Original Research Article

Questionnaire-based assessment of awareness among healthcare workers about Pharmacovigilance Programme of India (PvPI) in a tertiary care centre of Bihar: An observational, comparative and prospective study

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Abstract

Background: Adverse Drug Reactions (ADRs) is a worldwide health issue requiring attention of healthcare workers. Healthcare workers are backbone of pharmacovigilance programme and hence have a major role for better healthcare system.**Aim:** To assess the awareness of knowledge and practice of pharmacovigilance among healthcare workers in our healthcare centre.**Materials and Methods:** A questionnaire-based observational, comparative and prospective study comprising 15 questions pertaining to adverse drug reaction reporting and Pharmacovigilance Programme of India (PvPI) was conducted in two visits. 60 healthcare workers (34 assistant and 26 associate professor) from different clinical departments were included. Questionnaire was based on two alternative answers viz "Yes" or "No" and divided into four classes for evaluation of awareness using a grading scale. Sensitization of participants was done at visit 1 only. Results were compared (Visits 1 and visit 2) with same questionnaires and grading scale. **Statistical analysis**: Wilcoxon matched-pairs test using GraphPad Instat software. **Results:** After second visit there was significant increase in response in which education encompassing pharmacovigilance was recommended by 90% of healthcare workers. Percentage of healthcare workers responding "yes" regarding established independent body for reporting of ADRs was 80%. Further, evaluation of awareness in different aspect of pharmacovigilance showed that fundamental knowledge of pharmacovigilance among healthcare workers was excellent in 45%, good in 35%, average in 5% and poor in 15% of healthcare workers.**Conclusions:** Healthcare workers' knowledge towards ADR reporting is better however its practice needs to be encouraged with sincere approach. The reporting rate of ADR could be improved with proper and extensive sensitization about Pharmacovigilance to them at regular intervals.

Keywords: Faculty members, Grading Scale, Pharmacovigilance Programme of India (PvPI), Questionnaires, Sensitization.

Introduction

In any healthcare organization patient safety is the prime responsibility of all healthcare providers. Patients seeking any healthcare facility are mainly treated with the drug. The development of drugs has brought significant benefits for the patients, however at the same time the probability for Adverse Drug Reaction (ADR) has also increased remarkably. ADR is defined by World Health Organization (WHO) as ''a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function" [1,2] ADRs are untoward outcome of any drug use. Co-morbidities, polypharmacy, and regular acute illness experienced by the patients increases the risk of ADRs for them and makes detection more difficult[3]. It is an established fact that ADR is one of the major causes of hospitalization, and every drug has possible adverse effects and interaction which further affects quality of life, increases physician visits, and even death[4].The recent epidemiological studies have estimated that ADRs are fourth to sixth leading causes of death. It adds to undue health-care costs by increasing morbidity and duration of hospitalization in patients and at times it also leads to mortality[5]

In order to promote drug safety, World Health Organization (WHO) started Program for International Drug Monitoring in 1968 and consequently promoted pharmaco vigilance program in association with Uppsala monitoring Centre (UMC) for International Drug Monitoring in 1978 [6]

In India, in the year 2010, the Central Drug Standard Control Organization (CDSCO) launched nationwide Pharmacovigilance Program of India (PvPI) and made Indian Pharmacopoeia

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Commission (IPC) as National Coordinating Centre (NCC)[7]. Pharmacovigilance, a vital science in field of drugs is there to detect and spontaneously report ADR to ensure patient's safety. Pharmacovigilance ensures patient care and safety in context of drug use and also contributes in the assessment of benefit, harm, effectiveness and risk of drugs. Spontaneous reporting of ADRs has played a major role in the detection of unsuspected, serious, and unusual ADRs previously undetected during the clinical trials and healthcare workers are backbone of these spontaneous reports and hence have a major role in it.

However, current ADR reporting status does not appear to be a part of routine practice of healthcare workers and is a major obstacle in the complete success of Pharmacovigilance Program of India[8-11]. It has been seen, that only 6-10% of all ADRs are reported[12,13]. This high rate of underreporting is a matter of great concern which delays the detection of serious ADRs and consequently have negative impact on health of the patients. Hence, there is an imperative need to generate understanding among healthcare workers regarding pharmacovigilance[14]. In addition, previous studies have shown that optimizing knowledge and practices (KP) with regard to pharmacovigilance is important in framing strategies to encourage ADR reporting.

In view to the need of situation, we conducted the study to assess the awareness of pharmacovigilance among healthcare workers (Faculty Members) in a tertiary healthcare centre of Bihar.

Materials and Methods

Study site: ADR Monitoring Centre, Department of Pharmacology, IGIMS, Patna.

