Ochyra Dorota, Ochyra Bartłomiej, Misztal Zofia, Pawlicka Marta, Pawlicki Mateusz, Mroczek Anna, Bałabuszek Kamil. Importance of adverse drug reaction reporting in dental practice. Journal of Education, Health and Sport. 2018;8(9):1067-1073 eISNN 2391-8306. DOI http://dx.doi.org/10.5281/zenodo.1420103
http://ojs.ukw.edu.pl/index.php/johs/article/view/6006

The journal has had 7 points in Ministry of Science and Higher Education parametric evaluation. Part b item 1223 (26/01/2017).
1223 Journal of Education, Health and Sport eissn 2391-8306 7

The authors declare that there is no conflict of interests regarding the publication of this paper.

Received: 02.08.2018. Revised: 18.08.2018. Accepted: 15.09.2018.

Importance of adverse drug reaction reporting in dental practice

Dorota Ochyra[1], Bartłomiej Ochyra[2], Zofia Misztal[3], Marta Pawlicka[1], Mateusz Pawlicki[1], Anna Mroczek[1], Kamil Bałabuszek[1]

[1]Medical University of Lublin, Poland

[2]Pharmacovigilance Department, Teva Pharmaceuticals Polska, Warsaw, Poland

[3]Medical University of Lodz, Poland

Corresponding author: Dorota Ochyra, e-mail: dorota.sikorska@hotmail.com

ORCID ID

Dorota Ochyra https://orcid.org/0000-0002-8076-5622

Bartłomiej Ochyra https://orcid.org/0000-0003-1832-5164

Zofia Misztal https://orcid.org/0000-0003-2317-9667

Marta Pawlicka https://orcid.org/0000-0002-6631-979X

Mateusz Pawlicki https://orcid.org/0000-0001-8318-6573

Kamil Bałabuszek https://orcid.org/0000-0002-1352-153X

Anna Mroczek https://orcid.org/0000-0003-0077-5343

Abstract

Dentists in their daily practice could observe adverse drug reactions (ADR) in specific location and after specific medicinal products. As a dentist practitioner it is very important to be aware of what ADR is, what we can do to manage it and what it brings to everyday practice. The level of adverse drug reaction reporting by healthcare professionals (HCPs) is

definitely unsatisfactory. One of the most important reasons of this situation is low knowledge about ADRs reporting rules, especially among students and young HCPs. This situation can be changed through increasing the number of hours devoted to this issue during studies. Highlighting the importance of ADRs reporting, even one serious individual case safety reports (ICSRs), in the context of signal detection is necessary.

INTRODUCTION

Pharmacovigilance is the science and different activities relating to the detection, assessment, understanding and prevention of adverse drug reaction or any other medicine-related problem. Referring to Annex I Guideline on good pharmacovigilance practices (GVP) adverse drug reaction (ADR) is response to a medicinal product which is noxious and unintended [1].

Before a medicine is authorized for use, evidence of its efficacy and safety is limited only to the results from clinical trials, where patients are selected carefully and followed up very closely under controlled conditions. This means that at the time of a medicine's authorization, it has been tested in a relatively small number of selected patients for a limited period of time. After authorization the medicine may be used in a large number of patients, for a long period of time and with other medicines. Certain side effects may emerge in such circumstances. It is therefore essential that the safety of all medicines is monitored throughout their use in healthcare practice. Because of that reporting of adverse drug reaction is very important task which influence on safety of patients. Additionally it should be noted that different group of healthcare professionals such us physicians, dentists, pharmacists or nurses can observer different adverse drug reactions in different clinical situation. It is important to highlight the importance of adverse drug reporting by all stakeholders including consumers but also all various groups of HCPs.

