Short and long-term impact of pharmacovigilance training on the pharmacovigilance knowledge of medical students

M. Aylin Arici, Ayse Gelal, Yucel Demiral1, Yesim Tuncok

Departments of Medical Pharmacology and 1Public Health, School of Medicine, Dokuz Eylul University, Balcova, Izmir, Turkey

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Correspondence to:
Dr. M. Aylin Arici,
E-mail: aylin.akgun@deu.edu.tr

ABSTRACT

Objectives: The aim of this study was to evaluate the short and long-term impact of pharmacovigilance (PV) training on the 5th year medical students’ knowledge about definitions and on the awareness of the regulatory aspects in PV.

Materials and Methods: In academic year 2010/11, the students completed structured, questionnaire before and just after training. They also completed the same questionnaire 1-year after the training.

Results: The students’ knowledge about PV significantly increased after training in the short term (P < 0.001). However, the improvement decreased significantly in the long-term (P < 0.001). Although long-term scores were higher than the baseline score, the difference was not statistically significant. Total scores were 17.5 ± 2.0, 20.8 ± 2.0 and 18.0 ± 2.5; before, at short and long-term after the training.

Conclusion: PV training increased the students’ knowledge significantly. However, in the long-term, the impact of the training is limited. Repeated training of PV should be planned.

KEY WORDS: Awareness, impact, knowledge, medical training, pharmacovigilance

Introduction

According to the World Health Organization (WHO) definition, pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) or any other drug-related problem. More than 130 countries including Turkey are part of the WHO PV program. The studies on PV have increased in our country after Turkish Pharmacovigilance Center (TUFAM) was established in 2005 and the related regulations were released. Spontaneous reporting by healthcare professionals (HCPs) has been shown to play an important role in identifying drug safety issues. However, underreporting of ADRs has been a real problem in PV. In order to improve the reporting rate, it is important to educate the HCPs. The most appropriate time to do so, is during the undergraduate and the postgraduate training of the doctors.

Just after the release of the regulations on PV, Dokuz Eylul University School of Medicine (DEUSM) implemented PV training program in the curriculum of 5th year medical students. The aim of the program was to increase the knowledge of medical students on PV and ADR and to enable them to develop the attitude and practice of spontaneous reporting.

We aimed to investigate the short and long-term impact of the PV training on the awareness and the knowledge of PV in 5th year medical students of DEUSM.

Materials and Methods

Pharmacovigilance training is imparted at the 5th year curriculum of medical students in DEUSM. The training on PV, imparted to small groups of 10–12 students, consists of 1-h of theoretical information, followed by 1-h of ADR reporting practice.

This prospective study was conducted after approval from the Institutional Ethics Committee of the DEUSM (25.08.2011 no: 29-13/2011).

A structured questionnaire was used. Questions were divided into four groups: Group 1 questions tested the knowledge of TUFAM and written regulations for monitoring drug safety, group 2 questions tested the knowledge of WHO’s ADR, serious ADR (sADR) and unexpected ADR (uADR) definition, group 3 questions tested the knowledge of qualified professionals to
report an ADR according to regulations, group 4 questions tested the knowledge of the minimum criteria of ADR reporting.

The students completed the questionnaire before and just after PV training in academic year 2010/11. They completed the same questionnaire 1-year after (2011/12) the training in order to determine long-term effects of PV training. The completed questionnaires were named as questionnaire 1, 2, and 3, respectively.

**Statistical Analysis**

All collected data were recorded in Microsoft Excel (Microsoft Corp, Redmont, WA, USA). Correct answers were graded as one point and false answers were graded as zero point. The total score was 29. Statistical Package for Social Sciences for Windows 15.0 (SPSS 15.0 Inc.; Chicago, IL, USA) was used for the statistical analysis. Differences between the results of the questionnaires were assessed by using repeated measures ANOVA, followed by Bonferroni post-hoc test when distributed normally and the Friedman’s ANOVA test, followed by Wilcoxon signed rank test when distributed not normally. P < 0.05 was considered to be statistically significant. Bonferroni correction was applied for the multiple comparisons in post-hoc Friedman’s test statistics and significance level reduced to P < 0.016.

**Results**

Total number of the students in the 5th year was 117 in academic year 2010/11 but 77 students (65.8%) completing all three questionnaires were include for analysis. The mean age of the students were 23.1 ± 0.1 (range: 21–26). Female/male ratio was 0.87.

