

Original Research Article

Knowledge, attitude and perception of physicians towards adverse drug reaction (ADR) reporting: a pharmacovigilance study

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ABSTRACT

Background: Contribution of physicians, in adverse drug reaction (ADR) reporting and monitoring, to develop a global database is enormously significant to ensure safety of medicine. But, in reality, due to lack of awareness among the healthcare providers, under-reporting of suspected ADRs is a major problem, especially in countries like India. Present study aimed to evaluate the knowledge, attitude, and practices (KAP) of the physicians regarding self-reporting of ADR in a tertiary care hospital in Kolkata, West Bengal, India.

Methods: This was a cross-sectional, observational and questionnaire-based study involving physicians of different clinical departments. This questionnaire-based study was conducted to obtain the demography as well as information on knowledge, attitude and perception of physicians towards ADR reporting. Ethical clearance was obtained prior to start the study.

Results: 50 doctors were included in the study after their verbal consent. It was revealed that average time taken to complete the answering of questionnaire by the physicians was 15 minutes. Among the study population (n=50), 54% of the participants were Postgraduate doctors and the rest 46% were graduates. 92% believed that it is necessary and would be beneficial for the patient to report ADRs. 74% also believed that ADR reporting is a professional obligation for doctors.

Conclusions: Present study evaluated that majority of the healthcare professionals had good knowledge and attitude about pharmacovigilance and understand the need for reporting, but the rate of reporting was very low. More interactive training programme is needed to increase the awareness of reporting ADRs by healthcare professionals.

Keywords: Adverse drug reaction, Attitude, Knowledge, Pharmacovigilance, Practice, Reporting

INTRODUCTION

World Health Organization (WHO) defined 'Adverse Drug Reactions (ADRs)' as any noxious, unintended, and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or cure of a disease.¹ ADRs are already established reason for mortality and morbidity worldwide. Pharmacovigilance is "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any

other drug-related problems".¹ Uppsala Monitoring Centre (UMC), Sweden, is maintaining global database of adverse drug reaction reports on behalf of WHO. Spontaneous reporting is the main source of ADRs, a pre-requisition for effective Pharmacovigilance.² The involvement of health professionals, in reporting and monitoring of ADRs is immensely significant and is imperative in assessing the benefit-risk ratio of any drug.³ Though, there is advancement in the field of Pharmacovigilance, under-reporting remains a

noteworthy disadvantage, till date.^{4,5} It has been evaluated that only 6–10% of all ADRs are reported.⁶

India is a part of the Global Program of Pharmacovigilance, its contribution to the database is very small, till now.⁷ This is due to the absence of initiative from physicians to self-reporting of suspected ADRs or ADEs (Adverse Drug Events).

Thus, involvement of doctors is essential regarding reporting of ADRs. Study showed lack of knowledge awareness about pharmacovigilance among medical practitioners and other healthcare providers resulted in a high level of underreporting.^{8,9} Therefore, present study was aimed to assess the knowledge, attitude, and practices (KAP) of the physicians in regard to ADR reporting in a tertiary health facility in Kolkata, West Bengal, India.

METHODS

Study design

It was an observational, cross sectional, questionnaire based survey.

Study setting

R. G. Kar Medical College and Hospital, Kolkata, West Bengal, India.

Study population

The study was pursued after obtaining ethical approval from Institutional Ethics Committee of R. G. Kar Medical College, Kolkata. Physicians working in different clinical Departments of R. G. Kar Medical College and Hospital, Kolkata were included in the study. Doctors from departments of Medicine, Dentistry, Psychiatry, Pulmonary Medicine and Dermatology, participated in the present study. The selection of departments was random. The study was conducted by using a pre-designed, pre-coded, pre-tested questionnaire to obtain the demographic information as well as information on the knowledge, attitude and perception of physicians towards ADR reporting. The study was conducted from 01/01/2016 to 29/02/2016, i.e., for two months.

RESULTS

In this study, 50 physicians participated. The average time taken by the physicians to complete the questionnaire was 15 mins. Among them 52% (26) was male and 48% (24) was female. 54% (27) of the participants were postgraduate doctors and the rest 46% (23) was graduate (Figure 1).

In the present study population (n=50), 11 participants (22%) were less than 25 years old and 1 was more than 50 years. The rest 38 participants i.e. 76% of the total study population were of middle age between 25 years to 50 years old (Figure 2).

Table 1: KAP questionnaire responses of the study population (n=50).

Questions	No. of responses (%)		
	Yes	No	No comments
Have you ever experienced an adverse drug reaction (ADR)?	44 (88)	6 (12)	0 (0)
Do you think that ADR reporting and monitoring system would benefit the patient?	47 (94)	0 (0)	3 (6)
Do you feel confidentiality should be maintained while ADR reporting?	35 (70)	13 (26)	2 (4)
Is there any nearby ADR reporting and monitoring centre in your knowledge?	39 (78)	4 (8)	7 (14)
Do you support 'Direct ADR reporting' by the patients to the authority / regulatory body instead of physicians?	18 (36)	22 (44)	10(20)

It was revealed from the present study (Table 1) that among the 50 physicians participated in the present study, 44 physicians (88%) have experienced at least one adverse drug reaction (ADR) in their clinical practice.

