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# KNOWLEDGE OF ADVERSE DRUG REACTIONS AND PHARMACOVIGILANCE ACTIVITY AMONG THE UNDERGRADUATE MEDICAL STUDENTS OF GUJARAT

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## ABSTRACT

**Aims & Objectives**: The objective of this study was to analyze the baseline knowledge of awareness regarding the ADRs and Pharmacovigilance activity in the undergraduate medical students of different Medical Colleges in Gujarat, India.

**Settings and Design**: A cross-sectional questionnaire based multicentric study in six Government Medical Colleges of Gujarat (India).

**Material and Methods:** Questionnaire was developed to assess the knowledge of the ADRs and Pharmacovigilance activity. A total 18 questions were divided in two groups: Type-A regarding the ADRs and Type-B regarding the Pharmacovigilance. The questions were distributed to all 2nd and 3rd year undergraduate medical students and allowed to write down the answers independently. Each correct answer was given a score of '1' whereas the wrong/not given answer was given a score of '0'. The total score was 18.

**Statistical analysis:** We applied appropriate statistical test and used Epi Info software for analysed the data. Data was expressed in number as well as percentage.

**Results:** The study involved total 880 undergraduate medical students, of them 526 were the 2nd year students whereas 354 were the 3rd year students. Among 2nd year students, 54(10.3%) and 34(6.5%) have given the correct answer of type-A and type-B questions, respectively whereas in 3rd year, 22(6.2%) and 04 (1.1%) have given the correct answer of type-A and type-B questions, respectively. Overall knowledge of ADRs and Pharmacovigilance activity was poor in undergraduate medical students of Gujarat.

**Conclusions:** The undergraduate medical students are a future doctor in society. The deficiencies in knowledge regarding ADRs and Pharmacovigilance need the urgent attention on priority basis, not only for the success of the Pharmacovigilance program, but for the better clinical management of the patients in general.

**INTRODUCTION:** Adverse drug reaction (ADR) is a noxious, unintended and undesirable effect that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis and treatment [1]. ADR is associated with significantly prolonged length of hospital stay, increased economic burden and almost

2-fold increased death [2]. An ADR contributes to overall health care cost by increasing morbidity and even mortality in severe cases. An estimated $3billion is spent annually in the United States on ADR screening and treatment function [3].

ADRs are rather a complex issue which require special attention; they involve patients, medical professionals, the pharmaceuticals industries, drug regulatory agencies and academic scientist [4]. ADR reporting does not currently appear to be considered a part of routine professional practice by health care professional [5].

The Uppsala Monitoring centre (UMC, WHO), Sweden is maintaining the international database of ADR reports (currently about 4.7 million case reports) received from several national centres (96 member countries). However, still, it is estimated that only 6-10% of all ADRs are reported [7]. Although, India is participating in the program, its contribution to UMC database is very little. This is essentially due to the absence of a vibrant ADR monitoring system and also lack of a reporting culture among health care professionals.

In order to improve the reporting rate, it is important to improve the knowledge, attitude and practices (KAP) of the healthcare professionals regarding ADR reporting and Pharmacovigilance. The best period to improve the KAP regarding ADR and Pharmacovigilance activity is during the under graduate and post graduate education.

This study is a step in the direction to evaluate the baseline knowledge of the undergraduate medical students at six different Government Medical Colleges and teaching hospitals of Gujarat, regarding ADR monitoring and Pharmacovigilance

**MATERIAL AND METHODS:** After the permission of Institutional Review Board, Government Medical College, Bhavnagar and from head of the respective institutions, a cross sectional study was conducted at six different Government Medical Colleges and tertiary care teaching hospitals in the state of Gujarat (India). The centres included in the study were:

1) Government Medical College, Bhavnagar,
2) P.D.U. Medical College, Rajkot,
3) Shri M. P. Shah Medical College, Jamnagar,
4) Government Medical College, Surat,
5) Government Medical College, Vadodara, 6) B. J. Medical College, Ahmedabad.

