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Clinical Study of Acute Tramadol Poisoning in the Poison Control Center, Ain Shams University in 2012

Heba M Halawa[1]

[1] Forensic Medicine and Clinical Toxicology Department, Faculty of Medicine, Ain Shams University, Cairo, Egypt.

Abstract An increasingly alarming phenomenon of tramadol abuse in Egypt has been demonstrated in the recent ye Although the issue of drug abuse is not a newly introduced issue to Egyptian society but the wide range usage and illegal transactions associated with tramadol abuse making it the most easily accessible and rea provided drug at low cost.

Aim of the work: is to highlight the magnitude of tramadol poisoning and its patterns during the year 2012. Interpretation of the poisoning data through an annual report would be essential to face continuously challenging hazards**. Patients and methods:** This study was carried out on 1581patients presented to the emergency department of the Poison Control Center, Ain Shams University Hospitals *(PCCA)*due to acute tramadol poisoning, in the period from 1, January 2012 to 31,December 2012.A descriptive analysis and statistics of the medical records is accomplished. **Results**: The majority of patients (54.6%) were between 19 and 30 years, with male predominance representing (79.8%)of the total presented cases. The majority of admitted patients (56.6%) were male drug addicts, followed by suicidal attempt in (26.6%).Co- ingestion of other drugs or agents was recorded in (16%) of admitted tramadol patients which increase toxicity significantly. The most frequent clinical manifestations in admitted tramadol patients were coma in (52%), Constricted pupil in (30%)and seizures in (17.5%). Respiratory failure was present in 12.6% of admitted patients. Death occurred in 14 cases (0.9%) of the presented cases. The main cause of death was acute respiratory failure.

Keywords tramadol ,acute poisoning

Introduction

An increasingly alarming phenomenon of tramadol abuse in Egypt has been demonstrated in the recent years. Although the issue of drug abuse is not a newly introduced issue to Egyptian society but the wide range of usage and illegal transactions associated with tramadol abuse making it the most easily accessible and readily provided drug at low cost.

The alleged usages of tramadol had contributed greatly to its popularity and massive use especially among youth and middle aged groups as it relieves psychosomatic symptoms related to stress, like headache and abdominal pain, as well as depression and nervousness (Ahmadi et al., 2012). Also it is used as a remedy for premature ejaculatory dysfunction and for increasing sexual pleasure as promoted in many online drug stores and media (Salem et al., 2008).

The social and political changes in North Africa that began in Egypt, Libya and Tunisia in 2011 and were still ongoing in 2012 have reportedly caused deficiencies in the drug law enforcement capabilities in some of these countries. It seems that it is not only an Egyptian problem but also in neighboring countries, tramadol being the mostly used one. Its low price and availability without prescription make it very popular (INCB Annual Report, 2012) .

Tramadol is a centrally acting analgesic, which was first introduced in Germany in 1977. It's use has been approved in some countries since 1980 and became widely prescribed opioid worldwide (Shipton, 2000).Tramadol was approved for marketing as a no controlled analgesic in 1995 under the trade name of Ultram®. Although the producing company initially claimed that it causes only very weak narcotic effects, recent data demonstrate that opioid activity is the overriding contributor to the drug's pharmacological activity. Because of inadequate product labeling and lack of established abuse potential, many physicians felt this drug was safe to prescribe to recover narcotic addicts. As a consequence, numerous reports of abuse and dependence have been received (De Decker et al., 2008).

Abuse of tramadol as well as tramadol-related deaths have been increasing in Iran. Biological samples obtained during the autopsy were analyzed. Tramadol was detected in 294 cases by itself or together with other drugs. The majority of the cases were young male adults. Tramadol-related deaths in 2008 were 3.5 times more than in2005. These results suggest that tramadol-related fatalities are growing in Iran especially among substance abusers (Iravani et al., 2010).

