**Research Article**

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# Dentists' Knowledge on Pharmacovigilance: An Example Preliminary Study in a Dentistry Faculty

## Dişhekimlerinin Farmakovijilans Bilgileri: Diş Hekimliği Fakültesinde Bir Öncalışma Örneği

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**ABSTRACT**

Healthcare professionals have an important role in the management of diseases and they have the social and professional responsibility to be knowledgeable on efficacy of the therapeutics. And health professionals need to be aware of the the safety and be vigilant on side effects of medicines.. With this research, it was aimed to determine the knowledge and experience about adverse drug effects and pharmacovigilance of dentists, who are healthcare providers and pharmacovigilance stakeholders. The questionnaire method was preferred and the research questions were prepared by the researchers in line with the terms in the relevant legislation and the literature. Faculty of dentistry of a foundation university's practice hospital was selected as the pilot area. With a structured agenda, all dentists were invited to a training meeting and at the beginning of the training the questionnaires were given in which collected after the session. 32 dentists voluntarily participated in the survey. The demographic status of the participants was evaluated. Most of the dentists who participating in this study, stated that they applied medication "frequently". About 71,9% of the participants in the questionnaire stated that they did not experience any side effects such as medication whereas 90,6% of the participants have marked the option that they do not have information about pharmacovigilance. As in pharmacy faculties, it has been understood that it is important to transfer pharmacovigilance and toxicovigilance systems within the scope of undergraduate education in medical and dentistry faculties that are authorized to prescribe drugs after graduation. In addition, pharmacists trained on adverse drug effects and pharmacovigilance should continue to contribute to raising awareness and contribute to interprofessional interaction by collaborating with other healthcare professionals. This research should be regarded as a pilot study and should be repeated with a high number of participants in the dentist's field.

**Keywords:** Pharmacovigilance, pharmacists, dentists, patient follow-up, public health

**ÖZET**

Sağlık mesleği mensuplarının, tedavinin önemli bir bölümü olan ilaçların yan etkileri ve güvenliliği ile ilgili bilinçli olması ve izleme katılması sadece mesleki

değil aynı zamanda toplumsal bir sorumluluktur. Bu araştırma ile sağlık hizmeti sunucularından ve farmakovijilans paydaşlarından olan diş hekimlerinin, advers (ters) ilaç etkileri ve farmakovijilans konusundaki bilgi ve deneyimlerinin belirlenmesi hedeflenmiştir. Anket yöntemi tercih edilmiş ve araştırma soruları araştırmacılar tarafından ilgili mevzuattaki terimler ve literatür doğrultusunda hazırlanmıştır. Pilot bölge olarak bir vakıf üniversitesinin Diş Hekimliği Fakültesi uygulama hastanesi seçilmiştir. Yapılandırılmış bir gündem ile tüm diş hekimleri bir eğitim toplantısına davet edilmiş ve eğitim başında verilen anketler eğitim sonrasında toplanmıştır. Ankete 32 diş hekimi gönüllü olarak katılmıştır. Katılımcıların demografik durumları değerlendirilmiştir. Araştırmaya iştirak eden diş hekimlerinin çoğu "sık sık" ilaç uygulaması yaptıklarını belirtmişlerdir. Ankete katılanlardan %71,9'u ilaç yan etkisi gibi bir durumla karşılaşmadıklarını söylemiştir. Katılımcıların %90,6'lık bölümü farmakovijilans konusunda bilgi sahibi olmadıkları şıkkını işaretlemiştir. Eczacılık fakültelerinde olduğu gibi, mezuniyet sonrası ilaç reçeteleme yetkisi alan tıp ve diş hekimliği fakültelerindeki lisans eğitimi kapsamında, farmakovijilans ve toksikovijilans sistemlerinin aktarılmasının önemli olduğu anlaşılmıştır. Bunun yanında, advers ilaç etkileri ve farmakovijilans hakkında eğitim alan eczacıların da, diğer sağlık mesleği mensupları ile işbirliği yaparak farkındalık artırılmasına katkı sağlamaya devam etmesi ve meslekler arası etkileşime katkı vermesi gerekir. Bu araştırma, pilot bir çalışma olarak kabul edilmeli ve diş hekimlerinin bulunduğu alanlarda yüksek sayıda katılımcı ile yinelenmelidir.

