

RESEARCH ARTICLE

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Knowledge and Attitudes of Resident Physicians about Adverse Drug Reactions

ABSTRACT

Objective: WHO reported to all healthcare providers in its universal message that thousands of patients' lives could be saved by reporting adverse drug reactions (ADRs). In this study, we aimed to evaluate the knowledge levels and attitudes of the resident physicians about ADRs and pharmacovigilance in our university hospital.

Methods: This prospective study was performed by a questionnaire form consisted of 14 questions on 88 resident physicians who accepted to participate the study in Harran University Hospital. The study was started after taking the approval of Harran University Faculty of Medicine Ethics Committee. The results of the questionnaire were evaluated by using SPSS 18.0 package program by frequency and percentage tests.

Results: The exact definition of ADRs is correctly marked by 51.1% of doctors. Most of the physicians (69.3%) stated that they had never do ADR reporting. The rate of the participants who think that it is not the responsibility of the healthcare professionals to make ADR reporting is 9.1%. It was observed that only 6.8% of the physicians received professional information or training on ADR reporting. It was expressed by 72.7% of physicians that ADR is a serious problem in Turkey.

Conclusions: This study showed that the level of knowledge and attitude of resident physicians working in our hospital about ADR reporting was not sufficient. We believe that it is important to raise awareness among the healthcare professionals about the ADR reporting and the situation can be improved by effective and periodical training methods.

Keywords: Adverse Drug Reaction, Attitude, Knowledge, Physician.

Asistan Hekimlerin Olumsuz İlaç Reaksiyonları Konusundaki Bilgi ve Tutumları

ÖZET

Amaç: DSÖ, evrensel mesajında tüm sağlık hizmeti sağlayıcılarına, Advers İlaç Reaksiyonlarının (AİR) raporlanması sayesinde binlerce hastanın hayatının kurtarılabilceğini bildirmiştir. Bu çalışmada üniversite hastanemizdeki asistan hekimlerin AİR ve farmakovijilans konusundaki bilgi düzeylerini ve tutumlarını değerlendirmeyi amaçladık.

Gereç ve Yöntem: Bu prospektif çalışma, Harran Üniversitesi Hastanesi'nde çalışmaya katılmayı kabul eden 88 asistan hekim üzerinde 14 sorudan oluşan bir anket formuyla gerçekleştirildi. Çalışmaya Harran Üniversitesi Tıp Fakültesi Etik Kurulu onayının alınmasından sonra başlandı. Anketin sonuçları SPSS 18.0 paket programı kullanılarak frekans ve yüzde testleri ile değerlendirildi.

Bulgular: AİR'lerin kesin tanımı doktorların %51,1'i tarafından doğru bir şekilde işaretlenmiştir. Hekimlerin çoğu (%69,3) hiçbir zaman AİR raporlaması yapmadığını belirtmiştir. AİR raporlaması yapmanın sağlık profesyonellerinin sorumluluğu olmadığını düşünen katılımcıların oranı %9,1'dir. Hekimlerin sadece %6,8'inin AİR raporlaması hakkında mesleki bilgi veya eğitim aldığı gözlemlenmiştir. Hekimlerin %72,7'si Türkiye'de AİR'in ciddi bir sorun olduğunu düşünmektedir.

Sonuç: Bu çalışma hastanemizde çalışan asistanların AİR raporlaması konusundaki bilgi ve tutum düzeylerinin yeterli olmadığını göstermiştir. AİR'lerin raporlanması konusunda sağlık uzmanları arasında farkındalığın artırılmasının önemli olduğuna ve durumun etkili ve periyodik eğitim yöntemleriyle iyileştirilebileceğine inanıyoruz.

Anahtar Kelimeler: Advres İlaç Reaksiyonu, Tutum, Bilgi, Hekim

INTRODUCTION

A side effect is described as any undesirable effect of a pharmaceutical product at normally doses, related to the pharmacological properties of the drug. Any symptoms or disease, including an abnormal laboratory finding related to the use of drugs or not, may be considered an adverse event (1, 2).

ADRs are harmful, undesirable reactions that occur at doses, normally used against drugs and classified as serious and non-serious. Especially in elderly, inappropriate drug prescribing is one of the most common reasons for the development of ADRs (3).

