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Evaluation of Knowledge, Attitude and Practice of Pharmacovigilance in Medical, Dental and BSc Nursing students of a Govt tertiary health care hospital in Telangana through Pharmacovigilance awareness program

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Abstract:
Objective: *The primary objective is to assess the awareness of Pharmacovigilance (Pv) and to evaluate the impact of Pharmacovigilance Awareness Program in Medical, Dental and BSc Nursing students of Govt. tertiary care teaching hospital in Telangana.*
Secondary objective is to impress upon them ADR monitoring and educating patients about ADRs are two important duties of the medical professional.
Materials and methods*: Questionnaire based cross sectional study. Questionnaire contains twenty questions. Ten are designed to test knowledge, four for attitude and six for practice. 45minutes educational program was given about Pharmacovigilance including how to fill ADR form. Pre and Post test were conducted and compared. All statistical work was done using Microsoft Excel.*
Results*: In these Pv awareness programs 157 medical, 110 dental and 103 BSc Nursing students participated. Average Knowledge scores among medical students in pre & post test were 33% and 70%, in dental students 31 and 73%, in nursing students 28% and 85%. Average Attitude scores in all 3 groups was 93%. Average PV practice scores were 18% for medical students, 15% for dental students and 35% for BSc Nursing students.*
Conclusion*: This study revealed that the medical, dental and BSc Nursing student's knowledge about Pharmacovigilance was minimal. Pharmacovigilance should be included in the academic curriculum. Each student should report one or two ADRs in his/her clinical postings. Reporting ADRs as a practice must be cultivated among the future health care professionals for the benefit of patient and society at large.*

I. Introduction:

Due to the stressful mundane and unhealthy life style of humans, drugs have become the only cure for most of the diseases. Drugs not only cure the disease but also tend to produce some undesirable or unintended effects which we call adverse drug reactions (ADRs). Adverse drug reactions are 4th leading cause of death in USA.[1] 5% of all hospital admissions are related to ADRs in UK.[2]

Common ADRs are detected in phase III clinical trials but post marketing surveillance is needed for detection of rare ADRs. No drug is a perfectly safe drug, so every drug should be monitored for its life time for possible ADRs.

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse drug reactions and other possible drug related problems. International Drug Monitoring Program was established by WHO in 1971, in response to Thalidomide disaster of 1961.[3] Since 1978, this program has been carried out by Uppsala monitoring center (UMC) in Sweden. [4]

The Uppsala Monitoring Centre (UMC) is an independent foundation and a centre for international service and scientific research. UMC's mission is to support and promote patient safety through effective Global Pharmacovigilance practice. UMC has 134 member countries. In 1997, India became a member of the WHO Program of international Drug Monitoring managed by Uppsala Monitoring Center, Sweden. Indian ADR reporting currently makes up just 3% of ADR database at UMC.[5]

Pharmacovigilance Program of India(PvPI) was started in July 2010, with AIIMS, New Delhi as its national coordination center (NCC). In April 2011, NCC shifted from AIIMS to Indian Pharmacopeia Commission (IPC), Ghaziabad. Now, more than 200 ADR Monitoring Centers (AMC) are working under the PvPI. These AMCs are setup in all MCI approved Medical colleges. AMCs use a web-based Software called Vigiflow for reporting ADRs.

In India, we have 360 MCI-approved medical colleges, 200 dental institutions, 320 nursing institutions, 2000 pharmacy colleges and 90 Institutes of Pharma D. All these institutions are associated with patient care. PvPI is planning to establish AMCs in all of the above institutions to make the Pharmacovigilance program robust and to improve ADR reporting from all over the country.[6]

Early detection and rapid dissemination of information regarding ADRs are two important tasks in Pharmacovigilance. Voluntary reporting of ADRs by health care professionals can make the above task easy. Motivation and training of health care professionals towards Pharmacovigilance will improve ADR reporting [7].

The aim behind conducting Pharmacovigilance awareness programs to medical, dental and nursing students is to inspire and engage them in the Pv program and to transform them into responsible health care professionals.

II. Material and Methods:

A questionnaire-based cross-sectional study was conducted at Osmania Medical College, where the ADR monitoring Center (AMC) was functional since 2014. A Pharmacovigilance Awareness Program was conducted for MBBS, BDS and BSc Nursing students to educate them. The program was conducted for 4th semester MBBS students and 3rd and 4th year BSC Nursing students at Osmania Medical College, on two different days. For dental students, the program was conducted at the Govt. Dental College, 3rd & 4th year BDS students and internees attended.

