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## An Evaluation of Knowledge, Attitude and Practice of Adverse Drug Reaction Reporting in Dental Practice

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**Abstract:** While adverse drug reaction (ADR) reporting card (yellow card) system has started in 1998 in Iran, the ADR reporting rate was very low. To explore if the Iranian adverse drug reaction reporting system could be modified and to determine causes of under-reporting among dentists, a study to investigate the role of dentists in ADR reporting was done in marvdasht city (Fars province, south of Iran). A cross-sectional study was done between February and December 2014 in marvdasht city, Iran. After describing the study and its aims for each dentist, oral consent was taken. A number of 40 out of 50 dentists (80%) agreed to participate in the interview. All respondents were working in private dental clinic. Although level of knowledge regarding ADR was low among dentists, all of them admitted that paying attention to ADRs and timely reporting is very important. About ADR in the university, 10% believed that it was enough, 70% claimed that it was not satisfactory and 20% admitted that it was little. It is concluded that Our dentists have little knowledge about the process, goal and importance of ADR reporting system. Otherwise, education and training will be important in maintaining and enhancing ADR reports by dentists.

**Key words:** Dentists, knowledge, attitude, practice, adverse drug reaction, Iran

### INTRODUCTION

Adverse drug reactions (ADRs) are an important health issue, causing considerable harmful responses for patients and increase health costs. ADRs are a major cause of morbidity and mortality among patients (Green *et al.*, 2001). It is reported that ADRs have been responsible for about 6% of all hospital admissions to medical wards (Publications, 2002) and it is the fourth to sixth leading cause of mortality in the United States of America (Lazarou *et al.*, 1998; Vora *et al.*, 2011). The economic burden of ADRs is also considerable: a total cost of \$50 billion annually for 9 million drug-related admissions was reported in the United States (Johnson and Bootman, 1995). Therefore, safe use of medicines is a critical concern for all healthcare professionals, including prescribers, dentists and nurses.

After the thalidomide disaster in 1960s, most countries start their national ADR centers in which spontaneous reporting were used to collect data, analyze ADRs and identify signals (Scott *et al.*, 1990; Toklu and Uysal, 2008; Pirmohamed *et al.*, 2007).

Reporting in various countries is different. Although Denmark is a country with a small population, the ADRs reporting rate is 14000 per year (Boyd, 2002). In France, this rate is 24000 annually (Lacoste-Roussillon *et al.*, 2001). In china, the ADRs reporting rate increased from 800 in 1999 (Du *et al.*, 2008) to 700000 in 206 (Du *et al.*, 2008). According to studies less than 10 percent of all adverse drug reactions are reported worldwide (Rawlins, 1995; Li *et al.*, 2004).

The Iranian ADR center was established in 1997. While yellow card reporting system has started in 1998 in Iran (Sohrevardi and Heidari, 2009), the ADR reporting rate is very low (Hajebi *et al.*, 2010).

However, voluntary ADRs reporting must be a major responsibility for all health care professionals, dentists have a critical role to improve the quality of drug medication and reduce the incidence of adverse drug reactions. So, there are several reports of other countries which show the role and attitudes of dentists in and toward ADR reporting (Shubha Praveen *et al.*, 2013).

In order to improve ADR reporting and determine reasons of under-reporting, this study was performed to investigate the level of knowledge, attitude and practice of dentists about spontaneous reporting system in marvdasht, Fars province.

### MATERIALS AND METHODS

A cross-sectional study was performed between February and December 2014 in marvdasht city, Iran. 50 dentists were that working in private clinic selected. After describing the study and its goal for each participant, oral consent was taken. Three trained interviewers distributed the questionnaires among the dentists. Each Participant him/herself filled the questionnaire while the interviewer was there and answered the participant's questions (if any).

**Data collection form:** A semi-structured questionnaire which included the following three parts was used:

demographic information, knowledge about ADRs and attitude and practice regarding ADRs reporting.

The questionnaire has 33 questions and consists of 6 attitude practices 8 questions and 19 knowledge. Our team design questions by themselves and use expert opinion. Experts' opinions were used for checking its validity, while reliability was examined in a pilot study which included 20 dentists ( $\alpha$  Chronbach = 0.82).

