

KNOWLEDGE AND AWARENESS ABOUT PHARMACOVIGILANCE AMONG 2ND YEAR MBBS STUDENTS AT GOVERNMENT MEDICAL COLLEGE AND HOSPITAL

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Article Received on
31 January 2018,

Revised on 21 Feb. 2018,
Accepted on 14 March 2018,

DOI: 10.20959/wjpr20187-11557

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ABSTRACT

Background: Pharmacovigilance can be helpful in protecting patients from harmful effects of medicines. Under reporting of Adverse Drug Reactions (ADRs) is a common problem in Pharmacovigilance programs. Poor knowledge of pharmacovigilance leads to development of poor awareness which further leads to poor practice of pharmacovigilance. These medical students of today will be doctor's of tomorrow. They should consider adverse drug reaction (ADR) reporting as their professional obligation and should be aware of the existing pharmacovigilance mechanisms in their countries. According

to WHO Pharmacovigilance is "The science and activities which are related to the detection, assessment, understanding, and the prevention of adverse effects or any other drug-related problems." Every hospital should have a pharmacovigilance centre for adverse drug reactions reporting. **Objectives:** The purpose of the study was to assess the knowledge and awareness of pharmacovigilance & ADR reporting among 2nd year MBBS students and to evaluate the impact of an educational intervention. **Methods:** A suitable self-administered knowledge and awareness survey questionnaire was designed, based on previous studies. An interventional educational activity was organized and the impact of the educational intervention was evaluated by again administering the similar questionnaire. The statistical analysis was carried for comparing the pre- and post-intervention. **Results:** It was seen that the Knowledge and awareness of pharmacovigilance among the medical students were low which was understandable as these students were never exposed to educational intervention on Pharmacovigilance. The results also showed that there was an improvement about the over all perception of pharmacovigilance after an educational intervention. **Conclusions:** The

Knowledge and awareness of pharmacovigilance is low among medical students. These medical students of today are doctor's of tomorrow so regular educational intervention on pharmacovigilance can improve their perception about pharmacovigilance which is so important for each and every patient's safety.

KEYWORDS: Adverse drug reactions, Under reporting, Knowledge, Awareness, Pharmacovigilance, Educational intervention.

INTRODUCTION

Whenever we talk about a drug two aspect of it always comes in our mind one is efficacy and the other is safety.^[1] The efficacy of a drug can be easily quantified however the same cannot be said about the safety of a drug. The reason being the adverse effect of a drug may be uncommon (although very serious), and many patients may be affected or even subjected to a potential risk before the causal association relationship of a drug and adverse effect is established.^[2,3] Adverse drug reaction (ADR) is defined by World Health Organization (WHO) as "a response to a drug that is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function".^[4] ADR is related with significant mortality and morbidity. It is fourth leading cause of death in USA.^[4] Studies suggested that ADR is responsible for 0.2-24% of hospital admission.^[4] Adverse drug reactions (ADRs) are very important public health crisis striking a substantial financial burden on the society and health-care systems. It is one of the significant bases of hospitalization varying between 5% and 20%.^[5,6,7,8] In India the datas are very limited. An overall incidence of fatal ADRs is 1.8%.^[9] Minimum of one ADR has been reported to occur in 8% to 18% of hospitalized patients.^[10]

In order to identify the culprit drugs causing ADRs, many countries initiated pharmacovigilance programs in the past. As there is variation in drug response among individuals due to pharmacogenetics, prescribing habits, food habits, drug regulatory system and availability of drugs it has been recommended for every country to set up their own pharmacovigilance programs.^[11]

Pharmacovigilance is a science and activities relating to detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems WHO.^[12] The importance of pharmacovigilance was realised after Thalidomide Disaster in

1960s. This has forced many countries to set up their own observational systems for early detection of potential adverse drug reactions associated with drugs.^[13]

In a country like India, with a large population and vast diversity, it is necessary to introduce a standard pharmacovigilance program.^[5] Though pharmacovigilance program was started in India in 1982, the awareness about it is very less.^[14] It was revived in 2010 and a 5 years road map has been planned. Spontaneous ADR reporting schemes have been a major source of information in pharmacovigilance.^[15] One of the pivotal objectives of the spontaneous reporting of ADRs is to generate signals about new possible ADRs. Spontaneous reporting system basically relies on the voluntary reporting of suspected ADRs from health-care professionals and in some countries from the patients themselves. Spontaneous reporting can prevent the occurrence of new medicine tragedies and can improve the safety labeling of pharmaceutical products.^[15]