One of the important group of healthcare professionals are dentists who can observe rare adverse drug reactions in specific location and after specific medicinal products. Basically main concern about drugs are their efficiency, possible side effects and drug interactions. Fortunately, serious adverse drug reaction in dentistry are relatively rare. The most common dental interactions are relatively simple to avoid [2]. However, it is important that each of the medical professions participate in the development of drug safety, among other in the context of identification new and/or changed risks associated with the use of the drug. It should be noted that even one serious and well medically documented Individual Case Safety Report

(ICSR) of serious adverse drug reaction may be sufficient to detection of safety signal*. Because of that, the knowledge about adverse drug reporting should be introduced already in University on various fields of study, including dentistry to increase student knowledge about this topic.

*Signal - Information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verification action [IR 520/2012 Art 19(1)].

REASERCH

Research conducted by Zahra Talattof and Azita Azad in Iran were supposed to examine the dentists' knowledge about adverse drug reaction. It was performed on 40 dentists. Objects were divided into two separate groups, only depending on what they claimed they know about ADR: A (80%) – know about ADR and B (20%) – do not know about ADR. A questionnaire, that was divided into three sections, was prepared for them. It contained questions in the fields: demographic information, knowledge about ADRs, attitude and practice regarding ADRs reporting. The first part contained respondents' answers about sex, age, education and duration of practice. The second part checked the participants' knowledge about ADR. Questions verify whether the dentists are able to define ADR and some expressions such as "rare ADR", and "common ADR", etc. There was a point for each correct answer. The respondents' knowledge score ranged from 0-16. Those who had 12 points and more were consider to have an acceptable knowledge regarding ADR. In the third, practical section objects were asked if they had reminded ADRs to patients and what they do with patients who experienced ADRs. Whether they reported ADR or not and why. As a whole, only 3 persons from A group, got an acceptable knowledge score comparing with group B, in which no one got enough points. According to questionnaire, dentists' knowledge was unacceptably low. In practical part, most of dentists claimed that they had reminded to patients about each medicine's adverse drug reactions. The most common reason why some dentists did not inform patients about ADR is because they did not know which side effects are the most important [3].

Similar research was obtained from larger group of healthcare professionals: medical, dental and nursing professionals of People's university, Bhopal, Madhya Pradesh, India. The study

involved 392 participants including 169 medical professionals, 142 dental and 81 nursing professionals. The questionnaire was designed to examine objects of following details:

1. Knowledge and purpose of pharmacovigilance, knowledge of National Pharmacovigilance Programme, regulatory body responsible for monitoring ADRs and responsibility of reporting ADRs;
2. Attitude practices towards pharmacovigilance;
3. Practice on ADR reporting.

Research shows that dental professionals compared to other, that were participated, had the least number of correct answers. Less than half of healthcare professionals who comprised of 68.63% medical, 35.91% dental and 29.62% nursing professionals believed that ADR reporting is a professional obligation for them. Statistically every second participant of the examined healthcare professionals who included 34.50% dental professionals have experienced ADRs in patient during their practice. Only few healthcare professionals have ever reported ADR to pharmacovigilance center or Marketing Authorization Holder. Surprisingly none of the them were dentist or nursing professionals. Furthermore, less than 4% of examined dentists have ever seen the ADR reporting form. Additionally, it was found that none of the dentists were have been trained on reporting on ADR. Fortunately most of the healthcare participants answered that the most important purpose of pharmacovigilance is to identify a safety of the drug [4].

In the dental office, dentists may encounter with adverse drug reaction relatively common. This may occur even by administration of single drug. The risk is significantly high in case of elderly people that have prescribed a lot of medicines and are suffering from chronic diseases. According to research, elder people take on average from 3 to 8 medications, mainly analgesics, diuretics, cardiac drugs and sedatives, while those at nursing home who usually use more preparations: antipsychotic drugs, sedatives, hypnotics, diuretics, cardiac drugs, analgesics and antibiotics [5]. Survey research that has been performed on 1000 independent seniors at pharmacies, senior clubs and students of the third year university have shown that they regularly administrate an average of 7.6 medications [6]. Based on statistics collected by the Central Statistical Office, every second Pole (52%) suffers from long-term health problems or chronic diseases, that last at least 6 months [7]. In the light of these studies and being a dental practitioner it is very important to be aware of what ADR is, what we can do to manage it and what it brings to our everyday practice.

