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Pharmacovigilance: Current Scenario in a Tertiary Care Teaching Medical College in North India

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Abstract

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems. The Ministry of Health and Family Welfare, Government of India has set up National Pharmacovigilance Programe (NPP) in 2004 with the goal to ensure the benefits of use of medicine and outweighs the risks and thus safeguards the health of the Indian population. After observing the Pharmacovigilance programme of our institution we found that the problems of underreporting and lack of awareness were prevalent in the community of health professionals. This study shows poor knowledge, attitude and practices of pharmacovigilance among medical professionals so there is urgent need to improve the awareness of Pharmacovigilance among the healthcare professionals. ADR reporting should be intensively taught during undergraduate study, and this should be reinforced at the start of internships as well as periodically thereafter through continuous education programs.

Keywords: Adverse drug reaction; Medical college; Pharmacovigilance

Introduction

The safety of patients and the safe use of medicines are high priorities in the modern world. The first practical international co-operation in drug monitoring started in 1968. The ideas came up as a consequence of the so-called thalidomide tragedy. In the 1960s it was discovered limb deformities in babies may occur if thalidomide, ingested by mothers during pregnancy. This incident became the modern starting point of a science focusing on patient problems caused by the use of medicines. This science, and activities associated with it, is now most commonly called pharmacovigilance.

According to WHO, Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects of drugs, or any other drug-related problems [1]. Pharmacovigilance starts from the clinical stage and continues throughout the product life cycle of the drug, mainly divided as pharmacovigilance during pre-marketing (that is clinical trial phase) and post-marketing. Pharmacovigilance is particularly concerned with the adverse drug reactions (ADRs) which are defined as an unintended and noxious response to a drug that occurs at doses normally used for the prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function [2].

The Ministry of Health and Family Welfare, Government of India has set up national Pharmacovigilance Programme (NPP) in 2004 with the goal to ensure the benefits of use of medicine and outweighs the risks and thus safe guard the health of the Indian population. As India is now emerging as the 'Global hub for Generic Drugs, Clinical trials and Drug Discovery and Development', a vast number of new drugs are being introduced into the country which throws up the challenges of monitoring ADRs over large population base. All medicines (pharmaceuticals and vaccines) as a rule have known or unknown side effects. However many adverse drug reactions (ADRs) are preventable but it demands a good knowledge of pharmacology and good prescribing practices [3].

It is important to monitor every undesirable effect of medicines in order to determine any new information available in relation to their safety profile. In a vast country like India with a population of over 1.3 billion with vast ethnic variability, different disease prevalence patterns, practice of different systems of medicines, different socioeconomic status, it is important to have a standardized and robust pharmacovigilance and drug safety monitoring programme for the nation. Collection of this information and analysis of this data to reach a meaningful conclusion on the continued use of these medicines is the rationale of pharmacovigilance. The results thus obtained will be useful in changing the labeling of medicines indicating restriction in use or issue of statuary warning, precautions, or even withdrawal of the drug from the market. This also helps in educating doctors about ADRs and in the official regulations of drug.

In India the national coordinating center for Pharmacovigilance Programme is located at AIIMS with two zonal, five regional and a number of ADRs monitoring center (AMC). The whole programme is under the Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare, Government of India with the objectives of:

1. To monitor Adverse Drug Reactions (ADRs)
2. To create awareness amongst health care professionals about the importance of ADR reporting in India
3. To monitor benefit-risk profile of medicines
4. Generate independent, evidence based recommendations on the safety of medicines
5. Support the CDSCO for formulating safety related regulatory decisions for medicines

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6. Communicate findings with all key stakeholders
7. Create a national center of excellence at par with global drug safety monitoring standards

Spontaneous reporting is the core data-generating system of international pharmacovigilance, relying on healthcare professionals (and in some places consumers) to identify and report any suspected ADRs to their national pharmacovigilance center or to the manufacturer. Spontaneous reports are almost always submitted voluntarily. However, reporting of serious ADRs rarely exceeds 10% though the figures vary greatly between countries and in relation to minor and serious ADRs. Overall underreporting of ADRs is a common problem in pharmacovigilance programs [4-6].

Another problem is that overworked medical personnel do not always see reporting as a priority. If the symptoms are not serious, they may not notice them at all. And even if the symptoms are serious, they may not be recognized as the effect of a particular drug. After observing the Pharmacovigilance programme of our institution we found that the problems of underreporting and lack of awareness were prevalent in the community of health professionals. It was found that in the year 2011-2012 only 14 ADRs were reported from the health professionals. So undertaking all this consideration we plan to conduct a study to know the awareness of Pharmacovigilance among health professionals of our institute. Aim of our study is to create awareness of pharmacovigilance among health professionals and to uncover the causes of underreporting. In this study we also aimed to know the suggestions to improve the ADRs reporting. Since, there are considerable social and economic consequences of ADRs there is a need to engage health-care professionals, in a well structured programme to build synergies for monitoring ADRs.

