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Original Article

Pharmacology Section

Knowledge, Attitude and Perception of Pharmacovigilance Awareness among Interns at a Tertiary Care Teaching Hospital, Andhra Pradesh, India

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ABSTRACT

Introduction: Pharmacovigilance plays an important role in the healthcare sector, in terms of health and economic burden. Studies on interns are limited and it is an aspect that requires further study.

Aim: To evaluate the knowledge, attitude and perception of pharmacovigilance awareness among MBBS interns at a teaching hospital in southern India. Also, to study the reasons for under-reporting of Adverse Drug Reactions (ADR).

Materials and Methods: This questionnaire-based, cross-sectional study was conducted among the 112 MBBS interns at Konaseema Institute of Medical Sciences and Research Foundation, Amalapuram, Andhra Pradesh, India, in December 2013. The interns were asked to complete 25 predesigned questionnaire based on the Knowledge, Attitude and Perception (KAP). The answered questionnaires were statistically analysed by using Microsoft Excel worksheet.

Results: Out of total 112 MBBS interns, only 94 completed the questionnaire within the stipulated time. There were 41 males and 53 females, with a mean age of 25±2 years. The response rate was 83.9%. A 48 (51.1%) interns had come across Adverse Drug Reactions (ADR) cases during their practice, however, among them only 24 (50%) reported them. Difficulty to identify the causative drug, was the major cause for under-reporting as per 23 (24.4%) interns. Majority (60.6%) were of the opinion that, pharmacovigilance only covers drug-related side-effects, not other types of side-effects.

Conclusion: Interns are the upcoming doctors, hence, increased attention must be paid to their lack of pharmacovigilance knowledge, in order to improve the clinical management and rational use of drugs.

Keywords: Adverse drug reaction, Rational use, Under-reporting

INTRODUCTION

Adverse Drug Reactions (ADR) are unwanted effects of drugs. These are responsible for prolonging hospitalisation, significant increase in economic burden and increasing death [1]. ADRs are the main reason of mortality and morbidity worldwide [2]. Monitoring of ADRs is called as pharmacovigilance. Activities in pharmacovigilance include detection, assessment, understanding, prevention of ADRs. Postmarketing surveillance of drugs is very important in analysing and managing the risks associated with drugs, once, they are available for the use in the general population.

Adverse drug reactions are a complicated trouble which require attention of patients, scientific professionals, the pharamcological industries, drug regulatory bodies [3]. ADR reporting does not appear to be part of standard practice for healthcare providers now [4]. The Uppsala Monitoring Centre (UMC) World Health Organisation (WHO), Sweden is maintaining the international database of ADR reports. Although, India is participating in the program, its contribution to UMC database is very little. Furthermore, due to a lack of knowledge and poor training on drug safety monitoring among healthcare workers, the Indian National pharmacovigilance Programme lacks continuity [5].

According to studies from many contexts, healthcare workers have insufficient awareness about pharmacovigilance as well as attitudes that are linked to a high level of under-reporting [6,7]. Out of the several methods of detecting ADRs, spontaneous reporting is the one that has contributed significantly to improved levels of pharmacovigilance in many countries [8,9].

It is essential to enhance the knowledge, attitude, and perception of all healthcare workers for better reporting of ADRs. Among all healthcare workers, interns of MBBS course play a crucial role in clinical practice, as they are the future clinicians, and also will be the primary care providers for all types of ADRs. However, very few studies were conducted on interns, which show that more than half of the interns were lacking the knowledge and training on ADR reporting [10].

The present study aimed to evaluate the Knowledge, Attitude and Perception (KAP) of MBBS interns in a southern Indian teaching hospital. The study also aimed to look at the reasons for under-reporting of ADRs.

MATERIALS AND METHODS

This study was a cross-sectional, questionnaire-based study involving, 112 MBBS Interns (2013-14 batch), at Konaseema Institute of Medical sciences and Research Foundation, Amalapuram, Andhra Pradesh, India, in December 2013. The approval was obtained from Institutional Ethics Committee (Reg no: IEC/13/Nov/135/33).

Inclusion and Exclusion criteria: All 2013-14 batch MBBS interns were included in the study. Those who did not return the questionnaire within the given time, were excluded from the study.

Study Procedure

The participants were required to answer predesigned and validated questionnaire on KAP on pharmacovigilance, within 30 minutes. There were 25 questions that were face-validated by the professors of the Pharmacology Department for feasibility, readability, formatting, and clarity. All interns were assembled at one place to distribute the hard copies of the questionnaire. Participant's consent was assumed when they were willing to answer the questionnaire. Hence, out of

112 particpants only 94 were taken into consideration. Only one answer was supposed to be marked for each question.

STATISTICAL ANALYSIS

The answered questionnaires were statistically analysed by using Microsoft Excel worksheet (2013). Participant's names were not disclosed.

RESULTS

There were 41 males and 53 females, with a mean age of 25±2 years. The response rate was 83.9%. Important causes for under reporting of ADRs are depicted in [Table/Fig-1].

