

## Characteristics of adverse drug reactions and their antidotes in a dental hospital in Bangkok, Thailand

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### Abstract

The purpose of this descriptive study was to determine the characteristics of adverse drug reactions (ADRs) and to find out antidotes used to treat the patients that experienced adverse drug reactions in Outpatient department, Dental hospital. Data were collected from ADRs record document during the year of 2014 to 2016. Thirty two records were reported. Almost ADRs were cause from drug use in the hospital with the patients mean age 20-60. Together with the WHO Probability Assessment was mostly found in the scale of possible drug-related (29% in 2014, 58% in 2015 and 38% in 2016). And the dermatology skin rash was the most ADRs reported Classification of type of reaction. The suspected drug was most commonly associated with Analgesic (37.5%). Followed with, both with antibiotics and analgesic (18.75%), antibiotic (9.38%), anesthetic (6.25%), and steroid (3.13%), were found respectively. And the most antidote drug that used to treat these patients was CPM (75.0 %), followed by CPM and Dexamethasone (15.63%), Ondansetron (9.38%), Dimenhydrinate (3.13%) and metoclopramide (3.13%). In conclusion, this study was required in order to determine the characteristics of ADRs data and antidote prescribed pattern in dental practice, which could be beneficial not only use as the trigger tools to finding out the more ADRs situation but also use this trigger for further development as standard ADRs reporting system in the hospital.

**Keywords:** adverse drug reaction (ADR), antidote, dental

### 1. Introduction

According to the World Health Organization (WHO), an adverse drug reaction is harmful, which occurs at doses normally used in humans for the prophylaxis, diagnosis, or treatment of diseases or to modify a physiological function. Adverse drug reaction (ADR) is the fifth leading cause of death in the world. Thus the ADRs are important to detect and to report because the majority of them are considered preventable. [1, 2]

Adverse drug reactions (ADRs) are still among the leading causes of morbidity and mortality. [3] Reporting of ADRs has become an important component of monitoring and evaluation activities performed in hospitals [4]. The report encourage surveillance for ADRs, promote the reporting of ADRs of health professionals regarding potential ADRs [5]. A productive hospital-based reporting can be instrumental in providing valuable information regarding potential problems of drug usage in an institution. Through these efforts, problems are identified and resolved, which results in continuous improvement in patient care [6, 7].

In dental practice, the multiple adverse events are also found to be associated with a variety of widely used drug. Two examples of these are analgesic or local anesthetics, which are responsible for a great number of adverse reactions [8, 9] and the use of a sodium hypochlorite solution (2.5% to 5%) used for root canal irrigation in endodontic, which can cause oral cavity injury [10].

However, many studies have demonstrated that dental professionals are scarcely aware of the importance of ADRs report to patient safety [11, 12]. This fact implies underreporting and low-quality reporting, both of which represent limitations to risk management, because with the lack of monitoring is not known frequency and severity of adverse events which can interfere the quality of life of patients and increase the cost of the treatment.

Therefore, the effective report of adverse drug reactions (ADRs) is needed especially in dental practice. So the aim of this study is to determine the characteristics of ADRs in reporting documents and to finding out antidotes used to treat the patients that experienced adverse drug reactions.

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**Table 1** Patient characteristics

Characteristics	Year		
	2014	2015	2016
<b>Total Patients</b>	N (%)	N (%)	N (%)
<b>Gender</b>	7	12	13
Male	2 (29)	3 (25)	4 (31)
Female	5 (71)	9 (75)	9 (69)
<b>Age</b>			
mean	38	34.4	41.41
20–60	7 (100)	11 (92)	13 (100)
>60	-	1 (8)	-
<b>Cause from drug use</b>			
in the hospital	5 (71)	10 (83)	8 (62)
not in the hospital* (house, clinic, drug store, etc.)	2 (29)	2 (17)	5 (38)

\* ADRs occur during a dental treatment process, and causing from the drug that patients have been taking before, and outside the dental hospital.

## 2. Methods

The Descriptive cross sectional study was conducted at outpatient department of Mahidol Dental Hospital, Bangkok, Thailand over the period of 3 years between 2014 and 2016. All patients suspected of having ADRs report during the period of three years were evaluated by researcher. The patient reports were reviewed for ADRs (adverse drug reactions and Antidote drug that used to treat) previously identified by the dental professionals. The data were collected from a review of patient ADRs records, which were screened looking for find out antidotes that suited to be the triggers.

Patient records were reviewed with the aid of a checklist containing the following: patient characteristic (gender and age), Cause from drug use (in the hospital or not), WHO probability assessment scale, classification of type of reaction and classification of drug associate with ADRs (Class of drug and Antidote drug). The Description statistics were used for data analysis. For no normally distributed continuous data, median (interquartile range) was calculated.

## 3. Results

A total of 32 ADRs patients (were identified with 7 ADRs in 2014, 12 ADRs in 2015 and 13 ADRs in 2016. And, ADRs were more identified out of which in female than male (71% in 2014, 75% in 2015 and 69% in 2016). Age was also found to be an important criterion with the mean age 34–41. Followed by the ADRs report that cause of drug use was from drug in

the hospital (71% in 2014, 83% in 2015 and 62% in 2016) (table1).

From the WHO Probability Assessment Scale, in 2014, revealed that out of 29% ADR's were probable, possible, and unlikely drug-related. And 13% were identified as certain drug – related. In 2015, WHO scale revealed that out of 58% were possible drug-related, 17% were certain and unlikely drug-related and 8% found in probable drug- related. In 2016, WHO scale revealed that out of 38% were possible and unlikely drug-related, 16% was certain drug- related and 8% were in probable drug-related. (table2) The most commonly type of ADRs found in dermatology skin rash [13] (86% in 2014, 67% in 2015 and in 62% in 2016). While ADR's affecting other systems was as follows, Nausea and Vomiting found (14% in 2014 and 8% in 2016), tissue edema/ redness (8% in 2015 and 31% in 2016), chill (8% in 2015) and vertigo (17% in 2015) (Table3).

