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Original Research Article

A cross sectional study to assess knowledge, attitude and practices of pharmacovigilance by interns in a tertiary care hospital in North Karnataka

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ABSTRACT

Background: Adverse drug reactions (ADRs) are an important contributor to morbidity and mortality burden in modern health care system. Continuous monitoring of drug after entering into market is necessary as it helps in improving care and safety of patient. In India, there is ongoing National Pharmacovigilance program to monitor ADRs. However, there is marked under-reporting of ADRs due to various reasons. Hence this study was taken to evaluate the knowledge, attitude and practices by the next generation doctors i.e., interns working in a tertiary care hospital, Bagalkot, Karnataka.
Methods: After ethics committee approval, a pretested questionnaire containing 15 questions was given to 80 interns. Finally, 60 sets were used for analysis, as 20 were incomplete.
Results: In our study it showed interns have good knowledge about pharmacovigilance as 67.4% correct responses were seen in knowledge domain and similarly 79% responses related to attitude were correct. However, there was a marked difference in the practice of ADR reporting as only 9.6% participants have reported an ADR. This study highlights that in-spite of having knowledge and awareness there was lesser ADR reporting practices. Major reasons for hindering ADR reporting found were difficulty in identifying an ADR, lack of time, not knowing how and where to report, lack of incentives and no compulsion.
Conclusions: Under reporting issues can be addressed by conducting more educational activities especially at undergraduate and intern's level, including continuous medical educations, workshops, problem-based learning about pharmacovigilance in detail in curriculum. These activities will increase reporting culture and sensitize interns to inculcate it in their future clinical practice also.

Keywords: Pharmacovigilance, Interns, Knowledge, Adverse drug reactions

INTRODUCTION

Adverse drug reactions are one of the important contributors of morbidity and mortality in the world.[1] Adverse drug reactions are defined a 'one which is noxious and unintended, and which occurs in doses normally used in human for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological functions'.[2] Similarly World Health Organization (WHO) has defined serious ADR as 'untoward medical occurrence at any dose that results in death, life-threatening, requires or prolongs hospitalization, or results in persistent or significant disability or incapacity'.[3]

These adverse drug reactions contribute nearly 6% for inpatient admission in hospital irrespective of age and about 24% in elderly population and in turn add to burden

for hospital and national growth and economy at large.[4] In South India, ADRs are responsible for 0.7-3.4% hospital admissions, 3.7% hospital readmissions and 1.3% mortality.[5,6]

Hence it is important to know, understand and monitor the adverse drug reactions. As we know many drugs are withdrawn from the market because of successful pharmacovigilance activities.[7] Hence, adding to safety of patient and more vigilant monitoring of ADRs.

The International database of reported ADRs is maintained at Uppsala monitoring centre (UMC-WHO), Sweden. India is also participating in this pharmacovigilance programme however there is under-reporting because various reasons. Pharmacovigilance program of India (PvPI) was launched to cover whole population with voluntary reporting. In 2011 the national coordinating centre to monitor ADR shifted from AIIMS New Delhi to Indian pharmacopoeia commission Ghaziabad under the aegis of UMC-WHO.[8]

New drug even though well tested in clinical trials, after entering into market it is exposed to large patient population compared to study subjects in clinical trial. In addition to large number of patients, other factors like geographical variation, genetic factors, age, coexisting co morbidities, food pattern, and concomitant medications also play a large role in generation of ADRs. Hence it is important to monitor adverse drug reactions. In India any health care worker i.e. doctors, nurse, dentist, any health care worker can voluntarily report the ADRs. The active involvement of these health care workers plays an important role in successful implementation of pharmacovigilance programme.

Hence this study was taken to assess knowledge, attitude and practices among the budding doctors i.e. interns working in Hanagal Shri Kumareshwar Hospital, a tertiary care teaching hospital of S. Nijalingappa Medical College, Bagalkot in Karnataka. Primary objective was to assess the causation for under reporting of ADRs.

METHODS

This was a cross sectional questionnaire study, consisting 15 questions with multiple choice options. This study was conducted in Hanagal Shri Kumareshwar Hospital attached to S. Nijalingappa Medical College, a tertiary care medical teaching hospital situated in Bagalkot, Karnataka. Before starting the study, it was presented to Institutional Human Ethics Committee (IEC)and approval was taken (ref no SNMC/IECHSR/201516/A-64/1.1) Total duration of the study was 2 months i.e., February to March 2020.