**Anahtar Kelimeler:** Farmakovijilans, eczacı, diş hekimi, hasta takibi, toplum sağlığı

## 1. INTRODUCTION

According to World Health Organization (WHO), pharmacovigilance (PV) is defined as "the science and activities related to detection, assessment and prevention of adverse effects or any other possible drug-related problems" (1). It is a kind of paradox that, probably pharmaceutical industry is the most highly regulated one in the world but need to remove approved and licensed products from the market because of serious adverse effects. As it is very well known, one of the oldest of all drug disasters was the thalidomide tragedy of early 60's. Tragically, the drug caused major birth defects in an estimated 10,000 children in the countries where widely used in pregnant women. This fatal experience caused the development of pharmacovigilance in the world and in 1965, 18th World Health Assembly, focused on the problem of adverse drug reaction monitoring and following. In 1978, International Drug Monitoring Programme (Upsala Drug Monitoring Center, UMC) was established. Recently, 139 countries are participating in this programme. The programme functions on the basis of national pharmacovigilance centers coordination and aims to protect public health.

The concept of pharmacovigilance have been widened to include herbal, traditional and complementary medicines, blood products, biologicals, cosmetics, veterinary, medical devices and vaccines. Many other issues are also of relevance to the science of pharmacovigilance. These include substandard medicines, medication errors, lack of efficacy, use of medicines for indications that are not approved. Case reports of acute and chronic poisonings, assessment of medicine-related mortality, abuse and misuse of medicines and adverse interactions of medicines with chemicals, other medicines, foods and drinks, etc are also relates with vigilance system (2).

Pharmacovigilance system aims to improve patient care, protect and improve public health by controlling and interpretting the background data. Adverse drug events are mostly voluntarily submitted by health professionals including medical doctors, dentists and pharmacists, and pharmaceutical companies to the national pharmacovigilance centers. The success or failure of any pharmacovigilance activity depends on the reporting of suspected adverse reactions. To date, the mainstay of pharmacovigilance has been spontaneous reporting by health professionals. To detect the full spectrum of complications from pharmaceutical treatment and to gain a representative picture, all sectors of the health-care system need to be involved. This includes public and private hospitals, general practice, pharmacies, nursing homes, retail dispensaries and providers of traditional medicine. Wherever medicines are being used, there should be clear to observe and report unwanted and unexpected medical events (3).

In Turkey, The National Pharmacovigilance Center, TUFAM (Turkish Pharmacovigilance Center) was formed in 2005 with regulations depending on The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human

Use (ICH) guidelines (4). As all national drug monitoring centers, TUFAM also is responsible from post-marketing surveillance of medicines and have achieved a great deal in;

* collecting and analysing case reports of ADRs

* distinguishing signals from background 'noise'

* making regulatory decisions based on strengthened signals

* alerting prescribers, manufacturers and the public to new risks of adverse reactions and so on.

Each hospital administration, pharmacists, physicians, nurses, dentists, veterinaries, drug companies and even lay people (public) can fill the "adverse effect form", and inform TUFAM via internet, phone or within different ways. There is not enough official information and related literature regarding health professionals' spontaneous reporting number and the distribution of the professionals. It is clear that, like many health workers, dentists are not reporting adverse drug experiences, most probably due to be weak-informed and unaware on pharmacovigilance system. It is hypothesised that if the health care professionals know and realise the importance of pharmacovigilance system, they report the experiences of adverse drug reactions.

In many countries, researches focuses similarly on health care professionals' including dentists' knowledge on pharmacovigilance so as to measure and improve. Demographic and working conditions are not determining criteria in reporting adverse drug reaction. Dentists's or dentistry students's knowledge on pharmacovigilance and spontaneus reporting found to be low or moderate in Yemen, India, Nepal, etc. (5-11). In Turkey, most of the health faculties (medicine, pharmacy, dentistry, nursery, etc.) do not have "pharmacovigilance" course in their curriculum. That may be a reason why there is not sufficient spontenues reports.

Pharmacists as drug experts gave "pharmacovigilance courses and seminers" to pharmacy students and to various health care providers (12-14). Researchers intented to understand the pharmacovigilance knowledge level of dentists and form conciousness among health care workers. The aim of this present study is to measure and describe the pharmacovigilance knowledge of dentists. To form a future plan projection to improve awareness among dentists and to increase the spontaneous reporting rate of dentists are the driving force for the researchers.

## 2. METHODOLOGY

A brief seminer, a training was given to academic members of the dentistry faculty. Before the training sections, the survey was distributed to attenders. At the end of the training meeting, surveys were recollected. The survey questions were designed and results were evaluated depending on the correctness of regulations and literature knowledge.

The research was planned as a preliminary study and the the deans approvel made available to conduct the intention. All members of the faculty were formally invited to the training and to fill the survey in 2014 Spring. Totally 14 questions were asked in which 11 of the them were closed and the rest were open ended. The interpretations were done depending on contributers answers.

The data was analyzed using SPSS version 15 program. Descriptive statistical analyses such as frequencies and percentages were used to represent the respondents' demographic information. The relationship between the categorical data was examined with the chi-square test.

