

A Cross Sectional Pilot Study of Knowledge, Attitude and Practice of Pharmacovigilance among Pharmacists at Rajkot District

Piparva Kiran G, Singh Anil P

Pharmacology Department, PDU Government Medical College, Rajkot, Gujarat, India

ABSTRACT

Introduction: Adverse drug reactions (ADRs) enhance suffering of patients and increase morbidity and mortality. Pharmacovigilance (PV) is an integral part of drug therapy as it concerns with the detection, assessment, understanding and prevention of ADRs. The spontaneous reporting system is the most essential pillar of Pharmacovigilance system. Apart from drug dispensing and compliance, pharmacists can have a substantial role in ADR reporting and significant impact on spontaneous reporting of ADRs. **Aims and Objectives:** To assess the knowledge, attitude and practice of pharmacovigilance among pharmacists and exploring their participation in ADR reporting system. **Methodology:** A cross sectional study was conducted among pharmacists of Rajkot district, using a pre-tested questionnaire (15 questions, 5 questions of each on knowledge, attitude and practice aspects of pharmacovigilance). Descriptive statistics were used to analyse the results. **Results:** Response rate was 82%. 79.60% participants had bachelor degree of pharmacy and 70.93% were practicing as pharmacists (community pharmacists- 68.93%). Rest were academicians and working professionals. Pharmacists had insufficient knowledge of PV with poor mean knowledge score (mean score 1.46 out of 5). About two-thirds of the pharmacists expressed a positive attitude toward ADRs reporting and agreed that they are willing to participate in reporting of ADRs. Only single case of ADR was reported

by pharmacists disclosed that pharmacists were unawareness of such existing ADR reporting system in India. **Conclusion:** There is need for educational programs/workshop or training on how to report and where to report ADRs and also to emphasize their role and responsibility regards to PV.

Key words: Adverse drug reaction; knowledge; pharmacovigilance; pharmacists

Correspondence:

Dr. Piparva Kiran G,
12/15 Manhar Plot, Panchjanya, Rajkot,
Gujarat, India.
E-mail: kiranpiparva@yahoo.co.in

Access this article online

Website: www.jbclinpharm.org

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INTRODUCTION

No degree of care and caution at the pre-clinical and clinical testing stages can guarantee absolute safety, when a drug is marketed and prescribed to large populations across the country and outside. Because clinical trials involve several thousands of patients at most, less common side effects and ADRs are often unknown at the time a drug enters the market.^[1] Adverse drug reactions (ADRs) are the common clinical problems and have definite adverse impact on social, economic and health consequences. Safety monitoring of medicines is an integral part of clinical practice. The drug safety issues were globalised, strengthened and systematized after the establishment of Pharmacovigilance (PV) programme by World Health Organization (WHO).^[2] Pharmacovigilance programs have played a crucial role in detection of ADRs and banning of several drugs from the market.^[3] All health care professionals are expected to report ADRs to the national centre as part of the Pharmacovigilance program. Being the key healthcare professionals, the doctors, nurses and pharmacists have immense responsibility in reporting ADRs and strengthening the Pharmacovigilance that exists in their vicinity.^[3] However, underreporting is a huge common problem due to lack of reporting culture amongst healthcare professionals.^[4,5]

In India people have easy access to drugs through local or community pharmacists for many illnesses as it is convenient, less time-consuming and economical for them. There are thousands of community pharmacies which operate as a retailer or as a part of corporate chains.^[6] Pharmacists can play an essential role in both Pharmacovigilance activities and ADRs reporting since they are first to be contacted by patients.^[7-10] So pharmacists as drug experts are expected to have knowledge regarding the safety aspects of drugs, and reporting ADRs to health authorities. Pharmacist's perception of their role with regard to ADR reporting and related activities can greatly influence their contribution and same needs to be evaluated.^[11]

Few studies done in India have shown poor knowledge, attitude, and deficient practices involving ADR reporting among prescribers and healthcare professionals, mainly physicians.^[12-14] However, studies regarding role of pharmacists in reporting ADRs and PV are lacking in India.^[11] Hence, this pilot study was planned to evaluate the knowledge, attitude and practice (KAP) related Pharmacovigilance among pharmacists.