DENTAL MENAGAMENT

The drugs which dentists use in daily practice can be divided into few groups: analgesics, local anesthetics, antimicrobials (antibiotics, antifungals, antivirals), sedatives, and drugs that affect the autonomic nervous system (antihistamines, sympathomimetics, anticholinergics). Much less often, dentists use antidepressants and corticosteroids to manage chronic pain and treat oral autoimmune diseases.

ADRs can by classified into different subtypes. Type A (Augmented) ADRs are predictable and dose-dependent; caused by augmentations of known pharmacologic effects of the drug. Type B (Bizarre) ADRs are unpredictable and uncommon, depending on the known pharmacology of the drug; this type of ADRs are independent of dose and affect a small population. Hypersensitivity reactions to drugs (e.g. allergic reactions) are examples of type B ADRs. Type C (Chronic) ADRs are chronic reactions, which relates to both dose and time. Type D (Delayed) ADRs are usually dose related and delayed. Withdrawal later became the fifth category (type E - End of use), and last category is dose related and unexpected failure of therapy, often caused by drug interactions (type F - Failure). In dental practice type B adverse drug reactions are the most common, including allergic reactions. Patients most often admit to have allergies to penicillin, aspirin or codeine. In the light of that almost any drug or its compound can be allergen. The most common manifest of allergy in dental practice is a rash on the body, less perioal swelling or swelling in the throat or anaphylaxis. Delayed allergic reactions usually show up as skin rashes, blisters, and at times, oral ulcerations [2].

The best way to prevent allergies during daily dental practice is to check patients' medical history [2]. If patient claims to have had an allergic reaction, doctor should carefully verify it. Even the nonspecific symptoms should be noted and the drugs that caused them should be avoided. It is commonly known that often the second contact with the allergen can develop an allergic reaction. When reaction occur, general treatment is to withdraw the drug and sometimes administrate antihistamines or corticosteroids. If the reaction is severe, it may be necessary to give an injection of epinephrine.

Dental management of drug safety in daily practice is to minimize the risk of the adverse drug reactions. It can be done thanks to recognize the high risk patients and understand which specific drugs have the greatest probability of causing ADR [2].

Dentists should be sensitive to changes in the mouth after taking various medications. Some drugs, more than others, can particularly manifest in the mouth. For example ACE inhibitors are connected to lichenoid reactions. Xerostoma can be caused by diuretics, antidepressants and some anti-seizure. Calcium channel blockers and immunosuppressant drugs may lead to gingival hyperplasia [8].

When performing various treatments, dentists often use local anesthetics. They are relatively safe if used in proper doses and manner. However they can cause local and systematic toxicity. As its consequence, local anesthetics may induce ischemic necrosis of tissues and directly affect nerves causing persistent paresthesia. Some local anesthetics more than others are higher risk for certain patients, for example bupivacaine, have greater than other agents, direct cardiac toxicity [9].

Good example of adverse drug reaction closely related to dentistry are also bisphosphonates. They are used to reduce bone pain, hypercalcemia of malignancy and skeletal complications in patients with myeloma, lung, breast, other cancers, Paget's disease and also osteoporosis [10]. One of the most serious complications of bisphosphonates is related bisphosphonate-associated osteonecrosis of the jaw. It is characterized by exposed bone or bone that can be probed though an intraoral or extraoral fistula, maintain for than eight weeks and concern patients who have received current or previous treatment with antiresorptive or antiangiogenic agents and no history of radiation therapy to the jaws or metastatic disease to the jaws [11]. Most of the reported cases of bisphosphonate-associated osteonecrosis of the jaw appeared after dental procedures, for example tooth extraction. Bisphosphonate-associated osteonecrosis rarely occur by itself in patients during treatment of bisphosphonates [10].

