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Original Research Article

Knowledge attitude and practice of pharmacovigilance among community pharmacy in India: a questionnaire study

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ABSTRACT

Background: Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. The Pharmacovigilance Program of India (PvPI), which has been functioning since July 2010, was renamed by the Ministry of Health and Family Welfare of the Indian government. This study main objective to assess the current knowledge, attitude and practice of pharmacovigilance in community pharmacist.
Methods: Self-prepared and validated questionnaires were distributed among community pharmacists in India through online forms for 8 months, a cross-sectional questionnaire-based survey was used, with convenience sampling utilized. Responses from 2205 subjects were analyzed.
Results: The primary objective of this study was to assess the demographic details of the community pharmacists as well as the distribution of knowledge, Attitude, Practice on Pharmacovigilance, out of 2205 Community Pharmacist 1109 (50.3%) were male and 1016 (49.7%) were female. More than half of the respondents (54%) was familiar about the definition of pharmacovigilance. Out of 2205 respondents, 240 respondents thought that reporting adverse drug reaction is unnecessary. Among 2205 respondents, 445 respondents have not experienced ADR in their patients during their professional practice.
Conclusions This study determined the Assessment of Knowledge, Attitude and practice of Pharmacovigilance among Community Pharmacist in India. According to this study, community pharmacists are good in attitude but they were not knowledgeable and not effective in practice.

Keywords: Adverse effect, Pharmacovigilance, PvPI.

INTRODUCTION

Every day, a large number of drugs are introduced onto the market around the world nonetheless, the safety of medicines remains a key issue for many people due to lack of understanding.[1] Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products.[2] Pharmacovigilance heavily focuses on adverse drug reactions (ADR), which are defined as any response to a drug which is noxious and unintended, including lack of efficacy (the condition that this definition only applies with the doses normally used for the prophylaxis, diagnosis or therapy of disease.[3] Since 1986, India has seen an increase in activities related to detecting, monitoring, and reporting adverse occurrences (AE). The Pharmacovigilance Program of India (PvPI),

which has been functioning since July 2010, was renamed by the Ministry of Health and Family Welfare of the Indian government.[4] The major way of reporting for ADRs under PvPI is spontaneous reporting. It is early detection of signals, rare and serious ADRs early. ADRs are reported on an as-needed basis. It's also one of the most affordable ways to keep track on the environment throughout the world medicine's safety by way of a system of spontaneous reporting. Prescribers have helped with the detection, monitoring, and treatment of patients and patient reporting of adverse events.[5-7] The pharmacovigilance (PhV) programme is critical in assuring patient safety, yet under-reporting is one of the major obstacles to PvPI success.

Many nations have permitted hospital pharmacists, community pharmacists, nurses, and even patients to report ADRs to increase reporting. Because community pharmacists deal with over-the-counter medicines, they have the chance to detect possible ADRs and so can assist in the treatment and reporting of ADRs.[8] Therefore, community pharmacists can significantly contribute in PvPI by reporting ADRs. This study main objective to assess the current knowledge, attitude, and practice of pharmacovigilance in community pharmacist.

METHODS

A cross-sectional observational study was conducted among community pharmacists in all over India. The study involves Community Pharmacist to assess knowledge, attitude, practice of Pharmacovigilance in pharmacy which is located in the community.

Study period

The study period was conducted from May 2021-February 2022.

Study area

The study site is all over India. The study proposal was approved by Institutional Ethics Committee of Sri Ramachandra Institute of Higher Education and Research, (DU), Porur, Chennai, Tamil Nadu, India and prior to participation each community pharmacists provided an informed consent permission. Community Pharmacists participated in the study using self- administered and validated KAP questionnaire and the data was collected and evaluated.

Sample size

The sample size was calculated using n master 2.0 with a precision 7%, Confidence Interval 95%. The estimated sample size was found to be 2003 with 10% dropout rate of 202. Total required sample size was 2003+202=2205. The inclusion criteria are Community pharmacists and the exclusion criteria are Health care professionals–Physicians, Nurses, Clinical Pharmacist and Students and Community pharmacist unwilling to give informed consent. Data will be collected from them with their consent by request them to complete the questionnaire (self–administered). The collected data were analysed with IBM.SPSS statistics for Windows version 23.0. Armonk, IBM NY: Corp. To describe about the data descriptive statistics frequency analysis, percentage analysis was used for categorical variables and the mean and S.D were used for continuous variables. To find the significance in categorical data Chi-Square test was used. In the above statistical tool, the probability value .05 is considered as significant level.