MATERIALS AND METHODS

This was a cross-sectional, questionnaire-based study conducted among pharmacists of Rajkot district. Using the information from literature, the questionnaire was prepared to evaluate knowledge, attitude and practice of Pharmacovigilance and it was validated before conduct of the study. Ethical clearance from institutional ethic committee was obtained. Participants were explained about the research study. Anonymity and confidentiality were ensured. Consent for participation was implied by the completion of questionnaire. Pharmacists were provided 10 min to fill up forms. Data entry was done in Microsoft Office Excel 2007 and appropriate descriptive statistical analysis was done. Knowledge score was calculated from five knowledge related questions, one mark was provided for each correct answer. Association of socio demographic parameters (gender, education, professional status) and knowledge score was analysed by independent T test using Graph Pad trial version 7.

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RESULTS

Demographics: Two hundred and six of the 250 pharmacists completed the questionnaires, giving a response rate of 82.4%. The demographic details of the pharmacists included in the study are shown in Table 1. The mean age of pharmacists was approximately 32 years with majority in young adult age group (20-50 years, 92.22%). Males were accounted for 62.13% (n=128) of total participants. 79.60% participants had bachelor degree of pharmacy and 70.93% were practicing as pharmacists (community pharmacists 68.93% and hospital pharmacists- 2%).

There were 5 questions assessing knowledge of the pharmacists about Pharmacovigilance. The Results on the knowledge questions were depicted in Table 2. Only 12 (5.82 %) responders were aware of the term Pharmacovigilance and less than half of cohort neither aware of ADR reporting programme nor about nearby ADR reporting centre. The mean knowledge scores of respondents was 1.46 (SD-0.87). Response to questions related to the attitudes of the pharmacists towards Pharmacovigilance was mentioned in Table 3. Majority respondents had a good attitude towards ADR reporting and Pharmacovigilance and considered it as a valuable tool. All respondents (n=168, 81.55%) expressed the opinion that ADR reporting will be beneficial for the patients for safe use of drugs in future. 67.96 % (n=140) pharmacists believed that ADR reporting should be mandatory for practicing pharmacist.

Responses to individual practice and activity of Pharmacovigilance were listed in Table 4. It was found that 14.56% (n=30) responders had experience of ADRs in their practice and only single ADR report was submitted to their working place. Few participants (n=36; 17.47%) reported that they were trained for how to report ADR and a sizable number of participants (n=128; 62.13%) disclosed that ADR reporting form were not available at their work place. Sociodemographic parameters like gender, qualification and professional status affecting knowledge score was evaluated and were statistically non-significant in this study [Table 5].

DISCUSSION

Unawareness about existing of Pharmacovigilance program and nearby ADR reporting centre was observed in more than half of respondent in this study. Such unawareness about Pharmacovigilance among pharmacists was reported not only in other states of India^[11,15] but also in different countries.^[16,17] A study done by Suyagh concluded that pharmacist's knowledge exerted a strong influence on ADRs reporting.^[17] A deficiency in knowledge and perceptions about Pharmacovigilance and ADRs reporting is accountable for under reporting ADRs in both developed and developing countries.^[18-21] Lack of knowledge is considered the starting point to deal with the problem of under reporting of ADRs. These findings advocate the need for awareness programs for the pharmacists about filling method of the ADRs form and the details of the reporting procedure.^[16]

Most of pharmacists expressed their positive attitude towards Pharmacovigilance and ADR reporting as more than half of participants agreed that ADR reporting should be mandatory and considered it as a part of their professional role. Such positive attitude towards ADR reporting was expressed by pharmacists in other studies also^[17,22] Majority pharmacists believed that ADR reporting will be beneficial for safe use of medicine and future prevention of occurrence of ADR. Electronic media (online or email) was preferred method for reporting ADR to reporting centre by participants.

A single reported ADR case by pharmacists indicates their very low participation in PV activities. Nil reporting by pharmacists was observed in another study conducted by Mahendra Kumarin^[11] in India and other countries like Malaysia, United Arab emirates and China.^[23-25] In contrast to this, Good knowledge of how to report ADR

Table 1: Demographic and professional details of respondents

Sociodemographic parameter	Respondents, N=206(%)
Age (yr) Mean (SD)	36(11.57)
Gender	
Male	128(62.13)
Female	78(37.86)
Education qualification	
Graduate(B. Pharm, D. Pharm)	164(79.60)
Postgraduate(M. Pharm)	42(20.38)
Professional status	
Practicing Pharmacists	142(68.93)
Working professional	45(21.84)
Academicians	10(4.85)

Working professional (involved in manufacture, marketing, distributors, research of drugs)