CONCLUSIONS

According to the Central Statistical Office the drug consumption in Poland is high, about 71% of Polish population takes medications [12]. Adverse drug reactions concern about 10-40% of all patients, furthermore 0.05-6% of all cases are assessed as life-threatening ADRs [13,14]. Adverse drug reactions are considered to be the cause of increased mortality, morbidity and are responsible for a significant increase of expenses in the health care system [15, 16]. It is estimated that ADRs are responsible for about 10-15% of all hospitalizations, thus costs associated with them absorb 5-10% of the total sum of costs intended for pharmacotherapy [14,15]. In Poland notification of adverse drug reactions is legal obligation of healthcare professionals including physicians, pharmacists, nurses, midwives, laboratory diagnosticians, feldshers and pharmacy assistants. Despite that level of adverse drug reaction reporting by HCPs is definitely unsatisfactory. One of the most important reasons of this situation is low knowledge about ADRs reporting rules, especially among students and young HCPs. This situation can be changed through increasing the number of hours devoted to this issue during studies. Highlighting the importance of ADRs reporting, even one serious ICSRs, in the context of signal detection is necessary.

REFERENCES

1. Guideline on good pharmacovigilance practices (GVP), Annex I
2. Peter L. Jacobsen. Adverse Drug Reactions
3. Talattof Z., Azad A. Department of Oral Medicine, School of Dentistry, Shiraz University of Medical Sciences, Shiraz, Iran. 'An Evaluation of Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting in Dental Practice'. Pakistan Journal of Nutrition 14 (10): 712-715, 2015
4. Arjun T., Sudhir H., Gouraha A., Jain S., Chavan K. et al. Assessment of knowledge, attitude and practice related to pharmacovigilance among the healthcare professionals in a teaching hospital in central india: an questionnaire study'. World Journal of Pharmacy and Pharmaceutical Sciences. 4 (4): 785-799, 2015
5. Ksiadzyna D., Szelag A. Special aspects of geriatric pharmacotherapy. PSYCHOGERIATRIA POLSKA;10(3): 115-126, 2013
6. Rajska-Neumann A. Leczenie farmakologiczne osób starszych – badania ankietowe. Rozprawa doktorska, Poznań 2004.
7. GŁÓWNY URZĄD STATYSTYCZNY. Notatka informacyjna, Zdrowie i zachowanie zdrowotne mieszkańców Polski. Warszawa, 1 grudnia 2015 r
8. Jacobsen P. Clinical Management of the Dental Patient Taking Multiple Drugs. The Journal of Contemporary Dental Practice. 6(4), 2015
9. Becker D. Adverse Drug Reactions in Dental Practice. Anesth Prog. 61: 26-34, 2014
10. American Dental Association Council on Scientific Affairss. Dental management of patients receiving oral bisphosphonate therapy. Expert panel recommendations. Jada, 137, 2006.
11. De-Freitas N-R., Lima L-B., de-Magalhães D. Bisphosphonate treatment and dental implants: A systematic review. Med Oral Patol Oral Cir Bucal. 21(5): e644-e651, 2016.
12. Zimmermann A. Reporting Adverse Drug Reactions in Poland – The Legal Situation. Journal of Pharmacovigilance. 2(1), 2014.
13. Wiela-Hojeńska A, Łapiński Ł. Niepożądane działania leków – rodzaje, podział, przyczyny i skutki ekonomiczne. Farm Pol. 66(4):275–288, 2010
14. Woroń J, Goszcz A, Wordliczek J, Bisaga W. Monitorowanie niepożądanych działań leków w praktyce klinicznej. Anest Ratow. 3:185–192, 2009.
15. Wiela-Hojeńska A, Jaźwińska-Tarnawska E. Międzynarodowe i krajowe systemy monitorowania niepożądanych działań leków – ich rozpoznawanie i zgłaszanie. Farm Pol. 65(10): 725–732, 2009
16. Sultana J, Cutroneo P, Trifirò G. Clinical and economic burden of adverse drug reactions. J Pharmacol Pharmacother. 4(suppl.1): 73–77, 2013