94% (47) expressed that the ADR monitoring and reporting system would be beneficial for the patient but 44% (22) did not support the direct ADR monitoring by the patients to the authority instead of physicians. 70% (35) of the physicians agreed that confidentiality of the ADR reporting should be maintained always. There is one Adverse Drug Reaction Monitoring Centre at the

study site, i.e., in the Department of Pharmacology, R. G. Kar Medical College, Kolkata, for a long time. 78% (39) of the total study population was aware about ADR reporting and monitoring centre in the institution.

Among the physicians, 42% (21) disagreed and 38% (19) strongly disagreed about the fact that all the drugs available in the market are safe.

Present study revealed that 92% (46) of the physicians believed in the necessity of ADR reporting and 88% (44) of the study population supported that ADR reporting

should be compulsory for the physicians. 74% of the physicians participated in the study indicated that ADR reporting is a professional obligation for the doctors (Figure 3).

Under-reporting of ADR being a major limitation of Pharmacovigilance, the physicians were asked about the probable reasons for this. They were allowed to select multiple options from the questionnaire and most of the physicians chose more than one probable reasons for

under reporting of ADRs. Therefore, the total number of responses for the 50 participated physicians was 129, i.e., n=129. The maximum response i.e. 27.91% designated that 'busy schedules of the physicians' were likely to be one of the reasons for under-reporting of ADRs. 19.38% of the total responses supported the lack of incentives from regulatory agencies and 13.18% supported the insufficient clinical knowledge of physician regarding ADR are another important probable reason for under reporting (Table 2).

Table 2: Physicians responses towards the probable reasons for under reporting of ADRs (n=129).

Probable reasons for the under reporting of ADRs	Percentage of responses (%)
Only safe drugs are available in the market	0.77
Reporting does not influence the treatment schedule	8.53
Busy schedule of the physician	27.91
Lack of incentives for regulatory agencies	19.38
Physician should rather collect data and publish himself / herself	3.88
Difficult to pin point suspected drug, so no need to report	8.53
ADR is known to physician so no need to report	3.1
Don't know whom, where, how to report	6.2
Reporting of ADR may indicate ignorance or negligence from the physicians	3.1
Difficult to admit harmful effects of drugs	5.43
Insufficient clinical knowledge of physician of ADR & its reporting	13.18
Reporting of ADR doesn't make any difference.	0
Others	0

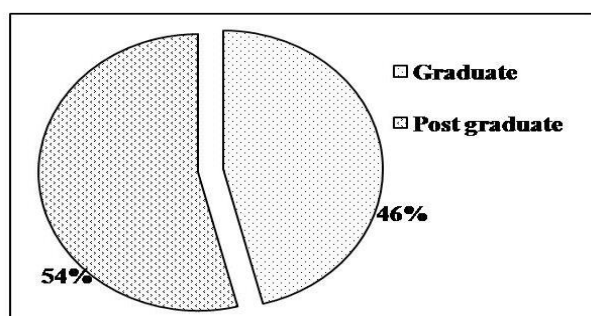


Figure 1: Distribution of study population (n=50) on education status.

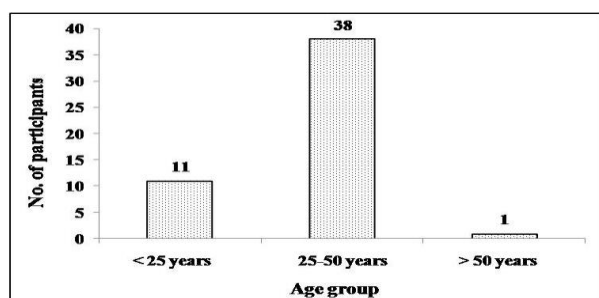


Figure 2: Distribution of study population (n=50) on age.

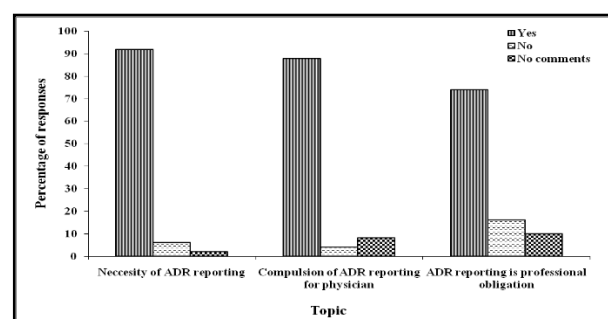


Figure 3: Distribution of study population (n=50) on perception regarding ADR reporting.