The Pharmacovigilance Awareness Program was a 45-minute long power point presentation based lecture. Its purpose was to educate the students about Pharmacovigilance, Adverse Drug Reactions, Adverse Events, PvPI, UMC-Sweden and how to fill the ADR form, various ways to report ADRs to PvPI and finally about AMC in Osmania Medical College. ADR forms were distributed among the students.

A pretest and a post-test were conducted before and after the educational program, respectively. The pretest was intended to assess the students' current knowledge about Pharmacovigilance, where as the post-test was designed to evaluate the knowledge gained from the awareness program.

The questionnaire contained 20 questions. One point was assigned to each question. There were ten questions about knowledge of Pharmacovigilance, four questions about attitude of students towards Pharmacovigilance and ADR reporting, six questions for assessing the practice of Pharmacovigilance. All questions were either multiple choice or yes/no questions. Pre and post-test papers were given to all the students but answering and submission were optional to the student.

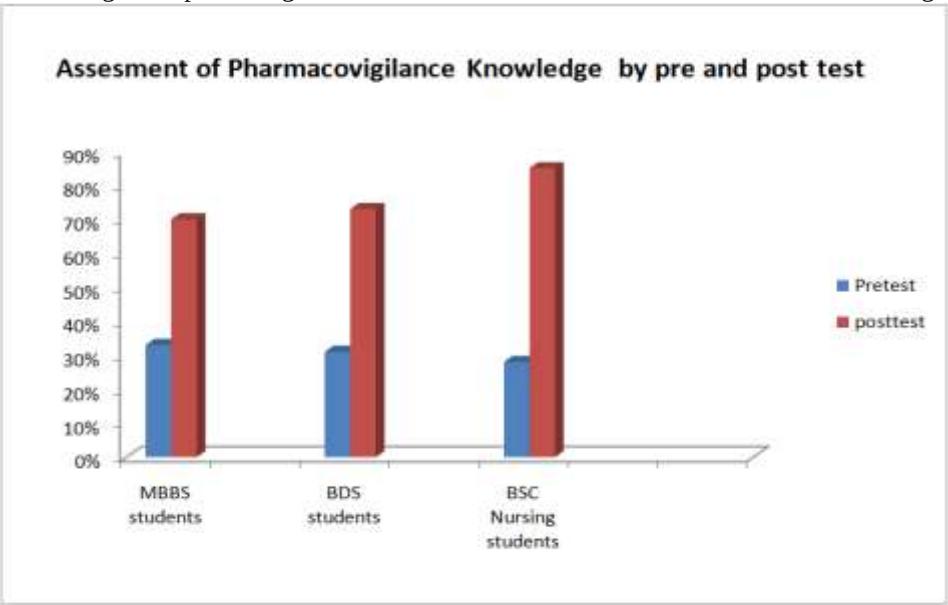
III. Results:

157 MBBS, 110 BDS and 103 BSc Nursing Students participated in pre and post-tests. The pretest score represent students' current knowledge in Pharmacovigilance. In pre-test knowledge average score was 33% for MBBS students, 31% for BDS students and 28% for BSc Nursing students. Scores were very less for all students, indicating that their knowledge about Pharmacovigilance was limited. Students gained appreciable amount of knowledge about Pharmacovigilance from the awareness program which was reflected in the post-test performance. The average scores for MBBS, BDS and BSc Nursing students were 70%, 73% and 85% respectively.