The first part, demographic information, contained respondents' sex, age, the university from which they were graduated and duration of practice. Working places were private. The second part was assessing respondent's knowledge regarding ADRs and ADR reporting. In the first question respondents claimed if they knew about ADRs concept, while in the second question they were asked to describe ADR in one or two sentences. The third question asked the respondents to define some expressions in ADRs; such as, "very rare ADR", "rare ADR", "occasional ADR" and "common ADR". Responses to these open ended questions were evaluated based on the WHO's definition (Scott *et al.*, 1990), however the concept was more important than the defined words. Also the respondents answered the questions regarding their knowledge about ADR, yellow card and reporting indications. Then we divided the respondents into two groups, A and B, according to their claims regarding their knowledge of ADR's meaning and compared other items in these two groups. For scoring the answers, one point was given to each correct answer; therefore, the respondents' knowledge score ranged from 0-16, while those who got 12 or more points were labeled to have an acceptable knowledge regarding ADRs. The third part, practice, was consisted of 8 questions designed to evaluate the respondents' reaction when encountering ADRs. In this part dentists were asked if they had reminded ADRs to patients and otherwise to explain the reason (multiple choices). We also asked the respondents about encountering patients referred with ADRs, whether they had reported ADRs; otherwise they were asked about the reasons for not having reported the case (multiple choices).

**Statistical analysis:** SPSS version 10 was used for statistical analysis. Student t-test was used to examine the statistical differences in knowledge scores between group A and group B. Furthermore, we used Chi-square test to examine the relationship between binary variables. A p-value less than 0.05 was considered to be significant.

## RESULTS

40 out of 50 dentists (80%) agreed to participate in the study. 15 out of 50 respondents were male (30%). 96 percent were graduated from Iranian universities and 4% from foreign universities. As mentioned in methods, responders were categorized into two groups; group A

(80%) and group B (20%). 5 (10%) dentists in group A and one(2%) in group B described ADR correctly. Asking some expressions regarding ADR, we found out that in group A, the rate of correct answers to "very rare ADR" was 1 out of 40 (3%), to "rare ADR" was 0%, while 2 out of 40 dentists (5%) answered "occasional ADR" correctly and 1(3%) described "common ADR" appropriately. No statistical significance was found between groups A and B in replying the questions (Table 1). As a whole, 3 (8%) dentists in group A got an acceptable knowledge score comparing with group B in which no one gave a correct answer.

Although level of knowledge regarding ADR was low among dentists, all of them admitted that paying attention to ADRs and timely reporting is very important. On the other hand, 10 out of 40 dentists found their education regarding ADR enough for working in the clinic (Table 2). However, the level of knowledge regarding ADR in this group ( $9\pm 3$ ) was lower than the other group who believed they had not learned enough in the university ( $10\pm 3.5$ ).

In practice, 30 (75%) respondents claimed that they had reminded each medicine's adverse reactions to patients. The most frequent reason stated by 30 dentists who did not notify ADR to patients was that they did not know which side effects should be reminded to them.

About three fourth (73%) of the dentists believed that severe ADRs that ended up mortality, amputation and hospitalization should be reported, 65% thought that reporting severe side effects of newly marketed medicines is necessary. Besides, they stated that side effect (s) of a special brand of medicine (53%), new adverse effect (s) of routine medications (49%) and rare side effects should be recoded and reported to the next level.

## DISCUSSION

The response rate in our study was good, although some questions were sensitive. The most important reason was data collection method. In this method while the interviewers answered the participants' questions (if any), respondents felt relaxed to answer the questions. Also, when each questionnaire was returned to the interviewer, he/she rapidly checked the questionnaire to see whether it was being answered completely. Implicitly, we could conclude that if a close relationship is conducted between the dentists and National pharmacovigilance center, a remarkable rise could be predictable in reporting rate. Our response rate was comparable to the response rate in the study conducted by Su *et al.* (2010). However, they had interviewed with dentists (Su *et al.*, 2010).