Table 2: Assessment of pharmacists' knowledge about pharmacovigilance

Pharmacovigilance knowledge related questions	Response, n= 206(%)		
	Yes	No	Not sure
Do you know ADR reporting programme in India?	90(43.68)	106(51.45)	10(4.85)
Do you know any nearby ADR reporting centre?	35(16.69)	165(80.09)	6(2.91)
Do you know term "Pharmacovigilance"?		155(75.24)	
Drug efficacy		32(15.53)	
Drug cost		12(5.82)	
Drug safety		2(0.9)	
Drug trial			
Centre of Pharmacovigilance programme in India is situated at.....?		10(4.85)	
AIMS –new Delhi		38(18.44)	
CDSCO- new Delhi		79(38.34)	
JIPMER- Pondicherry		31(15.04)	
IPC- Ghaziabad			
Which one of the following is the "WHO online databases" for reporting ADRs?		29(14.07)	
a. Med watch		1(0.48)	
b. Vigibase		92(44.66)	
c. Med safe		59(28.64)	
d. MedRA			

was observed in studies done in UK and Australia.^[26] The main reason for underreporting is the lack of knowledge about there is a legal authority/centres or existing national programme for ADR reporting. Large number of study participants admitted that they did not know about how to report an ADR and from where they could get the ADRs reporting forms.^[17] Most of pharmacists in the study neither had educational session about Pharmacovigilance nor trained about ADR reporting process. So, attention should be paid towards pharmacists to involve in the Pharmacovigilance activities.

Sociodemographic parameter (gender, qualification, professional status) did not affect knowledge score of the respondents in this study. Similar results observed in study done by Mahendrakumar in which such social parameters were not associated with knowledge of the Pharmacovigilance among pharmacists.^[15]

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Table 3: Response of pharmacists to attitude related questions

Pharmacovigilance attitude related questions	Response		
	Yes	No	Not sure
Does reporting will be beneficial in future?	168 (81.55)	6(2.91)	32(15.53)
Should reporting of adverse drug reaction be mandatory for practicing pharmacist?	140 (67.96)	31(15.04)	35(16.99)
Which ADR should be reported?			
Only serious or lifethreatening		21 (10.19)	
Only severe and new		4 (1.94)	
cMild- severe		7 (3.39)	
All type ADRs		156 (75.72)	
Which methods should be preferred by you for reporting adverse drug reaction?			
Online		55 (26.69)	
Telephone		11 (5.33)	
Email		56 (27.18)	
Post		75 (36.40)	
As per your opinion, who should report the ADRs?			
Medical & Paramedical personal		55 (26.69)	
Patients/ Consumers		11 (6.33)	
Pharmacists		56 (27.18)	
Anybody		75 (36.40)	

Table 4: Response of pharmacists about practice of adr reporting

Pharmacovigilance practice related questions	Answers		
	Yes	No	Not sure
Do you have any experience of ADR due to any drugs during your clinical practice?	30 (14.56)	166 (80.58)	10 (4.85)
Have you ever been come across educational session specific about Pharmacovigilance?	57 (27.66)	106 (51.45)	33 (19.41)
Have you ever been trained on how to report ADRs?	36 (17.47)	137 (66.50)	33 (16.01)
Did your work place provide any ADR reporting information or ADR form?	40 (19.41)	128 (62.13)	38 (18.44)
Have you reported any ADR to anywhere?	1 (00.48)	-----	-----

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Table 5: Association of sociodemographic parameters and knowledge score among pharmacists

Socio demographic parameters (variable)	Knowledge assessment score mean(SD)	P Value
Gender	1.4 (0.86)	
Male		
Female	1.5 (0.89)	0.630
Education qualification	1.4 (0.86)	
Bachelors (B. Phar & D. Pharm)		
Postgraduate (M. Pharm)	1.5 (0.89)	0.794
Professional status	1.4 (0.80)	
Practicing Pharmacists		
Others(Working professional, Academician)	1.5 (1.02)	0.604

Independent t test

CONCLUSION

Pharmacists have poor knowledge about the concept and process of Pharmacovigilance and spontaneous ADRs reporting system suggesting urgent need for educational programs/workshop to raise awareness toward ADRs, emphasize the role and responsibility of pharmacy students in Pharmacovigilance practice including training on how to report and where to report ADRs. Pharmacy Council should include PV in continuous pharmaceutical education in curricula to guarantee the incorporation of PV and ADRs reporting system conception.

Study limitation

The main limitation of our study was the relatively small number of participants. The opinion of the non-responders in general and participants who did not respond to certain questions could have also affected the interpretation.

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