WHO reported to all healthcare providers in its universal message that thousands of patients' lives could be saved by reporting ADRs (2).

In clinical trials, products can be explored in a limited number of selected populations. But, after the release of drugs, up to millions of people will be used and people with different diseases will be exposed to these new products. Additionally, some special groups like children elderly and pregnant women are excluded from clinical trials, since it's thought not to be ethical. Whether drugs are safe in these groups cannot be established until they are released (4, 5). For this reason, rare side effects, side effects that can be seen as a result of chronic exposure and also many drug-drug interactions may only be detected after the drug is released (5, 6).

It is known that serious health problems and hospitalization rates are increasing due to ADRs and therefore the ADRs are considered as an important public health issue. It is reported that ADRs constitute approximately 6.5% of all hospital admissions and 15% of ADRs develop in patients who are hospitalized and treated. In the United States in 0.32% of all hospitalized patients fatal adverse drug reactions being expected (7, 8).

According to Turkey Pharmacovigilance Center (TPC), the rate of ADR per year was 1.5 for one million people in 2005, while it increased to 32.1 in 2013 (9). The percentage of patients reported an ADR during hospitalization has been ranged between 1.5- 35 % in recent studies (10).

Against the chance of side effects due to drug use, TPC is developing protective measures in Turkey. By this way mortality and morbidity rates due to preventable events can be reduced. ADR reporting is one of the main data sources of TPC (11).

Reporting of ADRs can be done by spontaneously and accumulated. Spontaneous reporting is used in many countries to improve pharmacovigilance. Spontaneous ADR reporting aims to improve the system of recognition of early signals for drug toxicity not previously recognized (12, 13).

It is known that the responsibility to reporting ADRs belong to medical care providers such as medical doctors, nurses, pharmacists and

databases can be developed worldwide, especially with the leadership of doctors for self-reporting (2, 11, 14).

As far as we know, there is only a few number of studies on the knowledge and attitudes of physicians about adverse event reporting and pharmacovigilance in Turkey (14-16).

However, there is no study for physicians working in our university hospital. In this study, we aimed to evaluate the knowledge levels and attitudes of the resident physicians about ADRs and pharmacovigilance in our university.

MATERIAL AND METHODS

A prospective study was designed and performed by using a questionnaire form consisting of 14 questions to evaluate the knowledge and attitudes of the physicians about the reporting of ADRs. The study was started after the approval of Harran University of Faculty of Medicine Ethics Committee was taken at the meeting dated 27.06.2014 numbered 07-12. Among the 131 resident physicians working at Harran University Hospital, 88 people who agreed to participate in the study were included in the study. The questionnaire, which was prepared by the researchers by scanning the literature, was validated on 15 resident physicians. The results of the questionnaires were evaluated by using SPSS 18.0 package program by frequency and percentage tests. The resident physicians, who agreed to participate in the research, filled the questionnaire and collected the data. The data were evaluated with frequency and percentage tests using SPSS 18.0 package program.

RESULTS

Numbers of male physicians were 59 (67.05%) and female were 29 (33.95%). The mean age was 29.1 ± 3.1 years. The responses of physicians to the knowledge and attitude related questions such what ADR is, whether they have made ADR notification and how much reports are presented in Table 1. When participants were asked to give an example to ADRs, 63.6% replied as "diarrhea after antibiotic use", 23.9% of the responses were "drowsiness after using cough syrup" and 8.0% of were "accidents after drinking cough syrup". The rate of the participants reported that they had no idea was 4.5%. The ratio of the answers given to the question "to whom the ADR reaction should be reported"; 65.9% were to pharmacovigilance officers, 26.1% were to the doctors, 6% were to the pharmacists and 1.1% were to the nurses. When the physicians were asked the question "Who do you think is more susceptible to the adverse drug reaction?", 38.6% stated elderly people, 22.7% children, while 38.6% stated there would be no difference between individuals. Only 6.8% of the physicians stated that they received a

professional information or training about the ADRs notification.

When the participants were asked "how the ADR reporting method should be", 69.3% of the answers were "by computer filling forms", 12.5% "by filling out the forms manually", 8.0% "by phone reports". The rate of those who did not comment on this question was 10.2%. About the necessity of

informing patients about ADRs, 93.2% of doctors thought that it was necessary to inform patients. When resident physicians were asked how the method of informing patients about ADRs should be, 62.5% of the answers were "by doctors", 20.5% were "by the information leaflet during hospitalization" and 15.9% were "by nurse".