Study duration: 6 months from September 2020 to February 2021

Study design

This study was a questionnaire-based observational, comparative and prospective study. This study was approved by the Institutional Ethics Committee of IGIMS, Patna (Vide letter No-42/Acad./Dated-22-01-2018). All participants were informed that their participation in this would be voluntary.

Inclusion criteria: Assistant and associate professors willing to participate in this study.

Exclusion criteria

Additional professors and Professors were excluded as most of them would have certain knowledge or awareness about PvPI and ADR reporting because they are more experienced.

Convenient and purposive sampling was done in which 80 assistant and associate professors of different clinical department of IGIMS, Patna were approached. Out of which 60 (34 assistant and 26 associate professors) had consented to participate in this study. This study was performed in two visits (1 and 2).

A questionnaire was prepared consisting of 15 questions according to Sewal RK et. al[15] related to pharmacovigilance programme of India and ADR reporting.

Questionnaires

Questions were segregated into four classes for evaluation of awareness in different spheres of concept about pharmacovigilance programme of India and ADR reporting. Every question had two alternative answers viz "Yes" or "No". Every "Yes" response was given score one and every "No" was given score zero and cumulative score was calculated for the whole class of questions. A grading scale was used to determine the awareness of participants about pharmacovigilance (Table 1).

Table 1: Grading scale to determine the awareness of healthcare workers about pharmacovigilance programme of India and ADR reporting

Class	Aspects of PvPI and ADR reporting	Serial Number of questions	No of questions	Grading Scale			
				Excellent	Good	Average	Poor
A	Fundamental Knowledge	1, 3, 4, 6, 7 & 8	6	6	5, 4	3	≤2
B	Reporting system	2 & 5	2	2	-	1	0
C	Possible benefits	9, 10 & 11	3	3	2	1	0
D	Capability to give constructive opinion/ recommendations over the improvement of system	12, 13, 14 & 15	4	4	3	2	≤1

The participants were asked to answer the questionnaire according to their individual knowledge on visit 1 and visit 2. During visit 1 after filling up the questionnaire, sensitization about PvPI and ADR reporting was done and same questionnaire was given after 3 months in visit 2. In both visits they were not allowed to consult their group members for their opinion on any question. The participants were restricted to one sitting without any time constraint, to fill the questionnaire. All the filled questionnaires by participants were collected, compiled, analyzed and compared in both visits.

Statistical analysis and data collection technique

Data obtained from both the visits were tabulated in Microsoft excel and were statistically analyzed by using GraphPad Instat Software. Analysis was done using Wilcoxon matched paired test taking one tail P value using nonparametric samples. Data were interpreted as Mean, Standard Deviation (SD), Standard Error of Mean (SEM) and p value (≤0.05 was considered significant).

Result

The results had been compiled after completion of visit 01 and visit 02 for each healthcare worker.

Visit 01

Training and education encompassing pharmacovigilance (question no. 13) was recommended by 85% of respondents. Percentage of respondents responding "yes" regarding established of independent body (question no. 14) for reporting of ADRs was 70%. 80% of respondents were recommending the proper recommendation to be instituted in the area of organization, legislation, regulation and resources to improve surveillance and safe use of drugs (question no. 15) as shown in fig. 1.

The result is further segregated into four classes for evaluation of awareness in different spheres of concept about pharma-covigilance as shown in table 2.

1. It has been observed that knowledge of fundamentals of pharmacovigilance among respondents was excellent in 40%, good in 25%, average in 15% and poor in 20%. 20% of respondents had poor knowledge of pharmacovigilance of which 5% were found to have no basic knowledge and scored zero in class A.
2. The knowledge about the reporting system of pharmacovigilance was excellent in 40%, average in 50% and poor in 10 % of respondents in class B.
3. Among the respondents 25% were excellent, 25% were good, 45% were average and 5% were poor regarding knowledge of possible benefits of pharmacovigilance in class C.
4. The response was excellent for 50%, good for 20%, average for 15% and poor for 15% of the respondents. Out of 15% of respondents having poor knowledge 5% were found to be incapable of giving any productive recommendation or opinion over the betterment system of pharmacovigilance and fetched a score of zero in class D.