DISCUSSION

Reporting of ADR is an essential component of pharmacovigilance and is crucial for safety surveillance of marketed medicinal products. Many studies have evaluated the knowledge of healthcare professionals about pharmacovigilance. Present study was based on the knowledge, attitude and perception of physicians in a tertiary care hospital, on adverse drug reaction (ADR) reporting. This study comprised of 52% male and 48% female. A similar study from Riyadh, Saudi Arabia, showed 64.4% male and 35.6% female participants. Thus, the participation rate of the male physicians was

higher as compared to the present study.¹⁰ Studies from hospitals of Mumbai and Nagpur observed 57.6% and 64% male responders respectively.^{11,12} A similar study in Andhra Pradesh revealed almost equal participation of male (49.3%) and female (50.7%) responders.¹³ Present study reported that 76% of the total study population were of middle age between 25 years to 50 years old. Similar observations were reported in the studies in Mumbai and Nagpur where the mean age of the respondents was 26 years.^{11,12} Similar survey in Saudi Arabia observed 33.3 years was the mean age of the responders.¹⁰

The perception of physicians about ADR reporting showed, 92% believed that ADR reporting is necessary. Another study report also showed 89.5% physicians supported the necessity of ADR reporting.¹¹ Some other studies from Tamil Nadu, Sikkim and Ahmedabad revealed the similar data that total of 97% healthcare professionals agreed on reporting of ADR.¹⁴⁻¹⁶ But the ground reality is, in India, ADR reporting by physician accounted to 64.4%.¹⁷ However, survey in Saudi Arabia showed that 49.3% of the physicians suggested that only serious ADRs should be reported.¹⁰ In the present study, 74% of the physicians expressed that ADR reporting is a professional obligation. Study from Mumbai also supported the same, where 80.9% thought it to be an obligation.¹¹ Physicians from Sikkim (63%) and Indore (66.2%) also considered ADR reporting to be a professional obligation.^{15,18} Despite positive attitude from the physicians for the need to report ADRs, in practice there was scarcity of reporting.

Study from a Government Medical college in Nagpur revealed that 15.19% of the participants suggested that ADR reporting should be made compulsory by law.¹² However study from Mumbai revealed 89.5% of the responders agreed that ADR reporting should be made compulsory as observed in the present study (88%).¹¹ 94% of the present study population expressed that ADR monitoring and reporting system is beneficial for the patient. This was in agreement with study from Nagpur, where 93.61% of the study population believed that ADR reporting and monitoring system is benefit for the patients.⁶ Most of the physicians (70%) in the present study agreed that confidentiality should be maintained while reporting ADR and this was in agreement with a study in Saudi Arabia where 77.5% of the responders agreed this view.¹⁰ However, study in Mumbai revealed 57% of the responders supported that confidentiality should be maintained.¹¹

Present study revealed 78% of the physicians were aware of ADR monitoring centre (AMC) in their vicinity. On the other side, studies from Mumbai showed nearly 50% of the respondents and only 12.9% of a study population from Saudi Arabia were aware of ADR monitoring centre nearby.^{10,11} On the contrary, study from Sikkim revealed majority of the participants (79%) were unaware about any AMC in their institute.¹⁵

There were different views in the society on the issue “who can report ADR?” Present study observed only 36% responders supported the direct ADR reporting by the patients. This was similar to the data available from Saudi Arabia, where majority (58%) of the study population did not supported direct ADR reporting by patients.¹⁰ Same findings were also observed in Ahmedabad, where only about 26.2% of the respondents opined that patients should also be allowed to report ADR.¹⁶ This again indicated a lack of awareness of the principles and practice of pharmacovigilance among the respondents.

Under-reporting of ADRs is an obstacle commonly observed while monitoring adverse drug reactions. The physicians were asked about the reasons for under reporting of ADRs. They were given multiple choices and allowed to select multiple options from the questionnaire. Most of the physicians chose more than one probable reasons for under reporting of ADRs. The maximum response i.e. 27.91% designated the busy schedules of the physicians are likely to be one of the reasons for under reporting of ADRs. 19.38% of the total responses supported the lack of incentives from regulatory agencies and 13.18% supported the insufficient clinical knowledge of physician regarding ADR are another important probable reason for under reporting. Study from Indore stated that hesitancy (67.7%) and lethargy or lack of time (42.7%) would significantly affect the ADR reporting among the doctors working in a teaching hospital. Whereas in Ahmedabad, the major reason observed was ignorance about the reporting system, while the financial and legal aspects were given less importance.^{16,18}

CONCLUSION

This study revealed that majority of the physicians have good knowledge and attitude about pharmacovigilance and ADR reporting. There is a general agreement among doctors that ADRs reporting is beneficial and should be mandatory. In spite of that, the reporting rate of ADRs in practice is very low, still now. However most of the physicians thought it to be a professional obligation, but still there was gap between the ADR experienced and ADR reported by the physicians. Training on pharmacovigilance is necessary to increase the awareness and reporting of ADR by medical practitioners. Self-reporting practice of ADR is the backbone of any pharmacovigilance program. Only by increasing the quality reporting of ADRs, safe therapy can be ensured.

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