## 3. RESULTS AND DISCUSSIONS

Nearly all of the 45 academicians participated the meeting either in training lecture or discussion part. As it was a busy dental hospital some participants need to leave the meeting after the seminer. Only 32 participants (71 % represantation) concluded the research survey.

According to survey results, average interval for working year of the participants was around 16 years as shown in Table 1. Also the mean age of the participants was 40 years old. In Turkey, gender distribution of dentists showed that 60% of the dentists were male whereas in this study only 20% of the participants were male. This may be related to sector which is more women were settled in educational business.

Of the participants, most of the academic tittle was professors and associate professors (nearly 50% in total). Three of the participants were full-time professors who constituted 9.4% of the participants. Also, more than 85% of the dentists had Ph.D. degree an expert on a special subject (Table 2).


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Participants graduation school thougt to be an important variable. Pharmacology and pharmacovigilance knowledge were expected to be in the "learning goals" in professional educational curriculum. However, due to insufficient distribution of the data it was not possible to prove statistically.

The participants was from all departments of the Dentistry Faculty Hospital (Table 3). Only one participant was working on public health whom was supposed to be a physician.

It was supposed and known that dentists administer and write prescription. The administration rate and prescribing ratio was important in interpreting the adverse drug effects follow-up and pharmacovigilance complience. Participants declared that, in dental treatment the drug administration rate was

**Table 1.** The Age and Working Years of the Participants

| Years | Minimum | Maximum | Mean |
|---|---|---|---|
| Professional time | 1 | 41 | 16.79 |
| Age | 25 | 65 | 39.90 |

**Table 2.** Profession Degree Distribution

| Academic degrees | Frequency (n) | Ratio (%) |
|---|---|---|
| Professor | 3 | 9.4 |
| Assoc. Prof. | 12 | 37.5 |
| Assist. Prof. | 6 | 18.8 |
| Dentist | 6 | 18,8 |
| Ph.D. student | 4 | 12.5 |
| Unspecified | 1 | 3.1 |
| Total | 32 | 100 |

**Table 3.** Department Distribution of the Participants

| Departments | Frequency (n) | Ratio (%) |
|---|---|---|
| Oral diagnose and radiology department | 1 | 3.1 |
| Mouth, oral and maxillofacial surgery department | 5 | 15.6 |
| Department of orthodontics | 4 | 12.5 |
| Department of pediatric dentistry | 4 | 12.5 |
| Department of prosthodontics | 6 | 18.8 |
| Department of conservative dental treatment | 4 | 12.5 |
| Department of Periodontology | 3 | 9.4 |
| Department of Endodontics | 4 | 12.5 |
| Department of public health | 1 | 3.1 |
| Total | 32 | 100 |

"frequent". More than 80% of the dentists declared that they administered and practice medication during the consultation of the patient which was quite high and risky for adverse reaction propability.

Many of participants, 24 dentists (75%) declared that it was necessary to follow-up the patient, and they performed so. As shown in Table 4, 71.9 % of participants, nearly two third of the dentist practitioners, declared that they had never seen and experienced any adverse drug effect before. This may be due to "unawareness" and "non-vigilance" to adverse reactions of drugs. This could be discussed in this way because after the meeting these arguments were declared informally by the dentists.

When we focused on the adverse effects that have experienced, it was seen that there were "serious adverse effects" which should have been reported to TUFAM (Table 5). Although many participants had declared that they had "not experienced adverse reaction", 10% of the dentists had came across to serious event and this should not be ignored.

It was understood that dentists wrote prescriptions "frequently or rarely" in Table 6. 10% of the dentists mentioned that they didn't prescripe at all. On the other hand, the patients use other medicines prescribed by other physicians, and they had the probability to interreact with the dental treatment procedures and dental prescriptions.

Though 70% of the dentists declared that they follow up their prescriptions (Table 6), which was quite a large group and the reasons need to be clarified with future studies. "Following up the

**Table 4.** TheExperience of Adverse Effects

| | Frequency(n) | Ratio (%) |
|---|---|---|
| No | 23 | 71.9 |
| Yes | 8 | 25.0 |
| Unaswered | 1 | 3.1 |
| Total | 32 | 100.0 |

**Table 5.** Severity of Adverse Effect

| | Frequency (n) | Ratio (%) |
|---|---|---|
| Serious (fatal) | 3 | 9.4 |
| Allergic reaction | 1 | 3.1 |
| After the consultation | 3 | 9.4 |
| Other | 25 | 78.1 |
| Total | 32 | 100 |

**Table 6.** Frequency to Prescription

| | Frequency (n) | Ratio (%) |
|---|---|---|
| Very often | 0 | 0 |
| Frequent | 7 | 21.9 |
| Mid-frequency | 9 | 28.1 |
| Very rare | 13 | 40.6 |
| No prescription | 3 | 9.4 |
| Total | 32 | 100 |


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precriptions" might show the awareness of dentists on adverse reactions.