Dermatology skin rash is mostly found in the patients using antibiotics and analgesic (more than 60% in 2014–2016). While Nausea and Vomiting almost found in patient got anesthetic and steroid (more than a half in 2014–2016).

In 2014–2016, regarding ADR's commonly associated with certain drug it was found that ADR's were most commonly associated with Analgesic (37.5%). Followed with, both with Antibiotics and NSAID (18.75%), Antibiotic (9.38%), Anesthetic (6.25%), and Steroid (3.13%), were found respectively. While, the ADR's associated with uncertain drug (the drug that cannot typically identified because of currently multidrug usage in patients), that was also found (25.00%). (Table 4)

**Table 2** WHO Probability Assessment Scale (N=32)

WHO-UMC causality categories	Year		
	2014	2015	2016
	N (%)	N (%)	N (%)
Certain drug-related	1 (13)	2 (17)	2 (16)
Probable drug-related	2 (29)	1 (8)	1 (8)
Possible drug-related	2 (29)	7 (58)	5 (38)
Unlikely drug-related	2 (29)	2 (17)	5 (38)

**Table3:** Classification of type of reaction observed from reported ADRs (N=32)

Type of reactions	Year		
	2014	2015	2016
	N (%)	N (%)	N (%)
<b>Reactions</b>	7	12	13
Dermatology skin rashes	6 (86)	8 (67)	8 (62)
Nausea and vomiting	1 (14)	-	1 (8)
Tissue edema/redness	-	1 (8)	4 (31)
Chill	-	1 (8)	-
Vertigo		2 (17)	

**Table 4** Classification of drug associated with ADRs (n = 32) (years 2014–2016)

Type or Class of drug	N(%)
Analgesics	12 (37.50)
Antibiotics	3 (9.38)
Antibiotics and Analgesics	6 (18.75)
Anesthetics	2 (6.25)
Steroid	1 (3.13)
Others (uncertain drug)	8 (25.00)
<b>Antidote drug that used to treat</b>	
CPM	24 (75.00)
CPM and Dexamethasone	5 (15.63)
Ondansetron	3 (9.38)
Dimenhydrinate	1 (3.13)
Metoclopramide	1 (3.13)

In 2014–2016, regarding of each medication antidote, used to treat. The highest antidote signals were observed with CPM (75.0 %). Followed with in using CPM and Dexamethasone (15.63%), Ondansetron (9.38%), Dimen-hydrinate (3.13%) and metoclopramide (3.13%) (Table 4).

#### 4. Discussion

In the present study, the main age group affected by adverse drug reaction in the present study was 20-60 years which is supported by Shakti B. Dutta et.al

(2015), who reports ADRs in their study was between the same ranges of age years suffered [14]. And, because of among adults aged 65 years and older, there is the evidence that, this range of age spectacle the highest need of having to receive dental care [15].

And, the model assessment in the study was WHO Casualty Assessment Scale, which identified the adverse drug reactions. The assessment outcome was reported in belong to probable which is similar to the study conducted by Lazarou [16].

The characteristics of ADRs in the study focused on patient symptoms. Among the various symptoms by ADRs, Type of dermatology (Skin rashes) was the one most commonly found. A possible explanation may be that these symptoms are visible by the reporters. The profile of ADRs identified in our study is similar to that identified in a study conducted in a tertiary care hospital in Northern Brazil, where skin was found to be the most commonly affected organ system [13,17].

Also, in this present study, Analgesics and Antibiotics were most commonly involved in ADRs. Because not only there are the commonly use in dental practice, [13] but also there are ADRs of dermatology condition which is similar to mostly occur in many studies. Same as the study by Prosser TR (1990), where antibiotics were the most commonly implicated drug class for ADRs [18].

The antidote drug that used to treat in general were antihistamines and anti-allergy medications that can be common used in cases of adverse or allergic reactions. And drug used to reverse the action of other drug were also used as triggers for further ADRs collection [16].

The limitation of the study, because the study was conducted in specific dental hospital, So the ADRs are not as voluminous as they are in medical practice. This is based on the fact that most drug therapy in dental care is short term (comparing to the general medical) and the number of drug classes prescribed is small in comparison. For this reason, the cases that address are only the potential interactions according to the class of drug commonly prescribed in the hospital.

Another limitation was obtained from the limitation of ADRs reporting i.e. underreporting, which yielded 32 ADRs in the hospital over the 3 years period. These results needs to be taken into consideration and this result may not be generalizable to the entire whole population.

However during the periods of the studies, identification and collection of ADRs in this study done after the patient has left the hospital. Thus, to prove ADRs situation, developing trigger for better scientific tool and for more ADRs reporting than the traditional reporting system, the authorization plan is needed. First recommendations for improving may be making comprehensive review the data of ADRs involved, such as reviewing the duration of time between after taking drug and get allergy, the number of special patients (who having the chronic disease and drug problem) and the detail of patients with medication allergic records [19]. Second, it's a need of training regarding ADRs in the Health Care Professionals for better outcomes of patient in both the prospects health and safety. And there is a need to develop the strategies like electronically alert tool in all the dental hospital for the better patient safety services.

## 5. Conclusions

In Dental Hospital, there was very few active ADRs report. So, this study was required in order to collect the characteristics of ADRs data antidote prescribed pattern, which could be beneficial not only use as the trigger tools to finding out the more ADRs situation but also use this trigger for further development as standard ADRs reporting system in the hospital.

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