In this study we found that the dentists' knowledge regarding expressions was unacceptably low. We had the lowest rate compared with the studies which asked the same expression in Asian countries (Toklu and

Table 1: Dentists' claims on their knowledge regarding the ADRs reporting chain

Dentists' claims on their knowledge about (N = 40)	Positive claims	Negative claims
	Frequency (%)	Frequency (%)
Presence of ADR Center	10 (25)	30 (75)
ADR Center' performance	15 (40)	25 (60)
ADR Center' criteria	5 (13)	35 (87)
Yellow card system	14 (35)	26 (65)
How to work with yellow card system	15 (40)	25 (60)
Their responsibility regarding reporting ADR	10 (25)	30 (75)

Table 2: Comparing knowledge of dentists who claimed that they knew ADR completely with the rest of the study population

	Answers	Dentists who claimed they knew ADR well (n = 30)	Dentists who claimed they did not know ADR well (n = 10)	p-value
		Frequency (%)	Frequency (%)	
Describing ADR	Correct	27 (90)	2 (20)	<0.001
	Incorrect	3 (10)	8 (80)	
Very rare ADR	Correct	5 (17)	0	0.28
	Incorrect	25 (83)	10 (100)	
Rare ADR	Correct	2 (7)	0	-
	Incorrect	28 (93)	10 (100)	
Occasional ADR	Correct	1 (3)	0	0.534
	Incorrect	29 (97)	10 (100)	
Common ADR	Correct	3 (10)	0	0.388
	Incorrect	27 (90)	10 (100)	
Describing phamaco-vigilance	Correct	8 (27)	2 (3.4)	0.016
	Incorrect	22 (73)	8 (96.6)	
Acceptable level of knowledge	Achieved	1 (3)	0	<0.001
	Did not achieved	29 (97)	10 (100)	

ADR: adverse drug reaction. p-value less than 0.05 was considered as significant. (Very Rare), (Rare), (Occasional), (Common). Common (1/100 and <1/10). Occasional (1/1,000 and <1/100). Rare (1/10,000 and <1/1,000). Very rare (<1/10,000)

Uysal, 2008; Su *et al.*, 2010). As mentioned before, when a questionnaire was returned with some unanswered questions the interviewer asked the respondent to complete it and if he/she did not know the expressions, the interviewer asked the respondent to write "I do not know". dentist Apart from the participants' low level of knowledge, another reason could be type of the questions, namely, open ended questions. The participants might answer the questions correctly if they were multiple choice ones (Su *et al.*, 2010). one of the possible reasons for dentists' denial to participate in this category research might be low level of knowledge and interest toward this issue. So generally the real rate of dentists with sufficient level of knowledge regarding ADR and Pharmacovigilance is probably much lower than what was reported in the studies.

The rate was similar to the previous study conducted in the same study area, Shiraz, (Vessal *et al.*, 2009) while it was higher than other studies conducted in Asia and the Middle East (Toklu and Uysal, 2008; Su *et al.*, 2010; Sohrevardi and Heidari, 2009) Since in Iran all dentists are supervised by local Universities of Medical Sciences, this rate shows that University of Medical sciences had firmer rules in ADR reporting.

While in practice, about half of the dentists had reported ADRs to the next level, when we asked them about indications of ADRs reporting, most of them believed

that severe side effects should be reported either the medication is a newly marketed or a well-known one. Other items were new side effects related to a new brand in comparison with a routine one. All these results were in agreement with the studies of Toklu and Uysal, 2008; Vessal *et al.*, 2009; Su *et al.*, 2010; Sohrevardi and Heidari, 2009.

So, one possibility of under reporting could be that dentists who encountered a patient with ADR considered it as a trivial one, or they did not have enough knowledge to differentiate or diagnose the patient's symptoms and signs.

**Conclusion:** While all of the dentist at this study admitted that paying attention to ADRs and timely reporting is very important, under reporting of ADRs is still a remarkable problem. Different reasons underlay this problem mostly due to low level of knowledge in recognizing ADRs, which should be reported and often not being familiar with the process of reporting. So, more emphasis should be put on these issues in dental curriculum and on education during practice.

## REFERENCES

Boyd, I.W., 2002. The role of the Australian Adverse Drug Reactions Advisory Committee (ADRAC) in monitoring drug safety. *Toxicol.*, 181-182: 99-102.