Aim of the work

The objective of this study is to highlight the magnitude of tramadol poisoning and its patterns during the year 2012. Interpretation of the poisoning data through an annual report would be essential to face continuously challenging hazards. Analysis of data on the epidemiology of poisoning to issue warning reports and invite the health authorities to advocate steps towards preventive regulations for the welfare of the community.

Subjects and Methods

Subjects

The present study was planned as a cross-sectional hospital-based observational study in accordance with the ethical standards of the Poison Control Center, Ain Shams University Hospitals *(PCCA)* and after intake of permission from the director of the PCCA and names of patients were hidden. It was carried out on 1581patients presented to the emergency department of the *(PCCA)* due to acute tramadol poisoning, in the period from 1, January 2012 to 31, December 2012.

Methods

Computerized data of a specially designed program comprised demographic in addition to clinical and management data of acute tramadol poisoning cases received in PCCA in 2012. A descriptive analysis and statistics of the medical records is accomplished. All data were collected, summarized, presented and analyzed using an appropriate Statistical Package Program (SPSS version 17).

Qualitative drug screening in urine for tramadol detection in urine was carried out by using thin layer chromatography according to (Moeller, 2008). Records of the patients included:

I- Socio-demographic data

Age, sex and residence.

II- Clinical evaluation

(A) Medical history

It included:

1. Tramadol intake.
2. Mode of poisoning, whether suicidal, accidental, or addiction .
3. Route of intake of tramadol.
4. Time and Place of poisoning (including indoor and outdoor exposures).
5. Presence of co- ingestion of other drugs or agents and associated trauma or diseases.
6. Preconsultation management, faulty management

(B) General Examination

It included: pulse (heart rate),blood pressure ,temperature and respiratory rate , in addition to pupil and skin examination .

(C) Systemic Examination

Various body systems were examined to detect CNS, respiratory, cardiovascular, and gastrointestinal manifestations, according to (Nelson, 2007).

Results

The present study was conducted on 1581 patients presented with acute tramadol toxicity, of both sexes. The age of the presented patients ranged from 1 to 56 years, with mean value 23.8±6.7 years. The majority of patients (54.6%) were between 19 and 30 years, with male predominance (79.8%) of the total presented cases (Table 1).

Most cases originated from Greater Cairo (73.3%) followed by the nearby Kalioubeya (13.2%), Guiza (8.5%) while other governorates only (5%) (Table 2).

Poisoning severity score *(PSS)*,according to Junk et al. (2005), were (PSS 0/1) in 1185(75%) of presented cases (patients were asymptomatic or has mild manifestations, managed in the emergency department of the (PCCA) and discharged after observation period < 6h). 395 (25%) of presented cases were (PSS 2or 3), they were admitted in *(PCCA)*(237 (15%) of presented cases were moderate cases (PSS 2), admitted in the inpatient department, and 158 (10%) of presented cases were severe cases (PSS 3), admitted in the intensive care unit (ICU). Death occurred in 14 severe cases (PSS 4), representing (0.9%) of total presented cases (Table 3).

Regarding the mode of intoxication, The majority of admitted patients (56.6%) were drug addicts , followed by suicidal attempt in (26.6%), and then accidental exposure in (16.8%) of patients. 274 (69.4 %) of admitted patients were males while 121 (30.6%) were females (Table 4).

Route of poisoning was oral in all cases and all intoxication occurred indoor.

Co- ingestion of other drugs or agents was recorded in 63(16%) of admitted tramadol patients (Table 5). Co- ingested drugs include benzodiazepine in 20 cases (31.7% of 63 co-ingestion cases), cannabis–bango in 14 cases (22.2%), opiate in 9cases (14.3%), alcohol in 5 cases (7.9%), neuroleptics in 5 cases(7.9%), carbamazepine 4 cases (6.3%), cardiovascular drugs 3 cases (4.8%), Viagra 1case (1.6%), NSAIDs 1case (1.6%), and organophosphorous in 2 cases (3.2%). Table(5) showed that *PSS* was significantly higher among patients presented with Co-ingestion of drugs.