**Students’ Answers to Group 1 Questions**

The students were tested for their awareness about the ADR reporting center and the regulations for drug safety. After the training, all students correctly answered the group 1 questions. In the questionnaire administered 1-year after the training, 29.8% of the students remembered the name of TUFAM. Whereas most of the students were still aware of the presence of a PV center and related regulations in Turkey [Table 1].

**Students’ Answers to Group 2 Questions**

Questions about the definition of ADR were answered correctly by 72.7–93.5% of the students before the training. The total score of the correct answers was 8.5 out of 10. The score increased significantly after the training (P < 0.05). When ADR knowledge was tested using hypothetical case examples, the majority of the students knew which ADR was serious before the training. The total score of the correct answers was 4.2 out of 5. The score increased significantly just after the training (P < 0.01). However, the scores decreased significantly after 1-year.

The number of the students who gave correct answers to questions about the definitions of sADR and uADR increased just after the PV training and these were still high after 1-year [Table 2].

**Students’ Answers to Group 3 Questions**

Correct answers to the question “according to the regulations are the following HCPs responsible for reporting ADR?” increased significantly just after the training (P < 0.001). However, the number of correct answers decreased after 1-year [P < 0.001, Table 3].

**Students’ Answers to Group 4 Questions**

Just after the training, the number of the students who answered correctly to the questions about ADR reporting increased (P < 0.001). However, the results decreased after 1-year [P < 0.001, Table 3].

**Total Score**

The students’ knowledge about PV significantly increased after the training in the short term (P < 0.001). However, the increment decreased in the long-term (P < 0.001). Although long-term scores were still slightly higher than the baseline score, the difference was not statistically significant. Consecutive total scores were 17.5 ± 2.0, 20.8 ± 2.0 and 18.0 ± 2.5 in the first, second and third questionnaires, respectively.

**Discussion**

Spontaneous ADR reporting is an important tool of ADR reporting in the of national PV system. It was shown that medical students’ or physicians’ knowledge about PV was inadequate in some countries [7,8,10,11] and it was reported that ADR reporting’s increased after the training [14]. Therefore, medical students’ training is very important to increase ADR reporting [5,7,8,12].

The importance of the ADR reporting was recognized by pharmacologists after the establishment of national PV system and legal regulations in 2005 and in many medical and pharmacy faculties, some revisions were made in their curriculum. In our university, 5th year medical students have been attending 2 h sessions –1-h theoretical and 1-h practical related to basic definitions and regulations of PV since 2005. In this study, the knowledge of 5th year medical students about ADR reporting and Turkish PV program was evaluated before, just after and 1-year after the PV training. Overall, the knowledge of students increased soon after the training. However, the increase did not remain steady except for the awareness of the existence of the TUFAM and the presence of the PV regulations in Turkey.

In many studies HCPs have some knowledge about the PV program and their spontaneous ADR reporting rate was low and one of the reasons for this was inadequate awareness of reporting ADRs [9,13,14]. These show the importance of the PV training [5,14]. The rate of spontaneous ADR in HCPs who learned about the importance of reportings, how to report an...
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The number (n), percentage and the total scores of the students who gave correct answers for group 2 questions testing the knowledge of WHO ADR, sADR and uADR definition in questionnaires (n=77)

| Definitions | Questionnaire | 1 | 2 | 3 |
|-------------|---------------|---|---|---|
| AE is an undesired effect of drugs in therapeutic dose | 72 (93.5) | 74 (96.1) | 71 (92.2) |
| AE is an undesired effect of drugs in high dose | 65 (84.4) | 71 (92.2) | 60 (77.9) |
| AE is an undesired effect of drugs depending on their pharmaceutical form | 58 (75.3) | 61 (79.2) | 54 (70.1) |
| Causality relationship isn’t necessary for AE definition | 56 (72.7) | 72 (93.5) | 56 (72.7) |
| Only sADR should be reported for newly marketed agents | 77 (100.0) | 77 (100.0) | 77 (100.0) |
| Only ADR defined in prospectus should be reported for newly marketed | 61 (79.2) | 46 (59.7) | 45 (58.4) |
| Only ADR not defined in prospectus should be reported for newly marketed | 74 (96.1) | 77 (100.0) | 75 (97.4) |
| Only sADR should be reported for established products | 69 (89.6) | 75 (97.4) | 69 (89.6) |
| Only ADR defined in prospectus should be reported for established products | 55 (71.4) | 62 (80.5) | 47 (61.0) |
| Only ADR not defined in prospectus should be reported for established products | 69 (89.6) | 74 (96.1) | 68 (88.3) |