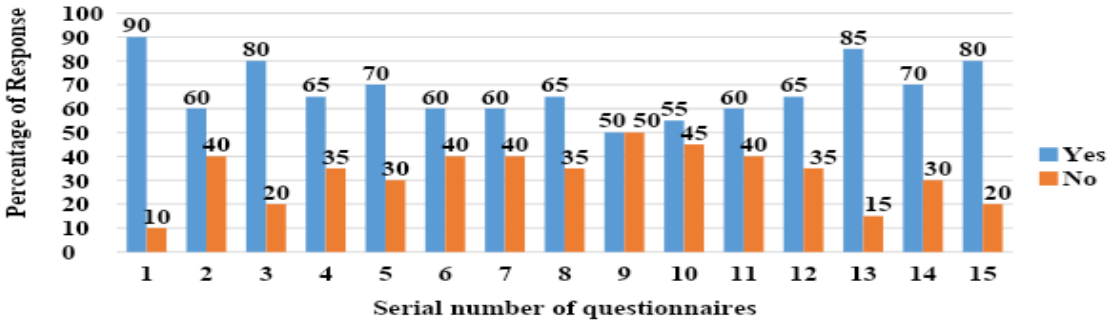

Fig 1:Percent response shown by healthcare workers for each question(Visit 1)

Visit 2

After five months second visit was conducted in which training and education encompassing pharmacovigilance (question no. 13) was recommended by 90% of respondents. Percentage of respondents responding "yes" regarding established independent body (question no. 14) for reporting of ADRs was 80%. 85% of respondents were recommending the proper recommendation to be instituted in the area of organization, legislation, regulation and resources to improve surveillance and safe use of drugs (question no. 15) as shown in Fig. 2.

The result is further again segregated into four classes for evaluation of awareness in different aspect of concept about pharmacovigilance as shown in Table 3.

1. It has been observed that knowledge of fundamentals of pharmacovigilance among the respondents was excellent in 45%, good in 35%, average in 5% and poor in 15%. No one scored zero in class A.
2. The knowledge about the reporting system of pharmacovigilance was excellent in 60%, average in 40% and poor in none of the respondents in class B.
3. Among the respondents 35% were excellent, 40% were good, 25% were average and none were poor regarding knowledge of possible benefits of pharmacovigilance in class C.
4. The response was excellent for 55%, good for 20%, average for 25% and poor for 0% of respondents. None were found to be incapable of giving any productive recommendation or opinion over the betterment system of pharmacovigilance.

Further, the mean score earned by the respondents in all four classes of different aspects of concept about pharmacovigilance were compared as shown in table 4. After completion of both visits, including study related interventions like; sensitization and training programs it was observed that the average monthly reporting of ADRs had increased. It was found that the average number of reports for three months increased from 29.33 to 51.67 after second visit.

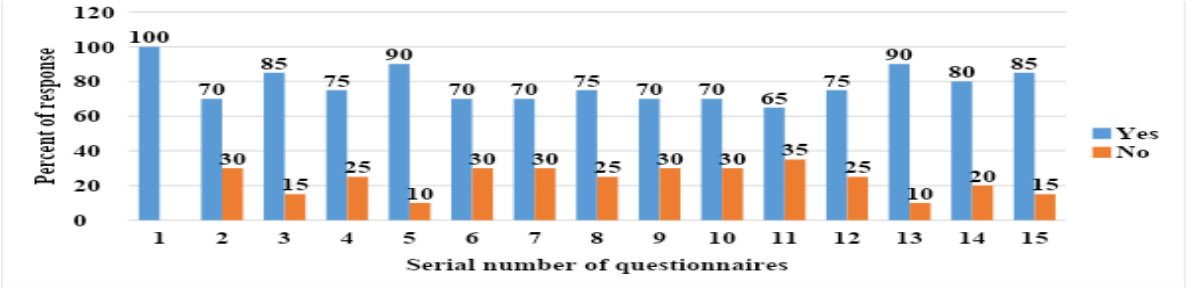

Fig 2:Percent response shown by healthcare workers for each question(Visit 2)

Table 2: Score earned by healthcare workers in different classes of questions (Visit 01)

Score Earned	Class A (N = 60)	Class B (N = 60)	Class C (N = 60)	Class D (N = 60)
0	3 (5%)	6 (10%)	3 (5%)	3(5%)
1	3 (5%)	30(50%)	27 (45%)	6 (10%)
2	6(10%)	24 (40%)	15(25%)	9 (15.00%)
3	9 (15%)	_	15 (25%)	12 (20%)
4	6 (10%)	_	_	30 (50%)
5	9(15%)	_	_	_
6	24(40%)	_	_	_

Table 3: Score earned by healthcare workers in different classes of questions (Visit 02)

Score Earned	Class A (N = 60)	Class B (N = 60)	Class C (N = 60)	Class D (N = 60)
0	0 (0%)	0 (0%)	0 (0%)	0 (0%)
1	3 (5%)	24 (40%)	15 (25%)	0 (0%)
2	6 (10%)	36 (60%)	24 (40%)	15 (25%)
3	3 (5%)	_	21 (35%)	12 (20%)
4	12 (20%)	_	_	33 (55%)
5	9 (15%)	_	_	_
6	27 (45%)	_	_	_

Table 4: Comparison of mean score earned by healthcare workers in different classes