The questions were first analysed in detail and pre-tested, validated by expert colleagues. Based on the feedback from colleague's certain ambiguous nature questions were re-framed. After finalizing questions and seeking approval from the IEC study was conducted.

Inclusion criteria

Inclusion criteria for the study were interns who voluntarily gave informed consent and responded to all the questions.

Exclusion criteria

Exclusion criteria were incomplete responses, those who didn't return the response sheet, and those who were not willing to participate in study.

Those participants who consented were given study response sheet, and asked them to complete within a week and return to us. Only those who responded to all questions were considered for final analysis. The questionnaire consisted of part A, basic demographic profile of the participants i.e. age and gender of the interns and part B, 15 multiple choice questions. Questions 1to 6 mainly focused on the knowledge domain of participant regarding ADRs and pharmacovigilance. Whereas questions 7 to 10 focused on attitude and questions 11 to 15 regarding practices by the participant. One last open-end question was about suggestions to improve the pharmacovigilance process. Each correct answer was given a score of '1' and wrong answer was given '0' total maximum possible score was 15. A convenient purposive sample of 80 was selected. After obtaining consent from the interns a printed questionnaire sheet was given to them with instructions to fill it and return back within one week. A total 80 interns were administered with questionnaire, whereas final numbers included for analysis was 60, as 20 were excluded from the final analysis as 8 were incompletely filled and 12 did not return filled sheet in spite of the reminder.

Statistical analysis

The results were tabulated and analysed question wise and their percentage, proportions and means are used for descriptive statistics with help of microsoft excel 2007 spread sheet software.

RESULTS

In this study 60 completed questioners returned from the interns were analysed after removing incomplete respondents and those who did not return. All the answers are described in terms of numbers, percentages and mean±SD, for the KAP questionnaire. In our study demographic profile of participants includes males n=22 (37%) and females 38 (63%). average age of all the participants was 23.6 years.

Questions 1 to 6 were regarding knowledge domain about ADR and pharmacovigilance. Question 1 was regarding

definition of ADR which was correctly answered by 84.6% participants. Question 2 was naming two drugs withdrawn from market due to adverse effects which was correctly answered by 63% participants. 78% of them were aware of existence of national pharmacovigilance program in India. However, only 26% were aware regarding location of regulatory body in India regarding pharmacovigilance. Whereas 58% answered correctly regarding international ADR monitoring centre located at Uppsala-WHO, Sweden. 94% responded correctly that any health care worker including doctor, nurse and pharmacist can report an ADR. Overall correct responses for knowledge domain were 67.4%.

Table 1: Responses of participants for knowledge domain questions.

Questions	Responses	N (%)
Knowledge of ADR	Correct	51 (84.6)
	Incorrect	09 (05.4)
Examples of two banned drugs due to pharmacovigilance	Correct	38 (63.08)
	Incorrect	22 (36.92)
Existence of national pharmacovigilance program	Correct	47 (78.02)
	Incorrect	13 (11.98)
Regulatory body for ADR monitoring in India	Correct	16 (26.56)
	Incorrect	44 (73.44)
Location of international centre maintaining ADR database	Correct	35 (58.10)
	Incorrect	15 (41.90)
Who can report an ADR	Correct	57 (94.62)
	Incorrect	03 (05.48)

Table 2: Responses of participants for attitude towards ADR reporting.

Questions	Responses	N (%)
Have you seen an ADR form	Yes	36 (59.7)
	No	24 (40.3)
Is ADR reporting a professional obligation	Yes	45 (75)
	No	15 (25)
Do you feel reporting an ADR necessary	Yes	56 (92.90)
	No	04 (07.10)
Which ADR to be reported	Correct	55 (91.6)
	Incorrect	05 (8.4)

Question 7 to 10 were regarding attitude of participants towards pharmacovigilance. It shows 59.7% were aware of existence of ADR reporting form. 92.9% feel reporting an ADR necessary and 74% feel reporting ADR is a professional obligation. 91.6% participants believe reporting has to be done for all types of ADRs. Overall correct responses for attitude domain were 79.7%.

Questions 11 to 14 were about practical behaviour of participants towards pharmacovigilance. Only 9.6% participants have reported an ADR. When questioned about factors hindering reporting an ADR, majority (53.1%) of them expressed it as difficulty in identifying an ADR, other factors include lack of time (11%), don't know how to report (8%), lack of incentive, legal issues and it is not compulsory process. 31% participants recall that they have been trained in ADR reporting and 95% of the participants stressed on there is need to teach pharmacovigilance in detail at undergraduate level.