Score (maximum=10)

| | Mean±SD | Median |
|-------------------------------|---------|--------|
| Questionnaire 1 | 8.5±1.2 | 9.0 |
| Questionnaire 2 | 8.9±1.3* | 9.0 |
| Questionnaire 3 | 8.1±1.4** | 8.0 |

Median

| Definitions n (%) | Questionnaire | 1 | 2 | 3 |
|-------------------|---------------|---|---|---|
| Generalized skin eruption and serious pruritus following the use of ampicillin | 47 (61.1) | 54 (70.1) | 43 (55.8) |
| Stomach bleeding following the use of varfarin | 68 (88.3) | 76 (98.7) | 68 (88.3) |
| Renal failure following the use of gentamicin | 72 (93.5) | 76 (98.7) | 73 (94.8) |
| Anaphylaxia following the use of intramusculer penicillin | 72 (93.5) | 76 (98.7) | 70 (90.9) |
| Cardiovascular malformation in a baby following the use of retinoic acid during mother’s pregnancy | 72 (93.5) | 76 (98.7) | 75 (97.4) |

Score (maximum=5)

| | Mean±SD | Median |
|-------------------------------|---------|--------|
| Questionnaire 1 | 4.2±0.9 | 4.0 |
| Questionnaire 2 | 4.6±0.5** | 5.0 |
| Questionnaire 3 | 4.2±0.8** | 4.0 |

Definitions n (%)

| | Questionnaire | 1 | 2 | 3 |
|-------------------|---------------|---|---|---|
| What is uADR | 5 (6.4) | 31 (40.3) | 31 (40.3) |
| What is sADR | 35 (45.5) | 75 (97.4) | 59 (76.8) |

*P<0.05 versus questionnaire 1, **P<0.001 versus questionnaire 2, ***P<0.001 versus questionnaire 1. ADR=Adverse drug reaction, sADR=Serious ADR, uADR=Unexpected ADR, SD=Standard deviation, AE=Adverse effect

ADR and the role of PV system were high. We think that our students will be serious about spontaneous ADR reporting in their professional life because most of them were aware of the existence of a national PV center and regulations in Turkey in their internship 1-year after the training.

The questions about the ADR definitions in the questionnaire were answered correctly by most of the students before the training because they had learning objectives about ADR of the drugs in previous years in their curricula. The number of the students who knew the definitions sADR increased just after the training. However, the number of the students who knew the definition of uADR were also low just after the training. Therefore, PV trainings must emphasize on how to report. We also trained the students about how to report ADRs and which information should be included in the PV form. In our study, a great number of the students answered all the questions on the minimum information that should be included in a report in order for it to be valid, 1-year after the training was given during their internship. This suggests that 1-year after the training most of the students will fill the ADR reporting form easily in the future.

Students’ knowledge level and awareness on PV were limited 1-year after training. This demonstrates our lectures training are inadequate and continuous training programs are needed.

Conclusion

The undergraduate medical students are prospective prescribers of society. Therefore, increasing awareness about PV program through training starting in medical school appears to be necessary to enhance reporting. The effects of the
Table 3:
The number (n), percentage and the total scores of the students who gave correct answers to group 3 and 4 questions testing the knowledge of qualified professionals to report an ADR according to regulations and testing the knowledge of ADR reporting in questionnaires (n=77), respectively

| Questionnaire | 1   | 2   | 3   |
|---------------|-----|-----|-----|
| **Knowledge of qualified professionals to report an ADR n (%)** |     |     |     |
| Medical doctor | 77 (100.0) | 77 (100.0) | 76 (98.7) |
| Dentist | 75 (97.4) | 75 (97.4) | 70 (90.9) |
| Pharmacist | 50 (64.9) | 71 (92.2) | 56 (72.7) |
| Nurse | 51 (66.2) | 71 (92.2) | 51 (66.2) |
| Physiotherapist | 13 (16.9) | 64 (83.1) | 39 (50.6) |
| Medical faculty student | 49 (63.6) | 68 (88.3) | 47 (61.0) |
| Health technician | 41 (53.2) | 60 (77.9) | 46 (69.7) |
| **Score (maximum=7)** |     |     |     |
| Median | 5.0 | 7.0 | 5.0 |
| **Knowledge of ADR reporting in questionnaires n (%)** |     |     |     |
| The identity of the patient | 43 (55.8) | 47 (61.0) | 28 (36.4) |
| The commercial name of the drug | 77 (100.0) | 77 (100.0) | 74 (96.1) |
| The information regarding the use of the drug | 76 (98.7) | 68 (88.3) | 65 (84.4) |
| The information about AE | 77 (100.0) | 77 (100.0) | 74 (96.1) |
| The identity of the reporter | 48 (62.3) | 75 (97.4) | 67 (87.0) |
| The address of the reporter | 32 (41.6) | 67 (87.0) | 60 (77.9) |
| The signature of the reporter | 56 (72.7) | 73 (94.8) | 65 (84.4) |
| **Score (maximum=7)** |     |     |     |
| Median | 5.0 | 7.0 | 6.0 |