Table 1. Responses of the physicians to the knowledge and attitude related questions.

ADR	N	%
What is an adverse drug reaction?		
The appearance of the harmful effects of drugs after taking at normal dose	45	51.1
The occurrence of side effects after taking drug	39	44.3
The occurrence of any of the undesired effects after taking the drug	3	3.4
No idea	1	1.1
As a healthcare professional, do you report any unexpected adverse effects that may be caused by the use of the medicinal product for human use and which may be thought to be related to the product?		
No	61	69.3
Yes	15	17.1
Reporting number		
1-2	11	12.5
3-5	2	2.3
6-10	1	1.1
More than 10	1	1.1
I never matched	12	13.6
*What is the reason for not reporting adverse drug reactions that you have identified?		
Being not sure, uncertainty	13	14.7
Insufficient time	18	20.3
Do not know where to report	41	46.5
Think that it is not the responsibility	8	9.1
Every time I did report	4	4.5
Others	15	17.0
What do you think is the purpose of reporting adverse drug reactions?		
To strengthen drug safety	45	51.1
To prevent the repetition of adverse drug reactions among other people	38	43.2
To help the doctor to determine ADRs	5	5.7
Are adverse drug reactions a serious problem in Turkey in your opinion?		
Yes	64	72.7
No	24	27.3

DISCUSSION

Although the reporting rate of ADRs has increased worldwide in the last decade, Güner et al. reported that this rate is relatively lower in Turkey compared to developed countries and health care providers are unaware of their responsibility for ADR reporting (9, 16). The reasons for underreporting may be the intensive working conditions, not knowing how and where the notification will be made and fear of misrepresentation (5). In the present study, it is seen that the ADR reporting rate is low, ADRs reporting system is not well known and not used adequately by physicians in our hospital.

The rate of the physicians who had no idea about ADR reporting is 1.1% in this study. Paveliuc et al. reported this rate as 4.7% (17). The definition of ADRs was correctly known by 51.1% of the

physicians in our study. Similarly, Şencan et al. reported this rate as 53.3% in their study (14).

The researchers reported that the proportion of participants who had never reported ADRs from both India (83.6%) and Romania (72.93%) were high. In our study, 69.3% of the physicians reported that they had never do ADR reporting. However, in a study performed in Bulgaria, this rate was lower (37.4%). Ergün et al. reported that only 8% of the physicians did ADR reporting and Altıntaş Aykan et al. showed that none of the physicians found to make any ADR reporting (15, 17-20).

Palaian et al. noted that the rate of not reporting ADRs due to not knowing where to be reported was as low as 3.6%. Although it was reported as 27.2% in another study from Turkey, our result was very high (46.5%) compared to other results (16, 21).

The rate of not doing ADR reporting is 20% due to not knowing where to report in the study by performed by Paveliu et al. in Romania. They reported that the most common cause of not reporting ADRs was uncertainty of the relationship between the drugs and ADRs (37.4%). Güner et al. found the result of uncertainty rate as 29.6%. This rate is twice of that of in our study (14.7 %). Khan et al. reported this rate as 30.9% in their study (16, 17, 22).

In this study the rate of the participants who think that it is not the responsibility of the healthcare professionals to make ADR reporting is 9.1%. Güner et al. found this rate to be 9.1% in the same way as in our study (16). This rate is reported as 2% by Ergün et al. and 19.1% by Palain et al. (15, 21).

Şencan et al. report that most (20%) of the physicians do ADR reporting to drug company while most of our participants (65.9%) were seen to report ADRs to pharmacovigilance officers (14).

Time deficiency as another reason for not reporting ADRs was reported as the second cause both in the present study (20.3%) and in Bulgaria (12.2%) whereas it was reported as 28.76% in Romania and 33.3% in Nigeria (17, 19, 23). Ergün et al. reported this rate higher (%55) than all of them (15).

Most common answer (51.1%) as a purpose for reporting ADRs is "drug safety" in the present study. Ergün et al. reported the most common answer (86%) given for the same question as "to define and determine new ADRs". In both studies, the second most common answer given as the reason for reporting ADRs was "safety and to prevent the repetition of adverse drug reactions among other people" (15).