Associated trauma was recorded in 3 cases (0.8% of admitted patients) (1skull fracture, 1

subarachnoid hemorrhage, 1 brain shot) and one case with suicidal hanging. Associated diseases include diabetes mellitus one case, hepatitis C in one case, meningitis in one case, and pregnancy in one case.

Referral from other general, private hospitals or clinics was documented in (86cases) 21.7% of admitted cases. Faulty management with salt emesis was recorded in4 cases.

The most frequent clinical manifestations on presentation were coma, seizures, Constricted pupil, nausea and vomiting as shown in (Table 6 and 7).

In the present study, respiratory failure was present in 50 cases (12.6)% of the admitted patients , diagnosed by arterial blood gases. 19 cases (38%) had respiratory failure type 1 (hypoxia only) and 31 cases (62%) had respiratory failure type 2 (hypoxia and hypercarpia) with respiratory acidosis.

Interventions offered to the 395 admitted acute tramadol poisoned patients include mainly: decontamination procedures were accomplished on 79 (20% of cases) either in the form of gastric lavage or ipecac emesis. Enhanced elimination in the form of activated charcoal was given for 112 cases (28.3%). Antidotes treatment with naloxone accounted for 39 cases (9.8%). Mechanical ventilation was needed in 32 cases (20 %of the ICU cases). Emergency and supportive treatments and other various therapies and interventions recommended by the PCC are displayed in (table 8).

Regarding the period of hospitalization, most of admitted cases (71.7%) were hospitalized for one day, while only 4.6% cases (severe ICU cases)were hospitalized for 4-7days (table 9).

Death occurred in 14 cases (0.9%) of the presented cases (table 3). The main cause of death was acute respiratory failure in 11 cases (79%), and myocardial ischemia in 3 cases (21%).

Table 1: The age and gender distribution of tramadol poisoned cases received in PCCA through the year 2012.

Age(years)	Male		Female		total	
	NO.	%	NO.	%	NO.	%
12>	95	6	79	5	174	11
12-<19	221	14	46	2.9	267	16.9
19- <30	699	44.2	164	10.4	863	54.6
30 –< 40	174	11	17	1.1	191	12.1
>40	73	4.6	13	.80	86	5.4
Total	1262	79.8	319	20.2	1581	100%

Table 2: The Residence of tramadol poisoned cases received in PCC through the year 2012.

Governorate	Number	%
Cairo	1159	73.3
Kalioubeya	209	13.2
Giza	134	8.5
Other Delta Governorates	55	3.5
Upper Egypt Governorates	19	1.2
Suez Canal Governorates	5	0.3
Total	1581	100%

Table (3): Distribution of 1581 acute tramadol poisoned patients according to Poisoning severity score (PSS).

Prognosis	PSS	Number of patients	Percent (%)
Discharge after observation < 6h	0 /1	1185	75%
Inpatient	1 / 2	237	15%
ICU	3	158	10%
Death	4	14	0.9%

0: Asymptomatic ,1: mild manifestations , 2: moderate manifestations ,3: severe manifestations ,4: Death

Table (4): Distribution of 395 admitted tramadol poisoned patients according to mode of intoxication

Mode	Male	Female	Total No	Total Percent (%)
Addict (overdose)	224	0	224	56.6%
Suicidal	9	96	105	26.6%
Accidental	41	25	66	16.8%

Table (5): Student's t-test statistical analysis comparing groups (classified according to co-ingestion of drugs) with the PSS in the 395 admitted tramadol poisoned patients.

Co-ingestion	Number of patients (%)	PSS (Mean±SD)	t	P
Positive	63(16%)	2.6±0.7	-2.052	0.008
Negative	332 (84%)	1.5±1.0		

P<0.001= highly significant, p>0.05 = non-significant, t:Student's t-test

Table (6): Incidence of abnormalities in general examination in the 395 admitted tramadol poisoned patients.