Most of participants (20/32) did not answer the question "mostly prescribed pharmaceutical groups", it was quite clear and understood that the majority of the precribed drugs were antibiotics as declared. The other pharmaceuticals were summarized in Table 7.

Most of the participants (60%) mentioned that their prescriptions did not cause adverse effects (n=18).

Of the 32 participants, 3 of them had declared that they had come across "serious adverse effect", and only 1 of them said it was reported (Table 8). This submission was not to TUFAM or to a pharmaceutical company, else it was reported to the hospital management as "drug treatment report". It also showed the "lack of awareness and knowledge" on reporting to TUFAM's pharmacoviginance system.

As shown in Table 9, after the "pharmacovigilance training seminer" 90%, nearly most of the the participant dentists declared that they had no pharmacovigilance knowledge untill the training meeting of this research. Also, 70% of the participants (22/32) declared that they would like to be in the platfom and in a study group relating pharmacovigilance, and learn more on the pharmacovigilance system. This was one of the subaim of the present study and it could be said that an awareness process has started.

It was analysed and seen that there was no correlation between gender/academic degree and patient follow up status. Also, no relationship found between "the

**Table 7.** Mostly Precribed Pharmaceutical Groups

| | **Frequency(n)** | **Ratio (%)** |
|---|---|---|
| Antibiotics | 7 | 21.9 |
| Non-steroidal antiinflamatory drugs (NSAID) | 2 | 6.3 |
| Oral antiseptics | 2 | 6.3 |
| Local anesthetics | 1 | 3.1 |
| Corticosteroids | 0 | 0 |
| Other | 20 | 62.5 |
| Total | 32 | 100.0 |

**Table 8.** Reporting of Adverse Drug Reactions

| | Frequency(n) | Ratio (%) |
|---|---|---|
| Yes | 1 | 3.1 |
| No | 14 | 43.8 |
| Unanswered | 17 | 53.1 |
| Total | 32 | 100 |

**Table 9.** Pharmacovigilance Knowledge

| | Frequency(n) | Ratio (%) |
|---|---|---|
| Yes | 3 | 9.4 |
| No | 29 | 90.6 |
| Total | 32 | 100 |

rate of adverse effect situation during consultation" and "profession degree" ($p>0.05$). It was hypothesised that "the frequency of writing prescription/ prescription followup and profession degree" might have a relationship, but had not found ($p>0.05$). Occurance of adverse reactions after prescribed medications and gender/academic degree had no relationship ($p>0.05$). No relationship found between the graduation faculty and knowledge of pharmacovigilance ($p>0.05$).

It was seen that more number of participants and data were needed to make statistically valid and reliable comparisons and discussions.

Various groups of drugs have been prescribed and administered to different patient groups by health care practitioners including dentists. So as to use the medicines appropriately in other words for establishing rational drug use; both the therapy and the drugs, need to be followed up. In the last two decades all around the world, dentists show a progress and improve their responsibility on adverse drug reporting (15-17). In Turkey, a breakthrough is needed and pharmacists may have an active part as real drug expertice.

Dentists get benefit from antibiotics, anesthetics and analgesic-antinflammatory drugs and else, for pre-, post- and maintanance treatments of their patients. While these type of drug parties that work quite spiked, the risks of improper use is also possible. There need to be a close relationship between dentist-patient-drug so as to protect the patient against alert situations. For this reason, during the application period of prophylactic, therapeutic and maintenance drug regimens; patients should be monitored by the dentist for adverse reactions.

Via this research, with the training session and the after the survey, it is understood and shown as, "pharmacovigilance knowledge level and the awareness of reporting" among the dentists need to be improved. More training and interprofessional meetings shoould be organised to be more vigilant.

## 4. CONCLUSION

To conclude it is obvious that dentists involving this research study were not the same health professionals any more. Hopefully they had realised that there was an opportunity for "pharmacovigilance system" for them to report. This research was a kind of social responsibility act. Namely, the health professionals have responsibility on adverse drug effects, and the vision is to split the importance of pharmacovigilance system to all health care givers. Pharmacovigilance is a "public health" issue, and this global system is needed to follow and report xenobiotics by all health professionals for their safety usages in all age groups and in all over the world.

## 5. LIMITATIONS OF THE STUDY

Participant numbers are few and results can not be generalised, but the present study is an example preliminary study. Also, real outcome of the education, that is the number of spontaneous reports can not be taken into considerations, due to data protection issues. Future attempts should be taken to reach and train more health care workers, including dentists, to improve the conciousness that drugs need to be followed up.

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