The studies showed that training has a positive effect over gaining ADR reporting attitude (24-26). The participant doctors of the study of Khan et al. offer some methods as refresher courses and continuous medical education to improve ADR reporting status (22). In the present study only 6.8% of the physicians stated that they received a professional information or training on the ADR notification. Only %2 of the participants think that they are sufficiently trained about spontan ADR reporting in the study performed by Ergün et al. Stoyanova et al. found the training rate as 47.2% in the entry research of their survey. The rate of the

health professionals having sufficient knowledge about ADR reporting was found 34.2% in another study (15, 19, 27).

Özcan et al. reported that ADR reporting rate is observed to be high on elderly and females in Turkey. In this study most common answer as 38.6% of the physicians stated that elderly people is more susceptible to the ADRs (9).

In this study, the most common method of reporting an ADR (69.3%) is found to be done by computer filling forms. In another study that questioned the best method for obtaining a spontaneous reporting form, with the rate 59%, the e-mail method was found to be the most common way (15).

In the present study, 72.7% of the physicians consider an ADR as a serious problem in Turkey. Özcan et al. reported that many ADRs developed due to self-medication in Turkey (9). It is known that self-medication related ADRs cause widely public health problem not only in Turkey but also all over the world (28, 29).

CONCLUSION

In today's world unwanted drug reactions become a medically major problem as a result of increased drug use. Sharing global knowledge about adverse effects strengthens drug safety in countries and is important to ensure patient safety. ADRs can occur in all areas where health care services are provided, including the primary care department and hospitals. Not only for the hospital doctors but also for family physicians who meet patients at the first admission, it is vital to be aware of the adverse drug effects they face. As a result of the present study we have seen that despite their important role in ADR reporting system, knowledge and the attitude level of doctors about ADR reporting is not sufficient. In our estimation this has a negative effect on the ADR underreporting and may be clarified by further studies. We believe that it is important to raise awareness among the healthcare professionals about the ADR reporting system and the status can be improved by effective and periodical training methods.

Limitations: This study is a survey-based study; the results are only due to the answers of the participant.

Conflict of interest: The authors declare no conflicts of interest.

REFERENCES

1. Farcas A, Bojita M. Adverse drug reactions in clinical practice: a causality assessment of a case of drug-induced pancreatitis. *J Gastrointest Liver Dis.* 2009;18(3):353-8.
2. World Health Organization. Quality A, Safety of Medicines T. Safety of medicines : a guide to detecting and reporting adverse drug reactions : why health professionals need to take action. Geneva: World Health Organization; 2002.
3. Passarelli MCG, Jacob-Filho W, Figueras A. Adverse drug reactions in an elderly hospitalised population. *Drugs & aging.* 2005;22(9):767-77.
4. Leape LL. Error in medicine. *Jama.* 1994;272(23):1851-7.