The questionnaire was designed by the researchers of the Pharmacovigilance centre in Government Medical College & Sir Takhtsinhji Hospital, Bhavnagar, Gujarat (India). The initial draft was made and circulated to the members of the research team and modifications were carried out as per the suggestions. Upon received the responses from medical students, its reliability was tested by finding the Cronbach alpha value (0.72). The questionnaires was pre-tested and pre-validated. We have divided total 18 questions, Type-A (1-3, 7, 9, 13-15, 18) were related to the knowledge about ADRs, Type-B (4-6, 8, 10-12, 16, 17) were related to the knowledge about Pharmacovigilance.

The study involved all second year and third year undergraduate medical students. The questionnaire was provided to the participants. The questionnaire was handed to the students after explaining the purpose of the study. Thirty minute time was given for filling the questionnaire. Any clarification needed in understanding the questionnaire was given. Each correct answer was given a score of '1', the wrong/not given/not attended answer were given a score of '0'. The total score was of 18.

**Statistical analysis:** We applied Chi-Square test for comparison of type-A & type-B questions in students of six Govt. Medical Colleges. We applied ANOVA test to compare mean scores of type-A & B questions between students from medical colleges of six cities and unpaired T-test to compare 2$^{nd}$ and 3$^{rd}$ year students within same Govt. Medical College in Gujarat. We also used Epi info software for analyzed data.

**RESULTS:** In **Table 1** shown, overall knowledge of all students (both second and third year) regarding type-B questions was poor. The data from this table was significant.

In **Table 2** shown, overall knowledge of all students regarding type-B questions was poor. The data from this table was significant.

**TABLE 1: COMPARISON THE STUDENTS OF DIFFERENT GOVT. MEDICAL COLLEGES**

| | | | City | | | | | | Total |
|---|---|---|---|---|---|---|---|---|---|
| | | | A | B | J | R | S | V | |
| Type A | Poor | Count | 158 | 92 | 124 | 73 | 208 | 148 | 803 |
| | | % within city | 92.4% | 73.6% | 96.1% | 100.0% | 97.7% | 88.1% | 91.4% |
| | Good | Count | 13 | 33 | 5 | 0 | 5 | 20 | 76 |
| | | % within city | 7.6% | 26.4% | 3.9% | .0% | 2.3% | 11.9% | 8.6% |
| Total | | Count | 171 | 125 | 129 | 73 | 213 | 168 | 879 |
| | | % within city | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

Applying Chi-Square Tests value 73.700, p-value 0.000. The data is significant.

**TABLE 2: COMPARISON THE STUDENTS OF DIFFERENT GOVT. MEDICAL COLLEGES**

| | | | City | | | | | | Total |
|---|---|---|---|---|---|---|---|---|---|
| | | | A | B | J | R | S | V | |
| Type B | Poor | Count | 145 | 120 | 128 | 73 | 214 | 162 | 842 |
| | | % within city | 84.8% | 96.0% | 99.2% | 100.0% | 100.0% | 96.4% | 95.7% |
| | Good | Count | 26 | 5 | 1 | 0 | 0 | 6 | 38 |
| | | % within city | 15.2% | 4.0% | .8% | .0% | .0% | 3.6% | 4.3% |
| Total | | Count | 171 | 125 | 129 | 73 | 214 | 168 | 880 |
| | | % within city | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

Applying Chi-Square Tests value 66.179, p-value 0.000. The data is significant

**TABLE 3: MULTIPLE COMPARISONS OF MEAN SCORES OF STUDENTS FROM MEDICAL COLLEGES OF SIX CITIES**

| City | Ahmedabad | Bhavnagar | Jamnagar | Rajkot | Surat | Vadodara | Total |
|---|---|---|---|---|---|---|---|
| Type-A | 2.78±1.17 | 3.18±1.72 | 1.26±1.31 | 1.27±1.24 | 2.16±1.43 | 2.96±1.41 | 2.37±1.55 |
| Type-B | 2.43±1.86 | 1.62±1.53 | 0.47±0.81 | 0.67±1.08 | 0.40±0.69 | 2.01±1.29 | 1.30±1.52 |

To compare mean scores of type – A and B questions between students from selected medical colleges of six cities, we have applied ANOVA test and obtained its p-value. Here we get p-value 0.000 (<0.01) for both type – A and type – B questions.

