



Investigation of Dentists' Opinions on Pharmacovigilance and Reporting of Adverse Effects

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Abstract

Objective: In this study, it was aimed to examine the experience, knowledge, and awareness of dentists about adverse drug effects and pharmacovigilance.

Methods: In this cross-sectional and descriptive study, a 15-question questionnaire was applied to 100 dentists who are working at Diyarbakir Oral and Dental Health Hospital to evaluate their knowledge, attitudes and practices about adverse effects and pharmacovigilance.

Results: 55 percent of dentists stated that they had never encountered an adverse drug reaction (ADR) in their professional life. Even though 45 percent of them reported that they have rarely seen ADR in their professional life, the total number of declarations has been determined as 7.78% of dentists are aware that declaration is required and this is a professional responsibility (86%). Physicians stated that they had no idea how to report ADRs with their current knowledge (81%) and subject of pharmacovigilance was not well covered in the dental education (55%). 86% of them stated that education on this subject should be taken at undergraduate level (internship, education, clinical assignment) and 58% stated that it should be taken in their working life after graduation.

Conclusion: This study showed that the dentists participating in the study had a lack of awareness and knowledge about pharmacovigilance and ADR. It was observed that the rate of ADR reporting among physicians was very low compared to the encounter rate. Inclusion of pharmacovigilance in the educational program and providing pre- and post-graduate training to dentists for declaration practices can contribute positively to public health.

Key words: Adverse Drug Reaction, Drug Safety, Pharmacovigilance

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Farmakovijilans ve Advers Etkilerin Raporlanması Üzerine Diş Hekimlerinin Görüşlerinin Araştırılması

Öz

Amaç: Bu araştırma ile farmakovijilans paydaşlarından ilaç reçete etme ve kullanma oranı fazla olan diş hekimlerinin, advers (ters) ilaç etkileri ve farmakovijilans konusundaki deneyim, bilgi düzeyi ve farkındalıklarının incelenmesi amaçlandı.

Yöntemler: Kesitsel ve tanımlayıcı tipte yapılan bu çalışmada, Diyarbakır Ağız Diş Sağlığı Hastanesinde diş hekimi olarak görev yapan 100 hekime advers etkiler ve farmakovijilans ile ilgili deneyim, bilgi düzeyi ve farkındalıklarını değerlendirmek için 15 soruluk anket uygulandı.

Bulgular: Diş hekimlerinin %55'i mesleki hayatlarında hiç advers ilaç reaksiyonu (ADR) ile karşılaşmadıklarını belirttiler. Yüzde 45'i meslek hayatlarında nadir olarak ADR gördüğünü bildirmiş olsa da toplam bildirim sayısı 7 olarak tespit edildi. Diş hekimlerinin %78'i bildirim yapılması gerektiğini ve bu işlemin bir mesleki sorumluluk (%86) olduğunun farkındadır. Hekimler mevcut bilgileri ile ADR'leri nasıl raporlayacakları hakkında bir fikirleri olmadığını (%81) ve diş hekimliği müfredatında farmakovijilans konusunun iyi işlenmediğini (%55) belirttiler. Bu konu ile ilgili eğitimin %86 oranında lisans düzeyinde (staj, eğitim, klinik görevlendirme) ve %58 oranında ise mezuniyet sonrası çalışma hayatında da alınması gerektiğini ifade ettiler.

Sonuç: Bu çalışma, araştırmaya katılan diş hekimlerinin farmakovijilans ve ADR konusunda farkındalık ve bilgi eksiklikleri olduğunu gösterdi. Hekimler arasında advers ilaç reaksiyonu bildirim oranının karşılaşma oranına göre çok düşük olduğu görüldü. Eğitim programına farmakovijilans konusunun dahil edilmesi ve bildirim uygulamaları için diş hekimlerine mezuniyet öncesi ve sonrası eğitim verilmesi ile halk sağlığı açısından olumlu katkı sağlanabilir.

Anahtar kelimeler: Advers İlaç Reaksiyonları, Farmakovijilans, İlaç güvenliği.

INTRODUCTION

Adverse effects, which are defined as the harmful and unintended effects of a drug in the use of normal doses for the prevention, diagnosis, treatment of the disease or the modification of a physiological function, have a significant impact on public health^{1,2}. Although reporting adverse drug reactions is a public health problem, it has been seen that not reporting these reactions increases the length of hospitalization by 5-20%, which creates a financial burden on the health system³. In addition, deaths due to adverse drug reactions (ADR) were reported at a rate of 3,7% in studies. Therefore; detection, registration, and reporting of ADR are vital⁴. With pharmacovigilance, which is defined as the activities and scientific studies carried out to detect, evaluate, understand and prevent adverse reactions and other drug-related problems, safe use of drugs is ensured and the harm they may cause can be minimized.