Table 3: Practices towards pharmacovigilance by interns.

Questions	Responses	N (%)
Have you ever reported an ADR	Yes	05 (9.6)
	No	55 (90.4)
Time frame for severe ADR reporting	Correct	6 (9.6)
	Incorrect	54 (90.4)
Have you ever been trained in pharmacovigilance	Yes	14 (23.2)
	No	44 (64.8)
Do you feel pharmacovigilance to be taught in detail	Yes	57 (95.2)
	No	03 (4.8)

Table 4: Factors hindering reporting an ADR.

Factors	%
Difficulty in identifying an ADR	53
Lack of time	11
Don't know how to report	8
It's not mandatory	6.4
No incentives	3.2
Feel that it's not important	3.2
Fear of legal issues	3.2
Don't know where to report	3.2

DISCUSSION

Pharmacovigilance is defined as 'the science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other drug-related Problem.[9] As stated earlier ADRs contribute to burden on health care system, by increasing morbidity, hospital stay and mortality of the patient.

No drug is free from adverse effects only severity varies. It was thalidomide disaster which was an eye opener with respect to Pharmacovigilance.[10] Now pharmacovigilance is part of holistic approach towards patient care.

As a part of national pharmacovigilance program spontaneous reporting of ADRs is an important step, which involves all the levels of health care workers i.e. doctor, nurse, technician, pharmacist and even patient.

This study was conducted in interns posted in various clinical departments, in a tertiary care hospital in North Karnataka, as they shoulder responsibility of patient care for first time and also, they are the budding next

generation health care providers. There are many studies conducted to assess knowledge of health care providers regarding pharmacovigilance, however very few studies involved budding doctors i.e. interns.[11-13]

Hence this study was aimed to assess knowledge, attitude and practices regarding pharmacovigilance by interns and to also get insight for various reasons for under reporting of ADRs.

The questions 1 to 6 were regarding knowledge domain, as described in (Table 1) mainly definition of ADR, regarding awareness of existence of national pharmacovigilance programme, location of national monitoring centre and who all can report an ADR in India. Average score for correct responses of knowledge domain was 67.4% which is quite satisfactory. 84% of interns could answer definition of ADR correctly. 78.2% were aware of existence of national pharmacovigilance program in India, which was satisfactory. These results were comparable with other studies conducted by Thakuria et al and Korde et al.[14,15]

However only 26% answered correctly regarding national coordinating centre and similarly 58% could answer regarding international centre location correctly. Lack of knowledge on location and monitoring body will not influence attitude and practice of ADR reporting. 94% of participants answered correctly that any health care worker can spontaneously report an ADR. Overall knowledge of participants regarding ADR and Pharmacovigilance was good 67.4%. These results were better compared to study conducted by Korde et al, in which 80% of interns scored below 50% in knowledge domain.[15] In addition to knowledge, attitude towards pharmacovigilance in study participants was good, 79% of them showing correct positive attitude towards ADR reporting which was comparable to study conducted by Gupta et al.[16] 92% of participants have an attitude that ADR reporting is necessary and 74% believe it as an professional obligation. 91% state all ADR to be reported and remaining participants state only serious ADR, ADR related to only new drug or previously unknown ADR to be reported. Overall correct response score for attitude domain was 79% and satisfactory. Similar results of fare knowledge and attitude is shown by the participants in study conducted by Upadhaya et al and Desai et al.[8,12]

In our study participants answered satisfactorily towards knowledge and attitude, however there was poor response with respect to practical practices.

Similar results are seen study by Agarwal et al, where participants had good knowledge and attitude but there was a marked decrease in practice of reporting culture.[17] Only 9.6% of participants have ever reported an ADR in spite of having awareness regarding process of ADR reporting. The major factors which were hindering for ADR reporting as depicted in (Table 4) include difficulty in identifying an ADR (53%), lack of time (11%), don't know how to report (8%), others like it is not mandatory, fear of legal issues, don't know where to report and lack of incentives. Similar responses were found in other published studies describing hurdles in ADR detection and reporting.[18-20]

In our study 95% of participants have opined that there is need to teach the pharmacovigilance topic in detail in undergraduate curriculum. Hence in India the culture of under reporting of ADRs to be addressed at gross root level i.e. even including undergraduates and interns the budding future doctors.

Limitation of our study was generalization of observed findings, as these findings could not be applied to wider population and study period was short. Hence, we recommend many more studies of similar nature to be carried out in interns so that will add to the pool of data from different geographical parts of country and it will also help in develop strategies to improve knowledge attitude practice of pharmacovigilance in India.

