	53 (36.8)	144 (100.0)	1.5 (0.8–3.1)	0.158
Higher Secondary	140 (61.1)	89 (38.9)	229 (100.0)	1.4 (0.7–2.8)	
Graduate	78 (70.9)	32 (29.1)	110 (100.0)	2.2 (1.0–4.6)	
Postgraduate	21 (52.5)	19 (47.5)	40 (100.0)	1 (ref)	
Residence area					
Urban	191 (65.6)	100 (34.4)	291 (100.0)	1.27 (0.89–1.8)	0.178
Rural	139 (59.9)	93 (40.1)	232 (100.0)		
Type of mobile phone used by the participants					
Non user	27 (75.0)	9 (25.0)	36 (100.0)	1.4 (0.7–3.3)	0.03
Basic Phone	80 (52.3)	73 (47.7)	153 (100.0)	0.5 (0.4–0.8)	
Smart Phone	223 (66.8)	111 (33.2)	334 (100.0)	1 (ref)	
Total	330 (63.1)	193 (36.9)	523 (100.0)		

ADRs, adverse drug reactions; OR, odds ratio.

and practice of pharmacovigilance not only among patients but also among all healthcare professionals.

In our study, 57.7% of the participants believe doctors to be the one who shall report ADRs. This clearly indicates that they are still not very confident of reporting ADRs, which should be addressed at the earliest through various strategies to ensure the success of the PvPI.

Although the participants were aware about ADRs, they were grossly unaware about the PvPI—the national program to record ADRs (90.4%). The PvPI has provided various tools to report ADRs, but the awareness regarding the same was negligible as only 1.2% were aware of mobile app, 1.7% about helpline, 0.2% about medicine safety promotional materials, and 0.4% about ADR monitoring centers. This clearly highlights the state of the PvPI as although the participants are willing to participate in the program, they currently were unaware of the tools to do the same.

In line with our study, Alsaleh et al.²⁰ conducted a questionnaire-based study among pharmacists working in a government hospital, Kuwait, which concluded that they had good knowledge and positive attitude toward pharmacovigilance, but the practice was negligible. In a research work by Stalin et al.,²¹ it was expressed by their study participants that 40% of them perceived that mobile phones can be used to promote health, although in the present study, only a meager of 1–2% of the study participants were aware about the PvPI helpline and mobile applications. This reflects that despite people believing the benefits of mobile phone technologies in health promotion, their knowledge and awareness with respect to reporting ADRs with the help of these technologies remains significantly low.

The involvement of patients in reporting ADRs was least explored, and our study created baseline for establishing and further improving the vital role of patients in ADR reporting under the PvPI. The possible limitation of the study could

be that because of the decided study design and feasibility, this study lacked any intervention, which could have brought out any improvement in knowledge, attitude, or practice regarding pharmacovigilance.

Conclusions

The PvPI has granted access for patients to report ADRs; however, the consumers of Indian healthcare system are largely unaware about the existence of such a program. This should not discourage efforts to improve awareness of pharmacovigilance among patients, as even the healthcare professionals, who have adequate knowledge regarding pharmacovigilance, lack the practice of the same as brought out by various national and international studies. This study demonstrates that most patients are willing to participate in training program of the PvPI. The PvPI can be further strengthened by giving due care to the training of Indian healthcare consumers about the practice of pharmacovigilance and widespread dissemination of messages in mass media.

Conflicts of interest

The authors have none to declare.

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