The fact that the drug thalidomide, which was used in different parts of the world in 1961-1962, caused birth defects in approximately 10 thousand children, brought the first efforts to address the issue of drug safety⁵. Following this disaster, a solution was adopted at the 16th World Health Congress (1963) that indicated the need for early action to systematically collect information on serious ADR during drug development and post-marketing. Pharmacovigilance term was first defined by the World Health Organization (WHO) in 1972 as 'any attempt to determine possible causal relationships between drugs in a particular population and the adverse effects of their use⁶. In 1978, the database, known as VigiBase, began to be managed by the Uppsala Monitoring Center (UMC). Members of the program submit reports of suspected adverse effects associated with drugs to the VigiBase system. The center then reviews and analyzes these international reports and shares the results with the member

states⁷. It is very important to establish national pharmacovigilance systems as well as international collaborations. Within the scope of pharmacovigilance studies in Turkey, Turkish Adverse Effects Monitoring and Evaluation Center (TADMER) was established in 1985. Later in 2005, the name of the center was changed to Turkish Pharmacovigilance Center (TUFAM)⁸.

According to WHO standards, countries with good reporting rates give more than 200 declarations per 1 million people each year⁹. Based on this information, considering Turkey's population of 83 million, it is expected to make 16 thousand ADR declarations per year. On the other hand, only 2455 ADR were reported even in 2013, which is the highest number of reports with available data¹⁰. In addition, although regulations were published in 2014 to increase declarations in our country; the knowledge, attitudes and practices of healthcare professionals in Turkey regarding pharmacovigilance were found at very low levels in studies^{11,12}. Adverse effects occur with oral symptoms such as dry mouth, oral ulcers, loss or change in taste, and swelling. For this reason dentists, who are among the pharmacovigilance stakeholders, have an important role in prescribing and using drugs. In the 200 most prescribed drugs, 80.5% dry mouth, 47.5% dysgeusia and 33.9% stomatitis were reported as adverse effects¹³. Therefore dentists have an important role in define and declaration these symptoms. With this study, it was aimed to investigate the experience, knowledge, and awareness of dentists on pharmacovigilance.

METHOD

This study was carried out with the approval of Health Sciences University Diyarbakır Gazi Yasargil Training and Research Hospital Clinical Research Ethics Committee dated 2021/07 and protocol number 829. Our study, which was

planned as research, was carried out with 100 volunteer physicians working as dentists in Diyarbakır Oral and Dental Health Hospital. The purpose of the research was explained to the physicians verbally by face-to-face interview technique and also briefly stated in writing at the beginning of the questionnaire. Informed consent forms were obtained from the physicians who agreed to participate in the study. The datas in the study were collected by applying a 15-question questionnaire with the technique of face-to-face interviews with physicians (Table I). The principles of the 'Helsinki Declaration' were complied with in the study. Each question in the questionnaire was evaluated in itself, and descriptive statistical analyzes such as frequencies and percentages were used to represent the demographic information of the participants through the SPSS 21 program.

RESULTS

In the study, 100 usable physician questionnaires were obtained. The survey questions consist of three parts. Part I; 1,1.1 and 1.2 questions are about encountering and reporting ADR in professional life and the attitudes of physicians towards these reactions. Part II; 2.-5. questions aimed at measuring ADR and pharmacovigilance knowledge levels, Part III; 6.-15. were assessment and evaluation questions aimed at increasing awareness in questions and identifying deficiencies in the current education system.

According to the results of the our study, when the demographic information of the physicians were examined, it was determined that 48% were female and 52% were male. Considering the professional experience of the physicians; it was observed that professional experience was declared as minimum 1 and maximum 30 years (average 11.06 years), while most of physicians had professional experience between 1-10 years (Table II).

Table I: The survey questions consist of three groups. Part I: about encountering and reporting ADR in professional life and the attitudes of physicians towards these reactions. Part II: about measuring ADR and pharmacovigilance knowledge levels. Part III: about increasing awareness and identifying deficiencies in the current education system.

<p>Part I:</p> <p>1- Have you encountered Adverse drug reaction (ADR) while practicing your profession? (Number:)</p> <p>1.1-If your answer is yes, have you report ADR?</p> <p>1.2- In which pharmacological group do you see more adverse reactions?</p> <p>Part II:</p> <p>2- Are adverse drug reactions (ADR) required to be reported?</p> <p>3- Do you think reporting an ADR is a professional obligation?</p> <p>4- Do you think verification is necessary before reporting that an ADR is related to a particular drug?</p> <p>5- Do you think only serious and unexpected ADRs should be reported?</p> <p>Part III:</p> <p>6- Do you think pharmacovigilance should be taught to dental students during their education?</p> <p>7- Do you think that the subject of pharmacovigilance is well taught in the dentistry education?</p> <p>8- Do you know how to report ADRs to the relevant authorities in our country?</p> <p>9- Should information on reporting ADRs be well taught to all health care students in their education?</p> <p>10- Information on reporting ADRs is better learned during internship/education/clinical assignmen</p> <p>11- Information on reporting ADRs will be better learned in post-graduation working life</p> <p>12- Pharmacists are one of the most important healthcare professionals about reporting ADRs.</p> <p>13- Reporting known ADRs will not make a significant contribution to the reporting system.</p> <p>14- With my current knowledge, I can report any ADR.</p> <p>15- To improve my knowledge of ADRs, I would like to participate in a education program on ADRs and their reporting.</p>

Table II: Professional experiences

Professional experince (between year)	n (number of people)
1-5	28
6-10	29
11-15	21
16-20	9
21-25	9
26-30	4

55% dentists stated that they have never encountered ADR in their professional life. Although 26% reported that they encountered ADR with the highest rate rarely (and 19% very rarely), it was found that only 7 ADR were

reported to the relevant institutions (Table III). In the chi-square test conducted to investigate whether there is a relationship between encountering ADR and reporting, it was found that there was no relationship between them ($p > 0.05$) (Table IV). Of these 7 cases stated; it was observed that 4 of them were antibiotics, 1 of them was local anesthetic solution, 1 of them was analgesic mouthwash and the other one was analgesic.