**TABLE 4: COMPARISON WITH 2ND AND 3RD YEAR WITHIN SAME GOVT. MEDICAL COLLEGES**

| | Year | Govt. Medical colleges | | | | | |
|---|---|---|---|---|---|---|---|
| | | Ahmedabad | Bhavnagar | Jamnagar | Rajkot | Surat | Vadodara |
| Type-A | II | 3.05±1.24 | 3.47±1.82 | 1.28±1.45 | 1.05±1.11 | 1.70±1.52 | 2.63±1.31 |
| | III | 2.39±0.96 | 2.53±1.22 | 1.25±1.09 | 1.94±1.39 | 2.69±1.11 | 3.37±1.44 |
| p-value | | 0.000** | 0.004** | 0.895 | 0.007** | 0.000** | 0.001** |
| Type - B | II | 3.43±1.73 | 1.70±1.57 | 0.42±0.91 | 0.49±0.72 | 0.44±0.73 | 2.05±1.22 |
| | III | 1.03±0.93 | 1.45±1.43 | 0.53±0.61 | 1.22±1.69 | 0.36±0.66 | 1.96±1.38 |
| p-value | | 0.000** | 0.395 | 0.456 | 0.012* | 0.458 | 0.641 |

* indicates significance at 5% level; ** indicates significance at 1% level; Statistical analysis done by applying T-test in above data show significant difference found.

**DISCUSSION:** The present study evaluated the baseline Knowledge of all second and third year medical students who are studying in M.B.B.S of different Govt. Medical College and regarding ADR reporting and Pharmacovigilance. These are future doctor in our society Overall, the Knowledge was very poor. The World Health Organization (WHO) defines Pharmacovigilance as "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems." The ultimate aim of Pharmacovigilance is to ensure safe and rational use of medicines, once they are released for general use in the society. The most important outcome of Pharmacovigilance is the prevention of patients being affected unnecessarily by negative consequences of pharmacotherapy [7].

In Table 1 shown, overall knowledge regarding type-A questions of all students was very poor. A total 879 students, only 76 (8.6%) students had given correct

answer and others 91.4% students was not given correct answer, out of them, P.D.U Medical College, Rajkot (100%), Govt. Medical College, Surat (97.7%), Shri M.P Shah Medical College, Jamnagar (100%) and B.J. Medical College, Ahmedabad (92.4%), Govt. Medical College, Bhavnagar (73.6%) was not given corrects answer. The data was significant.

In Table 2 shown, overall knowledge of all students regarding type-B questions was also very poor. A total 880 students, only 38 (4.3%) students had given correct answer and others 95.7% students were not given correct answer. Out of them P.D.U Medical college, Rajkot (100%), Govt. Medical College, Surat(100%), Shri M.P Shah Medical College, Jamnagar (99.2%), Govt. Medical College, Bhavnagar(96.0%) and B.J. Medical College, Ahmedabad (84.8%) was not given correct answer. The knowledge regarding Pharmacovigilance is very much important to the undergraduate students and post graduate students.

In **Table 3** shown, the difference of mean scores (for type-A & B questions) between students from six medical colleges is statistically significant at 1% level (p- 0.000 (<0.01)). In type – A questions, students from Bhavnagar medical college had highest score whereas students from Jamnagar and Rajkot medical colleges had lowest score. In type – B questions, highest scores were found in Ahmedabad students and lowest score was found in Jamnagar students.

In **Table 4** shown, comparison with 2nd and 3rd year within same Govt. Medical Colleges, over all knowledge was very poor.

In **Figure 1** shown, Comparison of second and third year medical students of different Govt. Medical Colleges of Type-A Questions, total 525 2nd year, 354 3rd year medical students had attended questioners; only 54(10.3%) and 22 (6.2%) no. of students give correct answer respectively. Only 76 (8.6%) out of 879 medical students had given correct answer but No. of students shows very poor knowledge of adverse drug reaction.

In **Figure 2** shown, Comparison of second and third year medical students of different Govt. Medical Colleges of Type-B questions, total 526 2nd year, 354 3rd year medical students had attended questioners; only 34(6.5%) and 04(1.1%) no. of students give correct answer respectively. Only 38(4.3%) had given correct answer but No. also shows very poor knowledge of Pharmacovigilance.