However, spontaneous reporting schemes are associated with relatively low levels of reporting. It is likely that less than 10% of serious reactions are notified. Problems of motivating reporters, commitment, and lack of clarity about what should be reported and fear of being accused for errors may be some of the factors responsible.^[15]

Good pharmacovigilance programs will identify the risks and the risk factors in the shortest possible time so that harm can be avoided or minimized.^[8,16]

When communicated properly, this information allows for the intelligent, evidence-based use of medicines and has the potential for preventing many adverse reactions.

ADRs are global problems of major concern. They affect both children and adults with varying magnitudes; causing both morbidity and mortality.^[17,18,19]

Physicians, pharmacist and nurses are in a position to play a major key role in pharmacovigilance programs.^[20,21]

The Uppsala Monitoring centre (UMC, WHO), Sweden is maintaining the international database of adverse drug reaction reports received ADRs report data from several national centers of different countries. Although, India is one of 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 professional in India.

In order to improve the reporting and successful running of a pharmacovigilance programme and also prevent underreporting of ADRs, it is important to improve the knowledge, attitude and practices (KAP) of the health care professionals regarding ADR reporting and pharmacovigilance. The best time to do it is probably during the under graduate level as these medical students will be the doctors of tomorrow But this is our duty as doctor to continue this activity during actual practicing.

Therefore this study was planned and primary objective was to evaluate the knowledge and attitude towards Pharmacovigilance and adverse drug reactions reporting among 2nd year MBBS students.

MATERIALS AND METHODS

Institutional Ethical Committee permission was taken to carry out this study.

Study design

This was a cross-sectional, questionnaire-based study which was conducted in 2nd year MBBS students at AIIMS Patna. All the 2nd year MBBS students of either age and sex were included in the study. Absent students and submission of incomplete forms were excluded from the study. The study included a pre-designed questionnaire and it was prepared by the Department of pharmacology AIIMS Patna based on previous studies.^[5,14,22]

Study procedure

The Knowledge and Attitude questionnaire included twenty three questions (1 to 15 related to knowledge and 16 to 22 related to attitude). A pre-test was conducted, they were given 30 min to answer the questions. A lecture of 45 minutes was presented by a senior resident of Pharmacology department AIIMS Patna.

The impact of effectiveness of educational intervention among students was evaluated by means of post-KAP questionnaire survey, with reference to previous study.^[5,14]

Statistical analysis

The filled questionnaire was analysed question wise and their percentage value was calculated with the help of using Microsoft Excel spread sheet in MS Office 2010.

RESULTS

A pilot study was done on 5 students who were not included in the study. The students were asked not to write their names or roll no on the questionnaire sheets to avoid any type of biasing. Out of total 98 students, 5 were absent on that day and two forms filled were incomplete so excluded from study. Analysis was done for rest 91 students.

It was seen that the knowledge and attitude or awareness of pharmacovigilance among 2nd year MBBS students were low. The results showed that there was an improvement after the educational intervention.