Table III: ADR encounter rate

ADR encounter		Percent (%)
	Rare	26
	Very Rare	19
	Non	55
Total		100,0

Table IV: ADR encounter rates and reporting of ADRs.

ADR encounter rates	Reporting status		Total
	No	Yes	
Rare	22	4	26
Very Rare	16	3	19
Total	38	7	45

(relationship between encountering ADR and reporting; $p > 0.05$)

In another result of our study, although the reporting rate was so low, dentists also reported that 78% of the patients should be notified and this process is a professional responsibility (86%). While awareness was high, dentists stated that only serious and unexpected ADR should be reported.

On the subject of pharmacovigilance, participants stated that they had no idea about how to report ADRs with their current knowledge (81%) and that this subject was not handled well in the education of dental faculties (55%). 86% of them stated that education on this subject should be taken at undergraduate level (internship, education, clinical assignment) and 58% stated that it should be taken in their working life after graduation (Table V).

Table V: Effect of education on ADR report

Questions	Answer (Yes) (percentage %)
With my current knowledge, I can report any ADR.	19
Do you think that the subject of pharmacovigilance is well taught in the dentistry education?	55
Information on reporting ADRs is better learned during internship/education/clinical assignment	86
Information on reporting ADRs will be better learned in post-graduation working life	58

DISCUSSION

This study investigated the experience, knowledge, and awareness of dentists about ADR and pharmacovigilance. As a results of our study, the dentists participating in the survey agreed that reporting ADRs is a professional obligation (86%). Although 45% of the participants stated that they had seen an ADR developing before, much less than that rate (15.55%) was reported. In accordance with our results, in a study which made among dental research assistants by Karatas et al.¹⁴ emphasized that 90% of the ADR declaration was important, while they stated that the reporting rate was 0%. In the survey conducted by Plaian et al., it was seen that the reporting rate was less than one-third, although it was found that ADR declaration was significant at the rate of 96.6%¹⁵. Arjun et al. emphasized that the rate of ADR declaration was 9%, although they stated the importance of 72.53%¹⁶. In a similar study conducted among pharmacists in Hong Kong, the requirement to report ADRs was 93%, while the reporting rate remained at 14.7%¹⁷. With these studies and literature reviews, it has been proven that awareness about ADR is high but the amount of reports are very low.

Another important issue we obtained in our study is the lack of knowledge of dentists on how to report the ADRs. According to our results, although 6% of participants stated that they could report, 32% stated that they had no idea and 26% stated that they were insufficient. Similarly, Bishen et al. reported the level of reporting knowledge among the private dental practitioners between 5-10% in their study¹⁸. Talattof and Azad also showed in their study that dentists have little knowledge about the importance, declaration and purpose of ADRs¹⁹. Shalini et al. reported that the level of knowledge is low, but awareness of ADR and pharmacovigilance is high in the study they conducted with dentistry students at a

Malaysian university²⁰. Khan et al. similarly, argued that the low rate of ADR reporting by dentists in hospitals was mainly due to a lack of knowledge and attitude²¹. Studies provide evidence that the education of health professionals can positively affect the underreporting rates of ADRs, and it is reported that more education and training are needed in this regard²². In many studies on pharmacovigilance in our country, similar to the results of our study, it is understood that health professionals (doctor, dentist, midwife/nurse and pharmacists) do not have sufficient knowledge about pharmacovigilance²³⁻²⁶. In our study, 80% of the dentists stated that both the compulsory pharmacovigilance course during the education period and the post-graduate in-service training programs will contribute to the development of the level of knowledge. The subject of pharmacovigilance should be taught to healthcare professionals through detailed and continuing education programs (83%).

Dentists prescribe a variety of medications for oral and dental health. The most common medications routinely prescribed are analgesics, antibiotics, muscle relaxants, and the local anesthetics they commonly use. These drugs are known to cause various ADRs including tinnitus, anaphylactic shock, arrhythmia, ataxia and teratogenic effects, and headache in general. The mortality rate due to ADRs caused by the effect of these drugs was reported as 3.67%²⁷. ADRs reported in our study were related to antibiotics, analgesic mouthwash and local anesthetic solution, respectively.

As a result, this study showed there is a lack of awareness and knowledge about pharmacovigilance and ADR among dentists. We believe that including pharmacovigilance in the training program and providing pre- and post-graduate training to dentists for declaration practices will contribute positively to public health.

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