Material and Methods

This was a randomized, cross-sectional, observational, questionnaire-based study, conducted at a 550-bedded tertiary care teaching hospital in Moradabad, India. This questionnaire survey was conducted during October 2012 and approval from Institutional Ethical Committee was obtained prior to administering the questionnaire survey. The questionnaire, contains 16 questions regarding knowledge, attitude and practices of Pharmacovigilance along with suggestions to improve ADR reporting, was designed based on similar previous studies [7,8]. Factors that discouraged reporting and demographics of participants were also included in questionnaire. Study was done on health professionals (doctors, nursing staff and pharmacists) working in the medical college and hospital.

Pretesting of questionnaire was done with Pharmacovigilance committee and on 10 randomized selected health professionals of the institute to identify any potential bias and mistakes. In the modified questionnaire name of the health professional kept optional to avoid potential bias and to increase the number of responders but designation asked. The aim of study and questionnaire were discussed among the members of Pharmacovigilance committee and then personally briefed to the participants.

For submission of questionnaire a suitable time of 3 days were given and for those who had not submitted back/lost the questionnaire, we resupplied the questionnaire and requested the responder to fill it before us. The information was recorded and analyzed using the Microsoft Excel worksheet (Microsoft Office 2010) and the ANOVA test. The **p** value less than 0.05 was considered to be statistically significant.

Result

The questionnaire was supplied to 150 health professionals and we get back 116 responses making a 77.33% of responses. The response rate were 56% among senior faculty members (Professor and Associate Professor), 84% among junior faculty members (assistant professor, senior resident and junior resident) and 92% were among paramedics (pharmacist and nursing staff). The demographic profile of responders is shown in table 1.

Awareness about pharmacovigilance based on our assumption of response to question number 1of the questionnaire were calculated and it was found that 72.7% were aware and remaining 27.3% were unaware. Awareness of pharmacovigilance among senior faculty members was 88.8%, junior faculty members 91.6% while in paramedics were 59%. We did not include the responses of unaware respondents in further statistical analysis of questionnaire.

We assess the knowledge of respondents on the basis of question number 2-6 and gave maximum 10 marks. The mean knowledge of senior faculty members was 5.87, junior faculty members were 7.5 and paramedical staff was 6.69. Knowledge of junior faculty was significantly higher ($p<0.05$) as compared to senior faculty. When we talked about existence of pharmacovigilance committee in the institute only 62.5% senior faculty and 23.07% paramedical staff knew the committee while among junior faculty 81.8% were aware of pharmacovigilance committee. 87.5% senior faculty members, 91% junior faculty members and 77% paramedical staff thought that ADR reporting is a professional obligation.

Only 9% respondents receive training on how to report ADR to pharmacovigilance committee and 5% respondents had guided others on importance of ADR reporting but it is interesting that all respondents thinks that Pharmacovigilance should be taught in detail. Source of knowledge about ADRs of drugs of respondents are given in table 2. Only 25% senior faculty and 24% paramedical staff had recorded ADRs while in case of junior faculty 52% had recorded ADRs.

Discussion

In this study we involves the paramedical staff (pharmacist and nurses) along with doctors, doctors are divided into two groups, senior (Professor and associate professor) and juniors (assistant professor, senior resident and junior resident).

The paramedical staff could play an important role in ADRs reporting, because they are close to the patient and are responsible for drug administration and recording side effects. They can alert the responsible physician about possible ADRs without time gap. Thus it is crucial to encourage the paramedical staff towards ADR reporting [9]. This study has shown inadequate knowledge of doctors about ADRs and reporting, even a significant number (27.3) of the respondents were not aware of the Pharmacovigilance. Perhaps, the undergraduate training in pharmacovigilance may be either insufficient or improper. A major part of respondents not ever come across with ADRs and it shows poor attitude towards ADRs reporting.

Age (years)	Percentage	Male : Female
21-25	14	63:37
26-30	29	
31-35	25	
36-40	11	
>40	21	

Table 1: Demographic Profile of study population.

According to Inman [10], the reasons for under-reporting of ADRs can be complacency (belief that the serious ADRs are already documented when a drug is introduced in the market), diffidence (belief that reporting should be done when there is certainty that the reaction is caused by the use of a particular drug), financial incentives (rewards for reporting), ignorance (that only serious ADRs are to be reported), indifference (belief that a single report would make no difference), legal aspects (fear of litigation) and lethargy (excuses about lack of time or disinterestedness). Some of these reasons were also documented in previous studies in India [8,11]. In our study a major reason observed was ignorance which was also seen in a study conducted at Delhi [7]. A major part of all respondents not knew where to report ADR while 36.36% junior faculty and 42.3% paramedical staff not knew how to report ADR (Table 3). Lack of knowledge of where and how ADRs should be reported would automatically affect reporting, therefore, awareness programmes; through publicity, would appear necessary to improve ADR reporting among medical practitioners. It is satisfactory that almost all respondents think that ADR reporting is important but unaware respondents even don't know the importance of ADR reporting.