| Questions with options | Correct answer | Pre Test results | Post Test results |
|--|--|------------------|-------------------|
| 1. Pharmacovigilance is the study that is related to | c) Detection, assessment, understanding and prevention of adverse drug reactions | N= 91, N(%) | N= 91, N(%) |
| a) Therapeutic drug monitoring | | 32 (35) | 1 (1) |
| b) Safety and efficacy of drugs | | 35 (39) | 7 (8) |
| c) Detection, assessment, understanding and prevention of adverse drug reactions | | 23 (25) | 83 (91) |
| d) Rare drugs which is very beneficial to mankind. | | 1 (1) | 0 (0) |
| 2. Aim of Pharmacovigilance is | c) Safety | | |
| a) Efficacy | | 30 (33) | 3 (3) |
| b) Cost | | 17 (19) | 2 (2) |
| c) Safety | | 43 (47) | 85 (93) |
| d) None | | 1 (1) | 1 (1) |
| 3. Pharmacovigilance includes | d) All of the above | | |
| a) Herbal products and vaccines | | 18 (20) | 3 (3) |
| b) Medical devices | | 1 (1) | 1 (1) |
| c) Drug related problems | | 65 (71) | 7 (8) |
| d) All of the above | | 7 (8) | 80 (88) |
| 4. Pharmacovigilance Programme of India (PvPi) initially known as National Pharmacovigilance Programme (NPP) of India was officially inaugurated in the year: | a) New Delhi 2004 | | |
| a) New Delhi 2004 | | 61 (67) | 72 (78) |
| b) Ghaziabad 2005 | | 5 (5) | 16 (18) |
| c) Pondicherry 2001 | | 15 (17) | 3 (3) |
| d) Mumbai 2002 | | 10 (11) | 1 (1) |
| 5. PvPi in India is governed by: | d) CDSCO under the aegis of Health and Family Welfare | | |
| a) Medical Council Of India (MCI) | | 63 (69) | 15 (17) |
| b) Indian Council Of Medical Research (ICMR) | | 4 (4) | 2 (2) |
| c) Pharmacy Council Of India | | 17 (19) | 5 (5) |
| d) CDSCO under the aegis of Health and Family Welfare | | 7 (8) | 69 (76) |

| | | | |
|--|---|--------------------------------------|-------------------------------|
| 6. The International centre of Adverse Drug Reaction monitoring is located in | D) Sweden | | |
| A) Australia | | 5 (5) | 1(1) |
| B) United States Of America | | 56 (61) | 14 (15) |
| C) Germany | | 16 (18) | 0 (0) |
| D) Sweden | | 15(16) | 76(84) |
| 7. National Coordinating Centre for Pharmacovigilance in india is present in | b) IPC Ghaziabad | | |
| a) AIIMS Delhi | | 78(86) | 25 (28) |
| b) IPC Ghaziabad | | 4 (4) | 63 (69) |
| c) AIIMS Patna | | 5(6) | 1 (1) |
| d) JIPMER Pondicherry | | 4 (4) | 2 (2) |
| 8. Which one of the following is the “WHO online databases” for reporting ADRs | a) Vigiflow | | |
| a) Vigiflow | | 6(7) | 79 (87) |
| b) ADRs advisory Committee | | 70 (77) | 10 (11) |
| c) Google Scholar | | 5(5) | 1(1) |
| d) Medsafe | | 10(11) | 0 (0) |
| 9. Which of the following methods is commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market? | b) Post Marketing Surveillance (PMS) studies. | | |
| a) Meta analysis | | 33 (36) | 15(17) |
| b) Post Marketing Surveillance (PMS) studies. | | 21(23) | 73(80) |
| c) Population studies | | 25 (28) | 2 (2) |
| d) Regression analysis | | 12(13) | 1 (1) |
| 10. Rare ADRs can be identified in the following phase of a clinical trial | d) During phase-4 clinical trials | | |
| a) During phase-1 clinical trials | | 21 (23) | 3(3) |
| b) During phase-2 clinical trials | | 25 (28) | 1 (1) |
| c) During phase-3 clinical trials | | 24 (26) | 10 (11) |
| d) During phase-4 clinical trials | | 21 (23) | 77 (85) |
| 11. A serious adverse Event in India should be reported to the Regulatory body within | b) Within Seven calendar days | | |
| a) Within seven working days | | 26(29) | 25(28) |
| b) Within Seven calendar days | | 24 (26) | 59(65) |
| c) Within Fourteen calendar days | | 19 (21) | 7(7) |
| d) Within thirty calendar days | | 22 (24) | 0(0) |
| 12. The healthcare professionals responsible for reporting ADR in a hospital is/are | d) All of the above | | |
| a) Doctor | | 55 (61) | 8 (9) |
| b) Pharmacist | | 2(2) | 0(0) |
| c) Nurses | | 1(1) | 1(1) |
| d) All of the above | | 33 (36) | 82(90) |
| 13. Are you aware of any drug withdrawn from market due to safety reason? a) Yes b) No | a) Yes | a) Yes – 45 (49%) b) No- 46 (51%) | a) Yes- 91 (100) b) No - 0 |