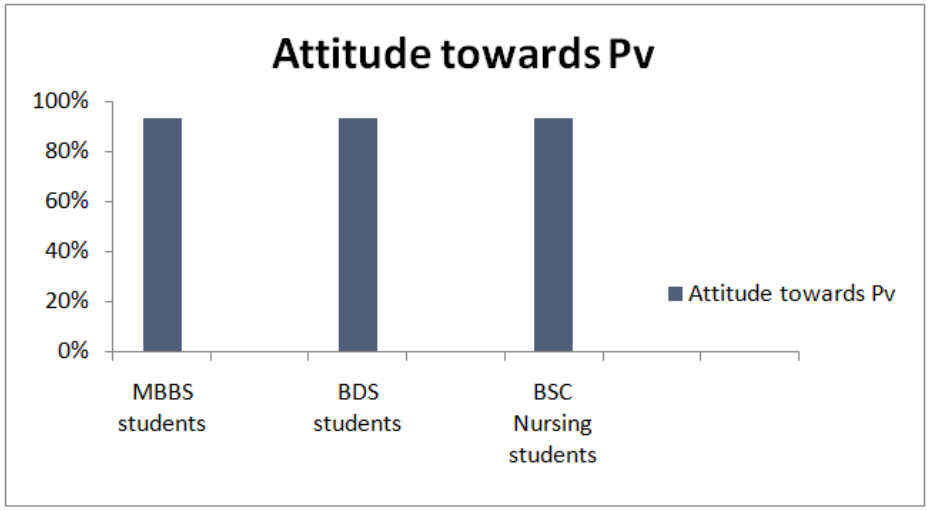
Table1: Assessment of Knowledge of Pharmacovigilance based on Pre and Posttest conducted in Pv Awareness Program:

	MBBS Students	BDS Students	BSC Nursing students
Pretest	33%	31%	28%
Posttest	70%	73%	85%

Graph 1: Bar Diagram representing Pretest and Posttest scores of MBBS, BDS & BSC Nursing students:

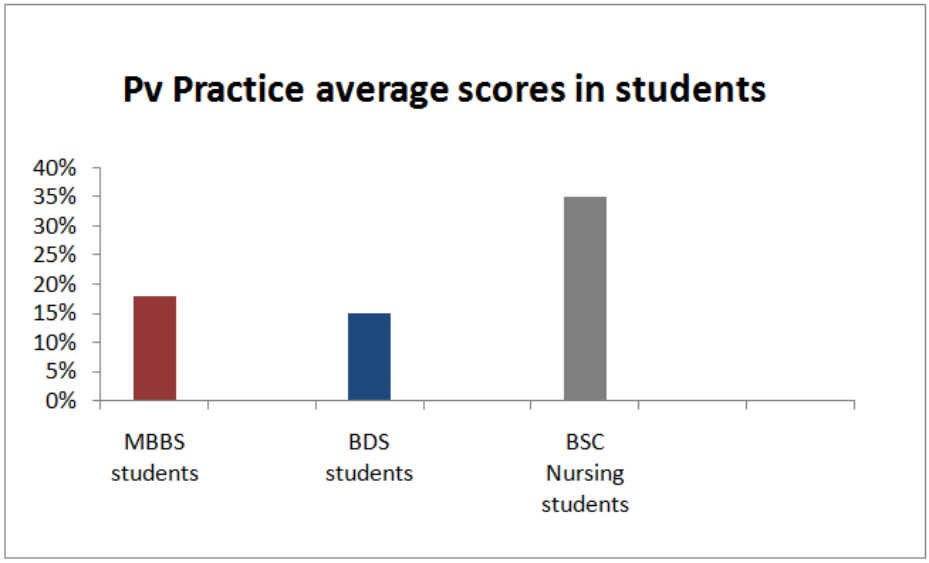


Attitude of the Students towards Pharmacovigilance:
Students have positive attitude towards Pharmacovigilance. Attitude levels are same in all three student groups. It is 93% in all groups. Same attitude levels are seen in both pre and post test.



Students' average scores in practice section of Pharmacovigilance:

	MBBS Students	BDS Students	BSC Nursing students
Pv Practice average score	18%	15%	35%



Student's Participation in Pharmacovigilance Activities:

46% of MBBS, 47% of BSc Nursing and 25% of BDS students knew about the presence of ADR monitoring (AMC) center in Osmania Medical College. 81% of BSc Nursing students, 17% of MBBS and 33% of BDS students were exposed to ADRs in their clinical postings. 9% of BDS and BSC Nursing students, 15% of MBBS students know about the ADR form. 10%, 14%, 29% of MBBS, BDS & BSC Nursing students stated that they knew about drug alerts.

Reasons given for 'Under Reporting of ADRs': 45% of MBBS students stated they were not aware of reaction causality and 53% didn't know how to report ADRs to PvPI. 64% of BDS and 69% of BSC Nursing students stated they didn't know how to report ADRs to PvPI.