***P<0.001 versus questionnaire 1, **P<0.001 versus questionnaire 2. ADR=Adverse drug reaction, SD=Standard deviation, AE=Adverse effect

educational intervention, however, were temporary and hence regular retraining is essential.

References
1. World Health Organization. WHO Policy Perspectives on Medicines. Looking at the Pharmacovigilance: Ensuring the Safe Use of Medicines. Geneva: WHO; 2004. Available from: http://www.whoqolbdoc.who.int/hq/2004/WHO_EDM_2004.8.pdf. [Last accessed on 2014 Apr 10].
2. Guide for the Monitorization and Evaluation of the Medicinal Products. Published in Official Gazete in 30th March, 2005 to Became Valid 30th June, 2005. Available from: http://www.rega.basbakanlik.gov.tr/. [Last accessed on 2014 Apr 10].
3. Begum SS, Mansoor M, Sandeep A, Mahadevamma L, Krishnagoudar BS. Tools to improve reporting of adverse drug reactions – A review. Int J Pharm Sci Rev Res 2013;23:262-5.
4. Chopra D, Wardhan N, Rehan HS. Knowledge, attitude and practices associated with adverse drug reaction reporting amongst doctors in a teaching hospital. Int J Risk Saf Med 2011;23:227-32.
5. Gupta P, Udopa A. Adverse drug reaction reporting and pharmacovigilance: Knowledge, attitudes and perceptions amongst resident doctors. J Pharm Sci Res 2011;3:1064-9.
6. Hema NG, Bhuvana KB, Sangeetha. Pharmacovigilance: The extent of awareness among the final year students, interns and postgraduates in a government teaching hospital. J Clin Diag Res 2012;6:1248-53.
7. Naritoku DK, Faingold CL. Development of a therapeutics curriculum to enhance knowledge of fourth-year medical students about clinical uses and adverse effects of drugs. Teach Learn Med 2009;21:148-52.
8. Shankar PR, Subish P, Mishra P, Dubey AK. Teaching pharmacovigilance to medical students and doctors. Indian J Pharm 2006;38:316-9.
9. Pimpalkhute SA, Jaiswal KM, Sontakke SD, Bajait CS, Gaikwad A. Evaluation of awareness about pharmacovigilance and adverse drug reaction monitoring in resident doctors of a tertiary care teaching hospital. Indian J Med Sci 2012;66:55-61.
10. Rehan HS, Vasudev K, Tripathi CD. Adverse drug reaction monitoring: Knowledge, attitude and practices of medical students and prescribers. Natl Med J India 2002;15:24-6.
11. Vora MB, Palival NP, Desai CK, Panchal J, Shah S, Dikshit RK. An evaluation of knowledge, attitude and practices of medical students and prescribers. Natl Med J India 2003;16:158-60.
12. Upadhyaya PA, Seth V, Moghe VV, Sharma M, Ahmed M. Knowledge of adverse drug reaction reporting among first year postgraduate doctors in a medical college. Ther Clin Risk Manag 2012;8:307-12.
13. Oshikoya KA, Senbanjo IO, Amole OO. Interns’ knowledge of clinical pharmacology and therapeutics after undergraduate and on-going internship training in Nigeria: A pilot study. BMC Med Educ 2009;9:50.
14. Hardeep, Bajaj JK, Rakesh K. A survey on the knowledge, attitude and practice of pharmacovigilance among the health care professionals in a teaching hospital in northern India. J Clin Diagn Res 2013;7:97-9.
15. Pedrós C, Vallano A, Cereza G, Mendoza-Aran G, Agustí A, Aguilera C, et al. An intervention to improve spontaneous adverse drug reaction reporting by hospital physicians: A time series analysis in Spain. Drug Saf 2009;32:77-83.
16. Desai CK, Iyer G, Panchal J, Shah S, Dikshil RK. An evaluation of knowledge, attitude, and practice of adverse drug reaction reporting among prescribers at a tertiary care hospital. Perspect Clin Res 2011;2:129-36.

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