| | | | |
|--|----------------------|-----------------------------------|-----------------------------------|
| 14. ADR reporting is required in following circumstances | | | |
| 1) When it is caused by herbal medicine a) Yes b) No | a) Yes | a) Yes- 58 (64) b) No- 33 (36) | a) Yes-76 (84) b) No-15 (16) |
| 2) When it is not certain that drug has caused the reaction a) Yes b) No | a) Yes | a) Yes- 40 (44) b) No- 51 (56) | a) Yes-63(69) b) No-28 (31) |
| 3) When it is caused by Over The Counter(OTC) drugs a) Yes b) No | a) Yes | a) Yes- 33 (36) b) No- 58 (66) | a) Yes- 77 (85) b) No- 14 (15) |
| 4) When it is caused by topical agents a) Yes b) No | a) Yes | a) Yes- 53 (58) b) No- 38 (42) | a) Yes- 69 (76) b) No- 22 (24) |
| 15. Which of the following scales is most commonly used to establish the causality of an ADR? | b) Naranjo algorithm | | |
| a) Hartwig scale | | 25 (27) | 22(24) |
| b) Naranjo algorithm | | 21 (23) | 51 (56) |
| c) Schumock and Thornton scale | | 29 (32) | 18 (20) |
| d) Karch & Lasagna scale | | 16 (18) | 0(0) |

Attitude

| Questions | Pre test N=91, N (%) | Post test N=91, N (%) |
|--|--|--|
| 16. Do you think adverse drug reaction reporting is necessary a) Agree b) Disagree | a) Agree- 56 (62) b) Disagree-35 (38) | a) Agree-79 (87) b) Disagree-12 (13) |
| 17. Do you think that ADR reporting system would benefit patient care a) Agree b) Disagree | a) Agree- 47 (52) b) Disagree-44 (48) | a) Agree-72 (79) b) Disagree-19 (21) |
| 18. Do you think it is necessary to confirm that an ADR is related to a particular drug before reporting it a) Agree b) Disagree | a) Agree-53 (58) b) Disagree-38 (42) | a) Agree-39 (42) b) Disagree-52 (58) |
| 19. Do you think pharmacovigilance reporting should be compulsory a) Agree b) Disagree | a) Agree-43(47) b) Disagree-48 (53) | a) Agree-64(70) b) Disagree-27 (30) |
| 20. Do you think that it is necessary to report only serious and unexpected reactions a) Agree b) Disagree | a) Agree-61(67) b) Disagree-30 (33) | a) Agree- 33 (36) b) Disagree-58 (64) |
| 21. Do you think reporting of seemingly insignificant ADRs is required a) Agree b) Disagree | a) Agree-22 (24) b) Disagree-69 (76) | a) Agree- 46 (51) b) Disagree-45 (49) |
| 22. Do you think ADR reporting should hide the identity of HCP's a) Agree b) Disagree | a) Agree-81(89) b) Disagree-10 (11) | a) Agree-69 (76) b) Disagree-22 (24) |

DISCUSSION

91 questionnaire sheets obtained from that many students. Q 1 to Q15 were related to the knowledge about pharmacovigilance. Question1 (Q1) sought the information about definition of pharmacovigilance pre study to post study result showed significant raise from 25% to 91%. Q2 was about aim of pharmacovigilance here pre study to post study result showed