IV. Discussion:

4th semester MBBS students, 3rd and 4th year BDS students and 3rd and 4th year BSC Nursing students participated in the Pharmacovigilance Awareness Program. The impact of Pharmacovigilance awareness program reflected as gain of knowledge in Pharmacovigilance.

Pharmacovigilance Awareness program was conducted to impress upon them ADR monitoring and educating the patient about ADRs are two important duties of the medical professional and to cultivate the habit of reporting ADRs.

Nurses are the health care workers, who administer drugs to patients, record vitals and document lab data. They observe the inpatient round the clock. Nurse is the first person to notice any change in a patient's health condition. Educating nurses about ADR monitoring and National Pharmacovigilance Program of India not only improves the patient safety but also the ADR reporting. Educating nursing students about Pharmacovigilance is a wise idea. [8]

Awareness about Pharmacovigilance was very limited in all students, which was reflected in pretest Knowledge score. All three groups' scores were around 30%. BSc Nursing students Knowledge average score was the lowest at 28%, MBBS students' knowledge average score 33% which is more than BDS and BSc Nursing students. The impact of Pharmacovigilance Awareness program was very satisfactory and is reflected as increase in their Knowledge scores in the post-test, which was more than 70%. Surprisingly, in the post-test BSc Nursing Students Knowledge average score was 85% which is more than MBBS and BDS students, whose Knowledge scores are 70% and 73%. This may be because of the one and half hour-long, detailed and interactive Pharmacovigilance educational program conducted for the BSc Nursing students after the pretest, whereas for MBBS and BDS students it was forty five minutes long.

Attitude of MBBS, BDS and BSc Nursing students towards Pharmacovigilance was positive. 93% of MBBS, BDS and BSc Nursing students expressed that establishing ADR monitoring centers in every hospital is required and reporting ADRs to PvPI was necessary. This indicates that the students are deeply concerned about patient safety.

Student's Participation in Pharmacovigilance Activities: Nearly half of the MBBS and BSc Nursing students and one quarter of BDS students know about the presence of ADR monitoring center in Osmania medical College. Govt Dental College & Hospital situated in separate campus may be the reason for BDS students' unawareness about presence of AMC in Osmania Medical College.

Students' exposure to ADRs was directly proportionate to their clinical experience. MBBS students, who participated in this awareness program, had less than six months of clinical experience and during this period, students tend to focus most of their attention toward learning clinical examination. Only 17% of MBBS students had an exposure to ADRs. For the Pharmacovigilance Awareness Program conducted in Govt Dental College 3rd, 4th year BDS students and internees participated. Their clinical exposure is 1, 2 and more than 2 years respectively, but it was limited to dental patients only with no general patient exposure. This might be the reason for only 33% of Dental students stating their exposure to ADRs. 81% of BSc Nursing students exposed to ADRs which reflects their clinical exposure.3rd and 4th year BSc Nursing students participated in the Awareness program. BSc Nursing students, while providing nursing care, visit every patient in the ward where the patient shares health problems with nurses. Number of patients visited by the nursing student is always more than the medical and dental students. In training the nursing staff, doctor advice nurses on what are the likely symptoms of an adverse reaction for a given drug.[9] They also have the advantage of firsthand exposure to ADRs as the patients approach nurses as a immediate response to any discomfort caused. This would be the reason for 81% of BSc Nursing students' experience of ADRs.

MBBS, BDS and BSc Nursing students were benefited by the Pharmacovigilance Awareness Program. They were provided with ADR reporting forms and detailed about how to fill the ADR forms, various ways to report ADRs to PvPI and about drug alerts. This type of Pharmacovigilance Awareness Programs should be conducted every year, to fulfill this it should be included in the academic curriculum. Medical students should work on ADR case studies and they should report the same to PvPI or to AMC in their Medical College, so that they will understand the clinical application of knowledge gained in Pharmacovigilance Awareness Programs.

Conclusion: Pharmacovigilance Awareness Programs were conducted for MBBS, BDS and BSc Nursing students in Osmania Medical College, Telangana. Pre-test and post-test conducted to assess their current knowledge in Pv, attitude and practice towards Pharmacovigilance and to evaluate knowledge gained by students from Pharmacovigilance awareness program. Inspection of pre and post-test results indicate significant increase in knowledge on Pv. Students learnt how to report ADRs. We can conclude that Pharmacovigilance should be added to the academic curriculum for BSc Nursing, MBBS and BDS students to improve clinical awareness and patient safety.

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