RESEARCH ARTICLE

An observational study to evaluate knowledge, attitude, and practice of pharmacovigilance among undergraduate medical students of a tertiary care teaching hospital

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ABSTRACT

Background: Present status of pharmacovigilance is not satisfactory in India due to underreporting of adverse drug reactions which may be due to shortcomings of knowledge, attitude, and practice (KAP) toward pharmacovigilance among health professionals. Best time to inculcate this is during their undergraduate studies. Aim and Objectives: The study aims to evaluate KAP of undergraduate medical students and compare the results. Materials and Methods: Pharmacovigilance KAP-based preformed questionnaire containing 23 questions was answered by second, pre-final and final year MBBS students of our tertiary care teaching hospital. Data obtained was analyzed statistically. Analysis was done by calculating mean score in each year and compared between respective MBBS years. Level of significance was assessed by Kruskal Wallis test. Results: Total 219 students participated in the study among which 93 were from second year (3rd term), 74 were from pre-final year and 52 were from final year MBBS. Mean score of second year, pre-final year, and final year for knowledge was (4.12, 5.34, 6.06), for attitude was (6.90, 6.99, 6.35) and for practice was (1.16, 1.55, 2.62). Statistically significant difference is seen between knowledge and practice, while attitude difference is not significant. Conclusion: Students have relatively better attitude but limited knowledge and less practice for pharmacovigilance.

KEY WORDS: Pharmacovigilance; Adverse Drug Reaction; Knowledge Attitude and Practice; Undergraduate Medical Students

INTRODUCTION

According to the WHO, pharmacovigilance is, “The pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long- and short-term side effects of medicines.”¹ Adverse drug reactions (ADRs) are a major issue of health care system. ADRs are among significant cause of hospitalization worldwide.² India contributes to international ADR reporting center through pharmacovigilance program of India (PvPI) which runs under the authority of Central Drug Standard Control Organization (CDSCO).³ Spontaneous reporting by health care professionals is important part of this program. Underreporting is major limitation of spontaneous reporting.⁴ Rate of ADR reporting by India is below 1%.⁵ Hence, it is evident that current status of pharmacovigilance in India is not satisfactory. A knowledge, attitude, and practices (KAP) survey is a quantitative method (predefined questions formatted in standardized questionnaires) that provides access to quantitative and qualitative information...
revealing misconceptions or misunderstandings that may represent obstacles to the activities that we would like to implement and potential barriers to behavior change.[6] Previously reported studies have found that underreporting of ADRs is related with shortcomings in the knowledge and attitude among healthcare professionals.[7,8] Education and training are the most recognized means of improving ADR reporting.[9] The best time to inculcate knowledge, attitude, and practice of doctors toward pharmacovigilance is during their undergraduate training, so that medical students can play an important role in ADR reporting activity in present time as well as in their future. Hence, this study was carried out with an aim of evaluating knowledge, attitude, and practice of undergraduate medical students of our tertiary care teaching hospital.

MATERIALS AND METHODS

The study was carried out at our tertiary care teaching hospital after obtaining written permission from Institutional Ethics Committee (Human Research) with number of CUSMC/IEC(HR)/APPROVAL-4/2017/4546. It was a cross-sectional, observational, and KAP-based questionnaire study. All the students who were willing to give written consent from second year (3rd term), pre-final year, and final year MBBS were included in the study. A KAP questionnaire, which contains 10, 8 and 5 questions of KAP respectively, was prepared on the basis of questions which were pretested, validated and used for analysis by other studies[10-12] conducted for knowledge, attitude and practice of pharmacovigilance. Few changes were made according to requirement of present study. Students were gathered year wise in the lecture hall. Before commencement of the study, all the students were explained about the purpose of the study and any doubt was clarified by investigator. Total 30 minutes of time was given to students to answer the questionnaire. Collected data were analyzed.