significant raise from 47 % to 93%. Q3 was about the constituents of pharmacovigilance. Here pre study to post study result showed significant raise from 8% to 88%. Q4 was related to pharmacovigilance programme inauguration year in India. The pre study to post study result showed raise from 67% to 78%. Q5 was related to governance of pharmacovigilance programme in India. The pre study to post study showed raise from 8% to 76%. Q6 was related to the location of International centre of adverse drug reaction (adr) reporting. The pre study to post study showed raise from 16% to a significant 84%. Q7 was related to the location of national coordinating centre for pharmacovigilance in India. Here the pre study to post study showed raise from 4% to 69%. Q8 was related to the WHO online database for ADR reporting. Here the pre study to post study showed raise from 7% to 87%. Q9 was related to method commonly employed by the pharmaceutical companies to monitor adverse drug reactions of new drugs once they are launched in the market. Here the pre study to post study showed raise from 23% to 80%. Q10 was related to Rare ADRs can be identified in which of a clinical trial. Here the pre study to post study showed a raise from 23% to 85%. Q11 was related to time frame of reporting serious adverse event to the Regulatory body in India. The pre study to post study showed raise from 26 % to 65%. Q12 was related to the healthcare professionals responsible for reporting ADR in a hospital. The pre study to post study showed raise from 36% to 90%. Q13 was related to their awareness of any drug withdrawn from market due to safety reason. The pre study to post study showed raise from 49% to 100%. Q14 was related to ADR reporting in various circumstances. 1) When it is caused by herbal medicine. The pre study to post study showed raise from 64% to 84%. 2) When it is not certain that drug has caused the reaction. The pre study to post study showed raise from 44% to 69%. 3) When it is caused by Over The Counter(OTC) drugs. The pre study to post study showed raise from 36% to 85%. 4) When it is caused by topical agents. The pre study to post study showed raise from 58% to 76%. Q15 was related to the following scale most commonly used to establish the causality of an ADR. The pre study to post study showed raise from 23% to 56%.

Q-16 TO Q-22 was related to their attitude towards pharmacovigilance. Q16 was related to their thinking about adverse drug reaction reporting necessary or not for which pre test to post test study showed raise from 62% to 87%. Q17 was related to their thinking about whether ADR reporting system would benefit patient care for which pre study to post study showed raise from 52% to 79%. Q18 was related to about their thinking whether it is necessary to confirm that an ADR is related to a particular drug before reporting it. Here the

pre study to post study showed raise from 42% to 58 %. Here I would like to add upon that if a patient taking any drug by any route develops ADR he must report to the nearby ADR reporting centre. It is not necessary for the reporting doctor to confirm whether ADR is related to a drug. The confirmation of this relation of ADR with the drug has to be done by a team at ADR reporting centres. Q19 was related to their thinking whether pharmacovigilance reporting should be compulsory. Here the pre study to post study showed a raise from 47% to 70%. Q20 was related to their thinking whether it is necessary to report only serious and unexpected reactions. Here the pre study to post study showed raise from 33% to 64%. Q21 was related to their thinking about whether reporting of seemingly insignificant ADRs is required. Here the pre study to post study showed a raise from 24% to 51%. Q22 was related to their thinking whether ADR reporting should hide the identity of HCP's for which both pre and post study showed that majority of them wanted to hide the identity. This result was similar to previous study.^[23]

A study conducted by Salehifa et al.^[24] in which there is a lack of satisfactory knowledge of pharmacovigilance among nurses and pharmacists should educate nursing staff in reporting and managing ADRs. A study by Clarkson et al.^[25] showed that establishment of a proactive scheme like regional pediatric ADR monitoring center in Trent, UK successfully increased the reporting of suspected ADRs in that region and also improved awareness toward drug surveillance in children. A similar type of focused approach for drug surveillance for children was also shown to be very successful in North America by Carleton et al.^[26]

Conducting CME and various training sessions on pharmacovigilance and to not only the students but also prescribers about pharmacovigilance seems to be an immediate necessity. Therefore from findings of the present study and previous studies it can be summarized that the knowledge and over all awareness of pharmacovigilance among students which includes medical, dental, pharmacy and nursing are low and several steps like educational intervention (conducting CME) on pharmacovigilance, adding pharmacovigilance to the undergraduate curriculum, teaching pharmacovigilance to nurses and pharmacist, setting up of a regional pharmacovigilance center can bring about improvement in the field of pharmacovigilance. This can help to improve ADR reporting and which in turn will lead to decrease in medical and economic consequence due to ADRs, i.e. it will lead to decrease in hospital stay, decrease in cost of treatments and risk of deaths attributed to ADRs.

CONCLUSIONS

The knowledge and awareness of Pharmacovigilance is low among medical students. Educational intervention (CME), various training sessions on Pharmacovigilance can improve knowledge and awareness.

It will minimize the risk to patient's health and improves the safety of patient's health.

Funding: No funding sources.

Conflict of interest: None declared.

Ethical approval: The study was approved by the Institutional Ethics Committee.

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