Only 39 (41.4%) interns [Table/Fig-1] could answer that pharmacovigilance means ADR monitoring. Many of the interns (57, 60.6%) believed that pharmacovigilance covers only drug related ADRs and not any other types of ADR. Majority of them (86.1%) felt that, they are not sufficiently trained in ADR reporting.

Knowledge questions	Options	n (%)
1. Pharmacovigilance means?	Adverse drug reaction monitoring	39 (41.4%)
	Monitoring of drug plasma levels	20 (21%)
	Inspection of the pharma company for good manufacturing practice	15 (16.5%)
	All	20 (21%)
2. Pharmacovigilance covers?	Drug related side-effects	57 (60.6%)
	Blood products side-effects	12 (13%)
	Medical devices side-effects	10 (10.6%)
	Vaccines side-effects	5 (5%)
	All	10 (10.6%)
3. Pharmacovigilance main aim is?	Mainly safety	81 (86.1%)
	Mainly efficacy	13 (13.9%)
4. Which type of ADR is very common?	Type A	59 (62.7%)
	Type B	12 (12.7%)
	Type C	9 (9.5%)
	Type D	14 (14.9%)
5. In which clinical trial phase rare ADRs also can be identified?	Phase-1	26 (27.6%)
	Phase-2	23 (24.4%)
	Phase-3	27 (28.7%)
	Phase-4	18 (19.1%)
6. The first alert due to serious Adverse Drug Reactions is called?	Red alert	26 (27.6%)
	Red signal	16 (17%)
	Signal	14 (14.9%)
	Notification	38 (40.4%)
7. An adverse event is serious when patient outcome is?	Disability	3 (3.2%)
	Life threatening	11 (11.7%)
	Prolongs hospitalisation	8 (8.5%)
	All of the above	72 (76.5%)
8. Mandatory elements for making valid report?	Identifiable patient and reporter	6 (6.4%)
	Identifiable reaction	8 (8.5%)
	Identifiable drug	9 (9.5%)
	All	71 (75.5%)
9. Both ADR (adverse drug reaction) adverse events are synonyms?	Yes	52 (55.3%)
	No	42 (44.7%)
10. Every medication on the market is safe?	Yes	4 (4.3%)
	No	90 (95.7%)
11. Confidentiality is mandatory requirement in ADR reporting?	Yes	47 (50%)
	No	47 (50%)
12. Do you know any nearby AMC (ADR monitoring centre)?	Yes	32 (34%)
	No	62 (65.9%)

[Table/Fig-1]: Knowledge questionnaire with responses (N=94).

Nearly half of the interns (48, 51.1%) had come across ADR cases during their practice, however among them only 24 (50%) reported ADRs. Half of the interns felt confidentiality is mandatory for reporting ADR. Knowledge about nearby ADR reporting and monitoring centre was lacking in majority (65.9%). Very less number of interns (37.2%) gave instructions regarding ADRs to patients while prescribing medicines. Though many of the interns (78.7%) had gone through ADR form, but only 18 (19.1%) of them knew that ADRs can be identified in phase-4. A total of 14.9% interns, marked correctly for first alert, as signal. About 55.3% interns, thought that both ADR and Adverse Event (AE) were synonyms.

The present study also highlights many positive aspects about pharmacovigilance-many of the interns (86.1%) believed that, the aim of pharmacovigilance is to assess safety over efficacy, majority of them (97.8%), also thought safety monitoring of medicines should be a standard aspect of clinical practice, 72.3% interns, knew the fact that ADR reporting can be done by any person not the healthcare professionals alone, more than 60.6% of interns knew about Pharmacovigilance Programme of India, 76.5% were able to identify correct seriousness criteria [Table/Fig-2]. A total of 71 (75.5%) interns, correctly knew which mandatory elements in ADR reporting need to be filled. About 59 (62.7%) knew that type A is the most common type of ADR. Many interns (84%) expected proper reply from ADR monitoring centre for better reporting. More than 92.5% interns were in opinion that ADR reporting will benefit patients; but very few interns (19.1%) felt that, ADR reporting is time consuming, without any benefit.

Attitude questions	Options	n (%)
13. Have you heard about Pharmacovigilance Programme of India (PvPI)?	Yes	57 (60.6%)
	No	8 (8.5%)
	Can't say	19 (20.2%)
	May be	10 (10.6%)
14. Pharmacovigilance would be beneficial to the patient?	Yes	87 (92.5%)
	No	7 (7.5%)
15. Training on ADR reporting was satisfactory?	Yes	13 (13.8%)
	No	81 (86.1%)
17. ADR reporting activity is just time consuming without any benefit?	Yes	18 (19.1%)
	No	76 (80.9%)
18. Do you instruct regularly about ADRs to patients when prescribing?	Never	26 (27.6%)
	Sometimes	33 (35%)
	Always	35 (37.2%)
19. Do you expect reply for ADR reporting?	Yes	79 (84%)
	No	15 (15.9%)

[Table/Fig-2]: Attitude questionnaire with responses (N=94).