Statistical Analysis

A score of 1 was given for each right or positive response and score of 0 was given for wrong, negative or un-attempted answer. Analysis was done by calculating mean score in each year and compared between respective MBBS years. Level of significance was assessed by Kruskal Wallis test using SPSS software version 17. p<0.05 was considered as significant.

RESULTS

Total 219 students participated in the study among which 93 were from second year, 74 were from pre-final year and 52 were from final year MBBS. There were total 10 knowledge-based questions. Total 89.25% students from second year, 89.19% from pre-final year, and 84.62% from final year were aware about definition of ADR. 80%, 67% and 50% students from second, pre-final and final year respectively responded correctly regarding who can report ADR. Details of all knowledge-based questions and their rate of response are listed in Table 1.

Table 1: Response of knowledge-based questions

<table>
<thead>
<tr>
<th>Knowledge-based questions</th>
<th>Second year MBBS (n=93)</th>
<th>Pre-final year MBBS (n=74)</th>
<th>Final year MBBS (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define ADR</td>
<td>83 (89.25)</td>
<td>66 (89.19)</td>
<td>44 (84.62)</td>
</tr>
<tr>
<td>Who can report ADR?</td>
<td>80 (86.02)</td>
<td>67 (90.54)</td>
<td>50 (96.15)</td>
</tr>
<tr>
<td>Is ADR reporting mandatory?</td>
<td>23 (24.73)</td>
<td>17 (22.97)</td>
<td>15 (28.85)</td>
</tr>
<tr>
<td>What is pharmacovigilance?</td>
<td>60 (64.52)</td>
<td>65 (87.84)</td>
<td>46 (88.46)</td>
</tr>
<tr>
<td>What is the full form of PvPI?</td>
<td>22 (23.66)</td>
<td>50 (67.57)</td>
<td>49 (94.23)</td>
</tr>
<tr>
<td>Where is National Pharmacovigilance Centre in India located?</td>
<td>20 (21.51)</td>
<td>18 (24.32)</td>
<td>17 (32.69)</td>
</tr>
<tr>
<td>Which regulatory body in India is responsible for monitoring ADRs?</td>
<td>19 (20.43)</td>
<td>23 (31.08)</td>
<td>17 (32.69)</td>
</tr>
<tr>
<td>Which scale is most commonly used to establish ADR causality?</td>
<td>20 (21.51)</td>
<td>19 (25.68)</td>
<td>29 (55.77)</td>
</tr>
<tr>
<td>What is the name of international collaborating center and where is it located?</td>
<td>19 (20.43)</td>
<td>20 (27.03)</td>
<td>16 (30.77)</td>
</tr>
<tr>
<td>Are you aware of any drug banned due to ADR? Specify if yes</td>
<td>34 (36.56)</td>
<td>51 (68.92)</td>
<td>33 (63.46)</td>
</tr>
</tbody>
</table>
Total 5 practise-based questions were asked to students. Total 16.13% from second year, 37.84% from pre-final year and 65.38% from final year had ever filled reporting form at clinical site. Details of practise-based questions with response are mentioned in Table 3.

Mean score of KAP for all the three years are shown in Table 4. It is evident that attitude score is better compared to knowledge score which is relatively better than practice score. Difference in mean score of knowledge and practice between all the three years was statistically significant, while attitude score was not statistically significant.

**DISCUSSION**

This study was carried out with an aim of evaluating knowledge, attitude, and practice of pharmacovigilance in our undergraduate medical students of second, pre-final and final year. Out of 219 students participated in the study 93 were from second year, 74 were from pre-final year and 52 were from final year MBBS. Knowledge and practice score were better in final year while attitude score was better in pre-final year students.