Statistical analysis

The collected data were analysed with IBM.SPSS statistics for Windows version 23.0. Armonk, IBM NY: Corp. To describe about the data descriptive statistics frequency analysis, percentage analysis was used for categorical variables and the mean and S.D were used for continuous variables. To find the significance in categorical data Chi-Square test was used. In the above statistical tool, the probability value .05 is considered as significant level.

RESULTS

Demographic details

A total 2205 Community Pharmacists from various Community Pharmacy in all over India were enrolled into the study. Out of 2205 Community Pharmacist 1109 (50.3%) were male and 1016 (49.7%) were female. Experience status of the Community Pharmacists is approximately 965 (43.8%) of the study population was 0-2 year experienced and 79 (3.6%) percent of the study population had more than 10 years of experience.

Regarding educational status majority of the respondents where D. Pharm 960 (43.5%), B. Pharm 807 (36.6%), M. Pharm 363 (16.5%) and others 75 (3.4%). The type of community pharmacy, most of the respondents are working Individual Pharmacy are 1186 (53.8%) and Chain Pharmacy 1019 (46.2%). The study population distribution throughout India, approximately 912 (41.4 %) of study population were from South zone and 794 (36%) from North zone and 382 (17.3%) from East zone and 11(5.3 %) from West zone. The demographic details of community pharmacists are categorized in Table 1.

Knowledge-wise response

More than half of the respondents (54%) was familiar about the definition of pharmacovigilance. Out of 2205 response 1113 respondents were aware about the purpose of pharmacovigilance. The 1203 respondents were correctly answered that PMS studies was commonly employed to monitor the ADR once it is marketed by the pharmaceutical company. Most of the community pharmacist were know about the regulatory body of India which is responsible for monitoring ADR.

Hence, it is statistically significant (p=0.002). The international centre for ADR monitoring is located in SWEDEN 1139 respondents were answered correctly. 1169 respondents answered appropriately for pharmacovigilance include "Drug Related Problems". 1798 respondents were agreed that they were aware of any drug that has been recently banned due to ADR. 89.9% of the respondents were aware of suspected ADR reporting system in India.

Attitude-wise response

Out of 2205 respondents, 240 respondents thought that reporting adverse drug reaction is unnecessary. 1612 respondents were agreed that pharmacovigilance should be taught in detail to community pharmacists. 210 respondents have not read any article or seen any news on prevention of ADR. 1611 community pharmacists gave their opinion about establishing of ADR monitoring centre in every Hospital.

Practice-wise response

Among 2205 respondents, 445 respondents have not experienced ADR in their patients during their professional practice. 996 respondents have been trained on how to report ADR. Most of them were seen the ADR reporting form (50.5%). 937 respondents were reported ADR to the pharmacovigilance centre. 818 respondents have not kept any records of ADR. "Are you willing for ADR reporting?" 1109 respondents were willing to report the ADR.

Table 1: Demographic details of the pharmacists.

Demographic profile	No. of respondents (N)	Percentage of respondents
Gender		
Male	1109	50.3
Female	1096	49.7
Experience (in years)		
0-2 years	965	43.8
3-5 years	781	35.4
5-10 years	380	17.2
>10 years	79	3.6
Qualification		
D. Pharm	960	43.5
B. Pharm	807	36.6
M. Pharm	363	16.5
Others	75	3.4
Pharmacy type		
Individual pharmacy	1186	53.8
Chain pharmacy	1019	46.2

Table 2: Knowledge wise response.

Question	Response		Percentage		P value
	Correct	Incorrect	Correct	Incorrect	
K1: Define pharmacovigilance?	1190	1015	54.0	46.0	0.271
K2: The important purpose of pharmacovigilance is?	1113	1092	50.5	49.5	0.404
K3: Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market?	1203	1002	54.6	45.4	0.017
K4: In India which regulatory body is responsible for monitoring of ADRs?	1171	1034	53.1	46.9	0.002
K5: The international centre for adverse drug reaction monitoring is located in	1139	1066	51.7	48.3	0.919
K6: Pharmacovigilance include	1161	1044	52.7	47.3	0.446
K7: Are you aware of any drug that has been recently banned due to ADR?	1798	407	81.5	18.5	0.020
K8: Are you aware of suspected ADR reporting system in India?	1983	222	89.9	10.1	0.340

Table 3: Attitude wise response.

Question	Response		Percentage		P value
	Correct	Incorrect	Correct	Incorrect	
A1: Do you think reporting of adverse drug reaction is necessary?	1965	240	89.1	10.9	0.626
A2: Do you think pharmacovigilance should be taught in detail to community pharmacist?	1612	593	73.1	26.9	0.0005
A3: Have you anytime read any article or seen any news on prevention of adverse drug reactions?	1995	210	90.5	9.5	0.008
A4: What is your opinion about establishing ADR monitoring centre in every hospital?	1611	594	73.1	26.9	0.225

Table 4: Practice wise response.