**TYPE-A QUESTIONS**

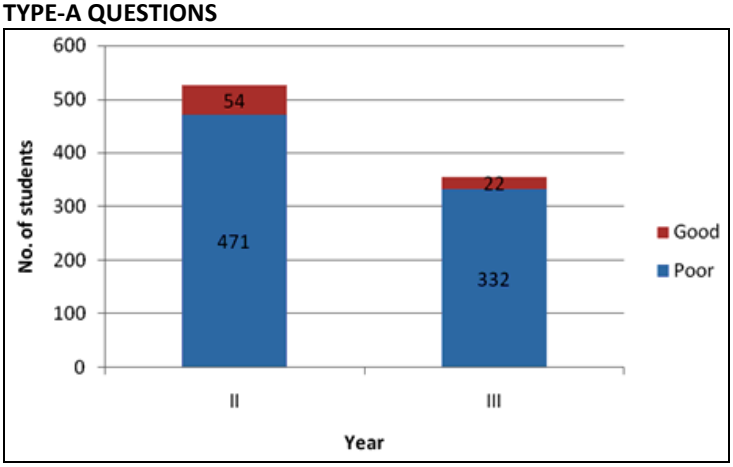


**FIGURE 1: OVERALL COMPARISON OF TYPE-A QUESTIONS IN BOTH YEAR STUDENTS**

Chi-square value is 4.436 with p-value 0.035. Statistical analysis done by applying T-test in above data show significant difference found.

**TYPE-B QUESTIONS**

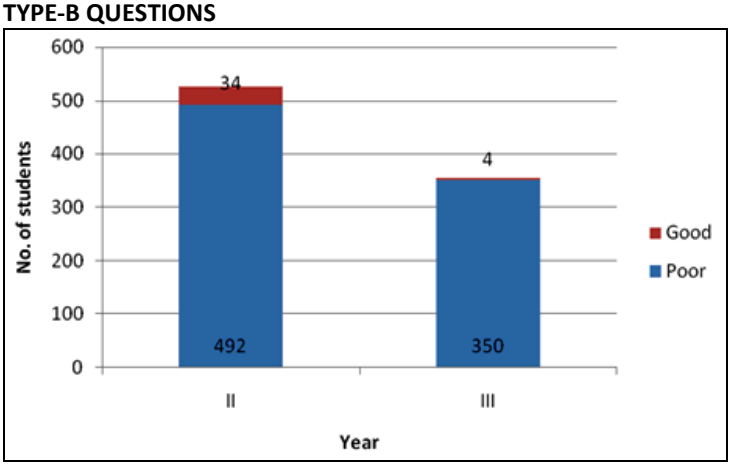


**FIGURE 2: OVERALL COMPARISON OF TYPE-B QUESTIONS IN BOTH YEAR STUDENTS**

Chi-square value is 14.570 with p-value 0.000.

Pharmacovigilance programs have played a major role in detection of ADRs and banning of several drugs from the market [7]. However, under reporting of ADRs is one of the major problems associated with Pharmacovigilance programs [8].

One of the better means of reducing the overcoming of under reporting is to increase the Knowledge of the healthcare professional regarding ADR monitoring and Pharmacovigilance programs. A study from Northern India reported that the Knowledge regarding ADR monitoring was low and the scores needed an improvement [9].

A study from Italy reported that doctors had little information concerning ADRs and ADR reporting systems [10]. A recent study from India also identified that the awareness about Pharmacovigilance program and the knowledge of ADR reporting were very low among the doctors [11]. These findings suggest the need for interventions to improve the knowledge of the undergraduate medical students in Gujarat.

**CONCLUSION:** The study was identified the knowledge of the undergraduate medical students regarding ADR monitoring and Pharmacovigilance. Overall the Knowledge score was very poor. Our findings suggest the need for educational interventions.

The intervention can be;

- It will be mandatory for organized training programme regarding Pharmacovigilance in undergraduate medical curriculum under Pharmacology department.
- Regarding the study results, it was suggested that health care systems must have training programmes for medical students who are future prescriber in the society about importance, detection, analysis, reporting and fallow-up of adverse drug reactions in the hospital and provide online and telephone line accesses to facilitate adverse drug reactions reporting system.

Strengths and limitation of this study;

- To the best of our knowledge, this was the first study in Govt. Medical colleges of Gujarat (India) that have evaluated the knowledge regarding adverse drug reactions and Pharmacovigilance in undergraduate medical students.
- The limitation of study, we do not intervene undergraduate the medical students of medical college of Gujarat.

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