One important reason of underreporting was lack of access to ADR reporting form that's why about 50% of respondents suggest electronic option of ADR submission (Table 4). A part of respondents were concerned that report will generate extra work and to legal issue, so it is crucial to make proper counseling and training and encouraged them to attend conferences and workshops on pharmacovigilance. The various methods suggested by the respondents to improve ADR reporting are presented in table 4.

Sources	Senior faculty (frequency %)	Junior faculty (frequency %)	Paramedical Staff (frequency %)
MR/ Doctor	37.5	36.35	50
Internet	25	41	50
Books	75	59	23
Journals	25	31.8	11.5
Conferences/ CME	37.5	36.35	11.5

Table 2: Source of information about ADRs of new drugs.

Factor	Frequency of Senior Doctors (%)	Frequency of Junior Doctors (%)	Frequency of Para medicals (%)	Frequency of Not aware respondents (%)
Did not know how to report	0	36.36	42.3	80
Not known where to report	37.5	59	42.3	80
Did not think it to be important	0	0	7.7	70.6
Managing the patient is more important than reporting ADR	25	31.8	46	0
Lack of access to ADR reporting form	37.5	40.9	23	0
Due to legal issue	25	9	26.9	0
Absence of fee for reporting	0	4.5	15.4	50.2
Concern that report will generate extra work	25	13.6	26.9	0
Concern that report may be wrong	0	4.5	7.7	0

Table 3: Discouraging factors for not reporting ADR's.

Conclusion

This study shows poor knowledge, attitude and practices of pharmacovigilance among medical professionals so there is urgent need to improve the awareness of Pharmacovigilance among the healthcare professionals. A questionnaire based study has certain limitations and it would be inappropriate to plan interventions based on the findings of this study alone but this study uncovers the importance of ADR reporting. ADR reporting should be intensively taught during undergraduate study, and this should be reinforced at the start of internships as well as periodically thereafter through continuous education programs.

Suggestions	Frequency of Senior Doctors (%)	Frequency of Junior Doctors (%)	Frequency of Para medicals (%)	Frequency of Not aware respondents (%)
Reporting of ADR to be made easy	87.5	81.8	38.46	22
Remuneration for ADR submission	62.5	45.5	11.53	53
Providing electronic option for submission	50	54.54	26.92	0
Making reporting mandatory	75	40.9	38.46	0
ADR reports to be kept confidentially	37.5	18.2	11.53	0
Provide toll free number for reporting	62.5	45.5	26.92	0
Make health professional more aware for ADR	62.5	68.2	69.23	85.6
Health care professional should be trained in ADR reporting	87.5	68.2	53.84	90
Having an ADR specialist in every department	25	22.72	38.46	75.2
Continuous medical education, training and refresher study	87.5	72.7	53.84	15.6

Table 4: Suggested methods of improving ADRs reporting.

References

1. World Health Organization (2002) Safety of Medicines: A guide to detecting and reporting adverse drug reactions. Geneva, Switzerland
2. International drug monitoring: the role of national centres. Report of a WHO meeting. World Health Organ Tech Rep Ser 498: 1-25.
3. World Health Organization (2002) The importance of pharmacovigilance - Safety monitoring of medicinal products. Geneva, Switzerland.
4. Green CF, Mottram DR, Rowe PH, Pirmohamed M (2001) Attitudes and knowledge of hospital pharmacists to adverse drug reaction reporting. Br J Clin Pharmacol 51: 81-86.
5. Subish P, Izham MM, Mishra P (2008) Evaluation of the knowledge, attitude and practices on adverse drug reactions and pharmacovigilance among healthcare professionals in a Nepalese hospital: a preliminary study. The Internet Journal of Pharmacology 6(1)
6. Ulfvarson J, Mejyr S, Bergman U (2007) Nurses are increasingly involved in pharmacovigilance in Sweden. Pharmacoepidemiol Drug Saf 16: 532-537.
7. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK (2011) An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res 2: 129-136.
8. Ramesh M, Parthasarathi G (2009) Adverse drug reactions reporting: attitudes and perceptions of medical practitioners. Asian J Pharm Clin Res 2: 10-4.
9. Bäckström M, Ekman E, Mjörndal T (2007) Adverse drug reaction reporting by nurses in Sweden. Eur J Clin Pharmacol 63: 613-618.
10. Inman WH (1996) Attitudes to adverse drug reaction reporting. Br J Clin Pharmacol 41: 434-435.
11. Gupta P, Udupa A (2011) Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions among resident doctors. J Pharm Sci Res 3: 1064-1069.