Nearly half of the interns (48.9%) worried about legal issues, while thinking of ADR reporting [Table/Fig-3]. Though majority of interns (95.7%) believed that, all the medications available in the market are not safe, but the difficulty to identify causative drug was the most common reason felt by interns (24.4%) for under-reporting [Table/Fig-4].

Perception questions	Options	n (%)
20. Have you ever seen ADR form?	Yes	74 (78.7%)
	No	20 (21.2%)
21. Who can report ADR?	All healthcare professionals	11 (11.7%)
	Patients	8 (8.5%)
	Lawyers	7 (7.5%)
	All of the above	68 (72.3%)
22. Have you come across any patient with ADR in your career?	Yes	48 (51.1%)
	No	46 (48.9%)
23. Have you ever reported an adverse drug reaction?	Yes	24 (25.5%)
	No	70 (74.5%)

24. Are you concerned about legal issues as you think about reporting ADRs?	Yes	46 (48.9%)
	No	48 (51.1%)
25. Medicine safety monitoring should be a standard aspect of clinical practice?	Yes	92 (97.8%)
	No	2 (2.2%)

[Table/Fig-3]: Perception questionnaire with responses (N=94).

Reason	n (%)
16a. Only safe medicines exist in the market	3 (3.2%)
16b. No incentives	8 (8.5%)
16c. It's hard to accept that the patients have been harmed.	9 (9.5%)
16d. Physician can publish the data rather than reporting.	18 (19.1%)
16d. Difficult to identify causative drug.	23 (24.4%)
16d. No idea to whom the report can be sent.	15 (15.9%)
16e. Unable to confirm the cause, whether drug or disease.	12 (12.7%)
16f. A single report has no value on the situation.	6 (6.3%)

[Table/Fig-4]: Causes for under-reporting of ADRs.

DISCUSSION

It was a questionnaire-based study to assess the knowledge, attitude and perception of interns on pharmacovigilance, in a tertiary care teaching hospital. As interns are upcoming doctors and also the primary contact persons for patients in all teaching hospitals, awareness about pharmacovigilance among them plays significant role.

The present study reveals that knowledge, attitude and perception scores among the 94 interns need to be enhanced. Majority of the interns (86.1%) felt that, they are not sufficiently trained in ADR reporting. A similar trend is seen in the studies, conducted at Dharwad, [10] Hyderabad, [11] where more percentage of interns and doctors felt the need for adequate ADR training. The majority (95.7%) interns believed that, all the drugs available in the market are not safe, which is in line with the Hyderabad study [11].

A study on interns at Dharwad showed that the major cause of under-reporting is due lack of time [10]. A study from Hyderabad on healthcare professionals reported that, the major cause was, 'Don't know whom to report' [11], however in the present study, 'Difficulty to identify causative drug' was the most common (24.4%) cause of under-reporting.

Nearly half of the interns (48.9%) have not come across ADR cases, in the present study. This may be due because they are not sufficiently trained to detect ADR. Prior clinical sensitisation for ADR will improve case detection. Few studies from Dharwad, [10] Junagadh, [12] Perambalur [13] reported a higher percentage of healthcare professional who came across ADR during their clinical exposure. Further, only half of those, who noticed ADR cases, in the present study, reported it to the ADR centre.

One needs to maintain confidentiality, while reporting ADR especially with regard to patients, but in the present study, only 50% interns felt confidentiality is mandatory. Contrarily, a Nigerian study reported a high awareness about confidentiality (65.95%) [14]. In the present study, unusually high number of interns (48.9%) worried about legal issues while thinking of ADR reporting. These findings are not in concurrence with a Gujarat study, where, 17.8% of the postgraduate medical students are concerned about the legal issues [15]. Hands-on training and awareness will help to minimise these apprehensions. In the present study, only 8.5% felt that an incentive will improve ADR reporting. Studies from conducted in Chennai [16], Sikkim [17] also, support remuneration for an increase in ADR reporting.

The ADRs are an unavoidable risk factors with the use of modern medicines. Studies in the USA and France, had shown that ADRs were the main contributors to morbidity and mortality [18]. As the data regarding ADRs keeps on upgrating, clinicians need to update themselves [19]. Undergraduate pharmacovigilance training may be insufficient or conducted in an ineffective manner for the duty of ADR monitoring and reporting [20].

Limitation(s)

The relatively small number of participants is a limitation. The opinion of participants, who did not return within stipulated time could have affected the overall interpretation of results.

CONCLUSION(S)

The present study concludes that interns were lack of proper knowledge regarding pharmacovigilance, however attitude and perception were relatively better. Even though majority of the interns came across ADRs and felt pharmacovigilance activity will be beneficial to the patient, reporting done by them is lower. Also, they were in opinion that training provided to them was inadequate, hence there is a need for regular training and motivation for ADR reporting. Importance should be given to various aspects of pharmacovigilance in medical curriculum. Further studies needed to strengthen effectiveness of pharmacovigilance activities.

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