In this study, it was noted that knowledge score of all the three years was average to poor, which is also marked by another study done by Vora et al. Among three groups, final year students had better knowledge score. Only 21–32% students were aware about national coordinating center of pharmacovigilance, which is much less compared to other studies Knowledge is important aspect of pharmacovigilance. Lack of knowledge and awareness is one of the important factors leading to underreporting of ADR. Hence, average knowledge among students is matter of concern and appropriate steps must be taken to improve knowledge and awareness among students who are the pioneers of future medicine practice. To improve this theoretical knowledge on pharmacovigilance, National Pharmacovigilance Programme and its centers should be included in the syllabus. Regarding attitude score it was observed that all the three year students had almost equal score and furthermore attitude score is better than knowledge and practice score. Similar kinds of findings were also noted by another study conducted by Gupta et al. on undergraduate students. In our study, around 91-92% students showed positive attitude toward making ADR reporting compulsory. This finding is in consonance with the study conducted by Shankar et al. which also showed positive attitude with 80% score. However, studies conducted on doctors and professional health care takers showed comparatively lower attitude toward pharmacovigilance. Students with better attitude can define future prospects of practice if similar attitude is maintained not only during their student life but also professional life, which can only be achieved by their continuous involvement in pharmacovigilance activities. In our study, it is clearly evident that practice score of all the three year students is very less. However, poor practice score has been also remarked by other studies but in contrast to both these studies in present study final year students scored better practice score. It reveals that not only knowledge but practical involvement of students is also required for better implementation of pharmacovigilance. Practice of pharmacovigilance should be implemented in all the three years in such a way that reporting ADR becomes integral part of training. Statistical analysis of mean score revealed that on comparing each score between 3 years attitude score was not significant whereas between knowledge and practice score it was significant.

<table>
<thead>
<tr>
<th>Attitude-based questions</th>
<th>No. (%) of students responded YES as answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you think reporting of adverse drug reaction should be made compulsory?</td>
<td>Second year MBBS (n=93)</td>
</tr>
<tr>
<td>Do you think ADR reporting benefits both patients and doctors?</td>
<td>86 (92.47)</td>
</tr>
<tr>
<td>Do you think including ADR reporting practical in second year practical is beneficial?</td>
<td>90 (96.77)</td>
</tr>
<tr>
<td>Do you think that ADR reporting is a part of professional obligation of all related to health care?</td>
<td>87 (93.55)</td>
</tr>
<tr>
<td>Do you think that medical students could play a role in ADR monitoring? If yes how?</td>
<td>78 (83.87)</td>
</tr>
<tr>
<td>Do you think that discussion on ADR during clinical posting has any relevance?</td>
<td>57 (61.29)</td>
</tr>
<tr>
<td>Do you think that there is a need of information on drugs causing ADRs and their management strategies?</td>
<td>76 (81.72)</td>
</tr>
<tr>
<td>Do you think establishing ADR monitoring center in every hospital will be useful?</td>
<td>89 (95.70)</td>
</tr>
</tbody>
</table>

Total 16.13% from second year, 37.84% from pre-final year and 65.38% from final year had ever filled reporting form at clinical site. Details of practise-based questions with response are mentioned in Table 3.
statistically significant. This finding is in contrast to the other studies,[10,12] where they found knowledge and attitude score having statistical significant difference while practice score among all the three years was not significant. This difference may be due to different working culture of the institutes.

Major strength of this study is that it allows us to have broader idea of student’s mind-set regarding pharmacovigilance using KAP score. All the findings in the present study indicate that present academics and practice require huge transformation for better implementation of pharmacovigilance. Based on the study our department is planning to include hospital-based ADR filling activities in 2nd MBBS students to create interest among them toward pharmacovigilance. KAP questionnaire-based studies have their own limitations, so further studies are warranted for better evaluation and implementation of pharmacovigilance.

**CONCLUSION**

From the results and discussion, we conclude that in the present study students have relatively better attitude but limited knowledge and less practice for pharmacovigilance. There is huge scope for improvement in the present status of pharmacovigilance. This study helps us to conclude that our education system should focus more on practical aspects like filling of real patient ADR form rather than hypothetical ADR form. It is also desirable to extend pharmacovigilance activity from 2nd MBBS to final MBBS and internship. Concrete steps must be taken to improve awareness and practice among undergraduate students, which is one of the inevitable steps to reach the top of pharmacovigilance.

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**REFERENCES**


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