5. Aykaç E, editor Farmakovijilansa Bakış ve Türkiye Farmakovijilans Merkezinin Çalışmaları. 12 Ulusal Aile Hekimliği Kongresi; 15-19 May 2013; Kuşadası-Aydın.
6. Brewer T, Colditz GA. Postmarketing surveillance and adverse drug reactions: current perspectives and future needs. *Jama*. 1999;281(9):824-9.
7. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *Bmj*. 2004;329(7456):15-9.
8. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *Jama*. 1998;279(15):1200-5.
9. Ozcan G, Aykac E, Kasap Y, Nemutlu NT, Sen E, Aydinkarahaliloglu ND. Adverse drug reaction reporting pattern in Turkey: analysis of the national database in the context of the first pharmacovigilance legislation. *Drugs-real world outcomes*. 2016;3(1):33-43.
10. Dormann H, Muth-Selbach U, Krebs S, Criegee-Rieck M, Tegeder I, Schneider HT, et al. Incidence and costs of adverse drug reactions during hospitalisation. *Drug safety*. 2000;22(2):161-8.
11. Türkiye İlaç ve Tıbbi Cihaz Kurumu TÜFAM. İyi Farmakovijilans Uygulamaları (İFU) Kılavuzu Modül I- Advers ilaç reaksiyonlarının yönetimi ve bildirimi. 2014 [cited 2020 June 20]. Available from: <https://www.titck.gov.tr/Dosyalar/Ilac/Farmakovijilans/%C4%B0FU%20Mod%C3%BCI%20I.pdf>.
12. Waller PC. Making the most of spontaneous adverse drug reaction reporting. *Basic & clinical pharmacology & toxicology*. 2006;98(3):320-3.
13. Dhikav V, Singh S, Anand K. Adverse drug reaction monitoring in India. *J Indian Acad Clin Med*. 2004;5(1):27-33.
14. Şencan N, Altınkaynak M, Ferah I, Özyıldırım A, Ceylan EM, Clark PM. The knowledge and attitudes of physicians and nurses towards adverse event reporting and the effect of pharmacovigilance training: A hospital experience. *Hacettepe Üniversitesi Eczacılık Fakültesi Dergisi*. 2010; 1:25-40.
15. Ergün Y, Ergün TB, Tokar E, Ünal E, Akben M. Knowledge attitude and practice of Turkish health professionals towards pharmacovigilance in a university hospital. *International health*. 2019;11(3):177-84.
16. Güner MD, Ekmekci PE. Healthcare professionals' pharmacovigilance knowledge and adverse drug reaction reporting behavior and factors determining the reporting rates. *Journal of drug assessment*. 2019;8(1):13-20.
17. Paveliu MS, Bengea-Luculescu S, Mihai T, Paveliu SF. Perception on adverse drug reaction reporting by physicians working in southern Romania. *Maedica*. 2013;8(1):17-25.
18. Singh J, Singh H, Rohilla R, Kumar R, Gautam C. Lack of awareness of pharmacovigilance among young health-care professionals in India: An issue requiring urgent intervention. *International Journal of Applied and Basic Medical Research*. 2018;8(3):158-63.
19. Stoyanova V, Getov IN, Naseva EK, Lebanova HV, Grigorov EE. Physicians' knowledge and attitude towards adverse event reporting system and result to intervention--randomized nested trial among Bulgarian physicians. *Medicinski Glasnik*. 2013;10(2):365-72.
20. Altıntaş Aykan D, Nazik H, Ergün Y. Advers İlaç Reaksiyonları Spontan Bildirimlerinin Değerlendirilmesi: Klinik Farmakoloji Deneyimimiz. *Kocaeli Tıp Dergisi*. 2019;8(2):230-9.
21. Palaiian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. *Pharmacy practice*. 2011; 9(4):228-35.
22. Khan SA, Goyal C, Chandel N, Rafi M. Knowledge, attitudes, and practice of doctors to adverse drug reaction reporting in a teaching hospital in India: An observational study. *Journal of natural science, biology, and medicine*. 2013;4(1):191-6.
23. Oshikoya KA, Awobusuyi JO. Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC clinical pharmacology*. 2009;9(1):14.
24. Fincham J. A statewide program to stimulate reporting of adverse drug reactions. *Journal of pharmacy practice*. 1989;2(4):239-44.
25. McGettigan P, Golden J, Conroy R, Arthur N, Feely J. Reporting of adverse drug reactions by hospital doctors and the response to intervention. *British journal of clinical pharmacology*. 1997;44(1):98-100.
26. Figueiras A, Herdeiro MT, Polónia J, Gestal-Otero JJ. An educational intervention to improve physician reporting of adverse drug reactions: a cluster-randomized controlled trial. *Jama*. 2006;296(9):1086-93.
27. Necho W, Worku A. Assessment of knowledge, attitude and practice of health professionals towards adverse drug reaction reporting and factors associated with reporting. *J Pharmacovigilance*. 2014;2(4):135. doi:10.4172/2329-6887.1000135
28. Asseray N, Ballereau F, Trombert-Paviot B, Bouget J, Foucher N, Renaud B, et al. Frequency and severity of adverse drug reactions due to self-medication: a cross-sectional multicentre survey in emergency departments. *Drug safety*. 2013;36(12):1159-68.
29. Schmiel S, Rottenkolber M, Hasford J, Rottenkolber D, Farker K, Drewelow B, et al. Self-medication with over-the-counter and prescribed drugs causing adverse-drug-reaction-related hospital admissions: results of a prospective, long-term multi-centre study. *Drug safety*. 2014;37(4):225-35.