- Du, W., J.J. Guo, Y. Jing, X. Li and C.M. Kelton, 2008. Drug safety surveillance in China and other countries: a review and comparison. *Value in health: J. Int. Soc. for Pharmaco. and Outcomes Res.*, 11: 130-136.
- Green, C.F., D.R. Mottram, P.H. Rowe and M. Pirmohamed, 2001. Attitudes and knowledge of hospital dentists to adverse drug reaction reporting. *Br. J. Clin. Pharmacol.*, 51: 81-6.
- Hajebi, G.M.S., J. Salamzadeh and A. Zian, 2010. Survey of Knowledge, Attitude and Practice of Nurses towards Pharmacovigilance in Taleqani Hospital Iranian *J. Pharmac. Res.*, 9: 199-206.
- Johnson, J.A. and J.L. Bootman, 1995. Drug-related morbidity and mortality. A cost-of-illness model. *Arch. Int. Med.*, 155: 1949-1956.
- Lazarou, J., B.H. Pomeranz and P.N. Corey, 1998. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA: J. Am. Med. Assoc.*, 279: 1200-1205.
- Lacoste-Roussillon, C., P. Pouyane, F. Haramburu, G. Miremont and B. Begaud, 2001. Incidence of serious adverse drug reactions in general practice: a prospective study. *Clin. Pharmacol. and Therapeutics*, 69: 458-462.
- Li, Q., S.M. Zhang, H.T. Chen, S.P. Fang, X. Yu and D. Liu *et al.*, 2004. Awareness and attitudes of healthcare professionals in Wuhan, China to the reporting of adverse drug reactions. *Chin. Med. J.* 117: 856-861.
- Pirmohamed, M., K.N. Atuah, A.N. Doodoo and P. Winstanley, 2007. Pharmacovigilance in developing countries. *BMJ.*, 335: 462.
- Publications, W., 2002. The importance of pharmacovigilance: safety monitoring of medicinal products Geneva, Switzerland: WHO Collaborating Centre for International Drug Monitoring 2002 Contract No.: 92-4-159015-7.
- Rawlins, M.D., 1995. Pharmacovigilance: paradise lost, regained or postponed? The William Withering Lecture 1994. *J. Royal College of Physicians of London*, 29: 41-49.
- Scott, H.D., A. Thacher-Renshaw, S.E. Rosenbaum, W.J. Waters Jr., M. Green and L.G. Andrews *et al.*, 1990. Physician reporting of adverse drug reactions. Results of the Rhode Island Adverse Drug Reaction Reporting Project. *JAMA: J. Am. Med. Assoc.*, 263: 1785-1788.
- Su, C., H. Ji and Y. Su, 2010. Hospital dentists' knowledge and opinions regarding adverse drug reaction reporting in Northern China. *Pharmaco. and Drug Safety*, 19: 217-222.
- Sohrevardi, S.M. and M.R. Heidari, 2009. Kerman Health System Workers Knowledge and Attitudes Regarding the pontaneous Reporting System for Adverse Drug Reactions. *Iranian J. Pharmac. Sci.*, 5: 4.
- Shubha Praveen, Jai R. Prakash, G.N. Manjunath and M.S. Gautham, 2013. Adverse Drug Reaction reporting among medical and dental practitioners: a KAP study, Naveen Kumar Ind. *J. Med. Speci.*, 4: 10-15.
- Toklu, H.Z. and M.K. Uysal, 2008. The knowledge and attitude of the Turkish community dentists toward pharmacovigilance in the Kadikoy district of Istanbul. *Pharm. World Sci.*, 30: 556-562.
- Vora, M.B., H.R. Trivedi, B.K. Shah and C.B. Tripathi, 2011. Adverse drug reactions in inpatients of internal medicine wards at a tertiary care hospital: A prospective cohort study. *J. Pharm. Pharmac.*, 2: 21-25.
- Vessal, G., Z. Mardani and M. Mollai, 2009. Knowledge, attitudes and perceptions of dentists to adverse drug reaction reporting in Iran. *Pharm. World Sci.*, 31: 183-187.