Class	Average score in Visit 1		Average score in Visit 2		
	Mean±SD	SEM	Mean±SD	SEM	p value
A	4.259±1.915	0.25	4.6±1.57	0.20	<0.0001- ES
B	1.30±0.64	0.08	1.59±0.49	0.06	<0.0001- ES
C	1.70±0.90	0.11	2.10±0.77	0.10	<0.0001- ES
D	3.00±1.23	0.15	3.30±0.84	0.10	<0.0001- ES

Discussion

This study was a questionnaire-based, done to assess the knowledge and practice of pharmacovigilance programme of India and ADR reporting by healthcare workers in a tertiary care teaching hospital. In this study we found that the knowledge of pharmacovigilance programme of India and ADR reporting was known to a good number of respondents instead the rate of reporting was not up to mark and this result was in accordance with study done by Herdeiro MT et. al. (2005) and Carbonin P et. al. (1991) [16,17] The constructivism towards pharmacovigilance should be emphasized as the awareness about PvPI was on the lower side up to some degree however, the awareness was found to be increased in our second visit as evident from a study done by Gupta P & Udupa A (2011)[18]During our conversation, it appeared that almost all of the respondents were aware of the concept of pharmacovigilance, despite many of them were not able to define the term "Pharmacovigilance". Eminent number of respondents were able to explain about ADRs including some examples that they encountered in their respective fields. However, many of them were not familiar with the reporting system and its procedure. This can be justified by the inconsistency in reporting pattern which was in contrast to the frequency of ADRs that they came across during their practice. Similar pattern was seen by Ganesan S. et. al. (2016) and Agarwal R et. al. (2013)[19,20].

Spontaneous reporting of ADRs is elemental to drug safety surveillance however its knowledge and practice was inadequate. This attributes to the under-reporting which is a matter of contention. Most respondents agreed that ADRs are an important untoward aspect of drug therapy and suggested that it should be reported to avoid future tragedies and to prevent avoidable ADRs. They also professed that due to heavy workload and lack of acquaintance regarding reporting procedure they were not able to report. However, they affirmed to inculcate the habit of reporting in their daily practice. Similar views were seen by the study done by Vallano A et. al. (2015)[21]Further, knowledge and awareness of healthcare workers regarding different aspect of PvPI and ADR reporting was assessed on the basis of four types of questions incorporated into the given fifteen questionnaires. In visit 01 the awareness/ knowledge of healthcare workers regarding different aspect of PvPI and ADR reporting was assessed, followed by which they were sensitized and given knowledge.After about three months visit 02 was done and respective respondents were re- assessed on the same questionnaires. In visit 01, 80% and in visit 02, 85% of the respondents were having average/above average basic knowledge of pharmacovigilance, whereas 5% in first visit and none in second visit were entirely unaware of concept of pharmacovigilance. In regard to the awareness of reporting system, 90% in visit 01 and all the respondents in visit 02 showed average/above average, whereas 10% in visit 01 and none in visit 02 were fully unaware of any reporting system. This exhibits dearth of ADR reporting by them which is also an observation by study of Grootheest V et. al. (1999) [22]Underreporting is a matter of concern and major obstacle for pharmacovigilance. This underreporting can be corrected by simplifying reporting system, providing toll free number assistance at the level of adverse drug reaction monitoring centers, facilitating communication between healthcare professionals and pharmacovigilance centers[23,24]95 % of respondents in visit 01 and all the respondents in visit 02 were having average/ above average knowledge while 5% in visit 01 and none in visit 02 were not having any knowledge regarding possible benefits of pharmacovigilance. 85% in visit 01 and all respondents in visit 02 of respondents scored average/above average in context of their ability to give constructive opinion for the betterment of pharmacovigilance system. These figures exhibit that level of awareness of respondents regarding reporting system of pharmacovigilance needs to be improved because 10% in visit 01 were found to have no knowledge of existence of reporting system. Further, the mean score earned by respondents in all four classes (A, B, C and D) of different aspects of pharmacovigilance were compared after both visits and were found to be extremely significant.After completing visit 01 & 02, we found that mean number of ADRs in three months increased. Similar pattern has also been observed by other study[25]. In addition, we found that the knowledge and practice regarding different aspect of pharmacovigilance also increased. This strongly exhibits the importance and benefit of sensitization of health care workers about pharmacovigilance.

Conclusion

This study concludes that the healthcare workers' knowledge towards ADR reporting is better however its practice needs to be encouraged with sincere approach. Under reporting of ADR is essentially due to absence of reporting culture among them. The reporting rate of ADR could be improved with proper and extensive sensitization about Pharmacovigilance to them at regular intervals. Strategies should be developed to incorporate the habit of ADR reporting among

healthcare workers with a more simplified process and without increasing the burden on them.

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