Question	Response		Percentage		P value
	Correct	Incorrect	Correct	Incorrect	
P1: Have you ever experienced adverse drug reactions in your patient during during your professional practice?	1760	445	79.8	20.2	0.448
P2: Have you ever been trained on how to report Adverse drug reaction?	996	1209	45.2	54.8	0.076
P3: Have you ever seen the ADR reporting form?	1115	1090	50.5	49.5	0.161
P4: Have you ever reported adverse drug reaction (ADR) to the pharmacovigilance centre?	937	1268	42.4	57.6	0.045
P5: Do you keep records of ADR?	1387	818	62.9	37.1	0.025
P6: Are you willing for ADR reporting?	1109	1096	50.2	49.8	0.001

DISCUSSION

The current study has focused on the Knowledge, Attitude, and Practice of community pharmacists working in community pharmacy about Pharmacovigilance.[9] 2205 community pharmacists answered KAP questionnaires that were distributed. All of them agreed to participate in our study, and they all answered our questionnaire. The percentage of pharmacists who took part in the study showed were significantly more male (63.9%) participants than female (36.1%). In our study, male (50.3%) exceed female (49.7%)in the community pharmacists, which is similar to a study by Udoye JA et al.[10] When respondents answered define pharmacovigilance, 54% of the study participants responded correctly, which is in line with the findings of Srinivasan et al.[11] The majority of community pharmacists (1113) gave correct responses to the purpose of pharmacovigilance which is similar to the study of Korde RA et al.[12] In this study, about 1203 of community pharmacists gave correct responses to the methods employed by pharmaceutical companies to monitor ADR; this is concordant with KAP of pharmacovigilance study carried out by Srinivasan et al and Gupta et al conducted a questionnaire study on a KAP of pharmacovigilance which is similar to our study with majority of community pharmacists responded correctly for regulatory body in India.[13] According to Hussain et al, community pharmacists (1139) gave correct responses to international centre for ADR which is similar to our study.[9] When

respondents answered pharmacovigilance includes drug related problems, 1169 of the study participants responded correctly, which is in line with the findings of Srinivasan et al.[11] Srinivasan et al, conducted a questionnaire study on a KAP of pharmacovigilance which is similar to our study with majority of community pharmacists (1798) were aware of recently banned drugs. In this study, about 89.9% of Medical Interns were aware of suspected ADR reporting system; this is concordant with KAP of adverse drug reaction monitoring study carried out by Gupta et al.[13] The majority of community pharmacists (1965) agreed that it is important to report adverse drug reactions (ADR) which is similar to the study of Korde RA et al and Upadhyaya et al.[12,14]

According to Srinivasan et al community pharmacists (1612) believed that thorough instruction in pharmacovigilance should be given to community pharmacists which is similar to our study.[11] Gupta et al, conducted a questionnaire study on a KAP of pharmacovigilance which is similar to our study with majority of community pharmacists (1995) embraced reading any articles or watching any news about preventing ADR.[13] In this study, about 1611 of community pharmacists gave some opinion about placing ADR monitoring centers in every hospital; this is concordant with KAP of adverse drug reaction monitoring study carried out by Korde et al.[12]

Similar to Korde RA et al the majority of community pharmacists (445) disagreed with the question, "Have you ever experienced ADR during your professional practice." In this study, about (996) of community pharmacists gave agreed to the question, “Have you been trained on how to report ADR” which is similar to KAP of pharmacovigilance study carried out by Srinivasan et al.[11] ADR reporting forms comparable to those used by Wadagbalkar P et al were reported by almost (50.5%) of community pharmacists in this study.[15] Similar to Wadagbalkar P et al about (1268) of community pharmacists in this study stated that they have never reported an adverse drug reaction to the pharmacovigilance centre.[15] About (1387) of the community pharmacists in this study agreed to keep an ADR record, which is similar to the KAP of Pharmacovigilance Hussain et al.[9] Comparable to Srinivasan et al 1109 of community pharmacists in this survey indicated that they would be willing to reporting ADRs.

CONCLUSION

This study determined the assessment of knowledge, Attitude and practice of Pharmacovigilance among Community Pharmacist in India. According to this study, community pharmacists are good in attitude but they were not knowledgeable and not effective in practice. In view of the previously stated, actions are required to instruct, empower, and train Community Pharmacists in the field of pharmacovigilance. Community Pharmacists should be well trained in reporting ADR by providing continuous educations like awareness programs etc. These are the suggestions for improving patient quality of life.

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