CONCLUSION

The results of the present study depict that interns had a fair amount of knowledge and positive attitude towards pharmacovigilance, however in contrast there is lack of reporting practices. Hence educational activities can enhance awareness and ADR reporting culture among them and also inculcate in their future clinical practice.

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REFERENCES

1. Srinivasan R, Ramya GS. Adverse drug reaction causality assessment. Int J Res Pharm Chem. 2011;1:606-11.
2. Sriram S, Ghasemi A, Ramasamy R, Devi M, Balasubramanian R, Ravi TK, et al. Prevalence of adverse drug reactions at a private tertiary care hospital in south India. J Res Med Sci. 2011;16(1):16-25.
3. Prajapati K, Desai M, Shah S, Panchal J, Kapadia J, Dikshit R. An analysis of serious adverse drug reactions at a tertiary care teaching hospital. Perspect Clin Res. 2016;7(4):181-6.
4. Onder G, Pedone C, Landi F, Cesari M, Della VC, Bernabei R. Adverse Drug Reactions as Cause of Hospital Admissions Results from the Italian Group of Pharmacoepidemiology in the Elderly (GIFA). J Am Geriatr Soc. 2002;50(2):1962-8.

5. Arulmani R, Rajendran SD, Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. Br J Clin Pharmacol. 2008;65:210-6.
6. Ahmad A, Parimalakrishnan S, Mohanta GP, Manna PK, Manavalan R. Incidence of adverse drug reactions with commonly prescribed drugs in tertiary care teaching hospital in India. Int J Pharm Sci. 2011;3:79-83.
7. Ahmad A, Patel I, Sanyal S, Balkrishnan R, Mohanta GP. A Study on Drug Safety Monitoring Program in India. Indian J Pharm Sci. 2014;76(5):379-86.
8. Upadhyaya HB, Vora MB, Nagar JG, Patel PB. Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Hospital in Gujarat. J Pharma Tech Res. 2015;6(1):29-34.
9. Coleman JJ, Pontefract SK. Adverse drug reactions. Clin Med. 2016;16(5):481-5.
10. Ito T, Ando H, Handa H. Teratogenic effects of thalidomide: molecular mechanisms. Cell Mol Life Sci. 2011;68(9):1569-79.
11. Gupta R, Sharma D, Malhotra P. Assessment of knowledge, attitude and practice of pharmacovigilance among the undergraduate medical students in a northern Indian tertiary care teaching hospital: an observational study. Int J Pharm Sci Res. 2017;8(6):2654-59.
12. Desai CK, Iyer G, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res. 2011;2:129-36.
13. Chatterjee S, Lyle N, Ghosh S. A survey of the knowledge, attitude and practice of adverse drug reaction reporting by clinicians in eastern India. Drug Saf. 2006;29:641-2.
14. Thakuria N, Deka D, Choudhury D, Ahmed N. A cross sectional study to evaluate the knowledge, attitude and practices of healthcare professionals on pharmacovigilance at Silchar medical college and hospital, Assam, India. Int J Basic Clin Pharmacol. 2016;5:1481-9.
15. Korde RA, Radhika MS. A KAP study of pharmacovigilance among junior residents and interns of a tertiary care hospital. Int J Basic Clin Pharmacol. 2018;7(11):2178-83.
16. Gupta P, Udupa A. Adverse Drug Reaction Reporting and Pharmacovigilance: Knowledge, Attitudes and Perceptions amongst Resident Doctors. J Pharm Sci Res. 2011;3(2):1064-9.
17. Agarwal M, Ahmed J, Roy V. Knowledge, Attitude, and Practice About Pharmacovigilance Among Healthcare Providers of a Tertiary Care Teaching Hospital in New Delhi (India). MAMC J Med Sci. 2017;3:146-51.
18. Pimpalkhute SA, Jaiswal KM, Sontakke SD, Bajait CS, Gaikwad A. Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. Indian J Med Sci. 2012;66:55-61.
19. Modi PK, Kohli SK, Advani U, Singh H. Evaluation of knowledge, attitude and practice of pharmacovigilance among health care professionals in tertiary care teaching medical college in North India. World J Pharma Res. 2014;3:2691-7.
20. Prakasam A, Nidamanuri A, Kumar S. Knowledge, perception and practice of pharmacovigilance among community pharmacists in South India. Pharm Pract. 2012;10:222-6.

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