	Number	Percent (%)
1- Pulse		
Tachycardia	69	17.5%
Bradycardia	12	3.1%
2- Blood pressure		
Shock	18	4.5%
Hypotension	14	3.5%
Hypertension	9	2.4%
3-Respiratory rate		
Bradypnea	23	5.9%
Apnea	18	4.5%
Tachypnea	4	1%
4-Temperature		
Hypothermia	7	1.7%
Hyperthermia	8	2.1%
5-Skin		
Cyanosis	26	6.6%
Sweating	14	3.5%
6-Pupil		
Constricted	119	30%
Dilated	17	4.2%

Table (7): Incidence of neurological, respiratory, cardiovascular and gastrointestinal manifestations in the 395 admitted acute tramadol poisoned patients.

	Number	Percent (%)
Neurological system		
Coma	205	52%
Seizures	69	17.5%
Disequilibrium	23	5.9%
Agitation	18	4.5%
Hallucination	3	0.7%
Respiratory system		
Respiratory distress	32	8%
Pulmonary edema	18	4.5%
Cardiovascular system		
S. tachycardia	18	4.5%
Myocardial ischemia	4	1%
Ventricular arrhythmia	1	0.3%
GIT system: nausea and vomiting	51	13.3%

Table 8: Interventions offered to 395 admitted acute tramadol poisoned patients.

Type of intervention	Number (%)	Type of intervention	Number (%)
1-Emergency Treatment		**5-Supportive treatment**	
Oxygen	131 (33.2%)	Mechanical ventilation	32 (8%)
Endotracheal intubation	117 (29.7%)	Inotropics	18 (4.5%)
Ambu resuscitation	36 (9%)	IVF and electrolytes	391 (99.3%)
Airway suction	18 (4.5%)	Sedative hypnotics	109 (27.6%)
2-Decontamination		H2 blockers	101 (25.5%)
Gastric Lavage	51 (12.9%)	Antibiotics	81 (20.6%)
Ipecac emesis	28 (7%)	Steroids	51 (12.9%)
3-Enhanced elimination		Antiemetic	16 (5.6%)
Activated charcoal	112 (28.3%)	Nebulizer therapy	18 (4.5%)
4-Antidote		Mannitol	9 (2.4%)
Naloxone	39 (9.8%)		
Bicarbonate	(2%)8		

Table 9: The period of hospitalization of395 admitted acute tramadol poisoned cases through the year 2012.

Period of hospitalization	No	%	Period of hospitalization	No	%
1day	283	71.7	3 days	32	8
2 days	62	15.7	4-7 days	18	4.6

Discussion

Tramadol, a synthetic codeine analog, is approved for mild to moderate analgesia. Both tramadol and its metabolite have weak mu receptor activity. It is easy to acquire and cheap to purchase on the street, and abuse has been reported (Yates et al., 2001).

In this study 1581 tramadol intoxications were identified during the year 2012 in the PCC of Ain Shams University, the first and largest national poison treatment center in Egypt.

An alarming figure has been the progressive rise of tramadol overdose amounting to 1595 cases in the year 2011 compared to 386 cases in 2009 and 760 cases in 2010. These data and daily observations of the magnitude of the problem enabled the PCCA to declare new recommendations concerning drugs of abuse screening list and issue several warnings in media that were given much concern by the health and drugs of abuse authorities (El-Masry and Tawfik., 2013).

The results of this study showed that, tramadol intoxications affect mainly young men with the most represented age gender range 19 to 30 years. The number of cases is almost four fold as high as women in the same age bracket , which seems to be in relation with youth characteristics, as reported in other studies (Shadnia et al., 2008 and Ahmadi et al., 2012).

The residence data revealed that most of cases originated from Cairo (73.3%) followed by Kalioubeya and Giza where they represented 13.2%, and 8.5% respectively. This is attributed to the proximity of these governorates to the PCCA and not to the higher magnitude of the poisoning health problem (table 2).

Regarding the mode of intoxication, the majority of admitted patients (56.6%)were male drug addicts, followed by suicidal attempt in (26.6%). 91% of suicidal cases were females. These results coincide with Marquardt.et al.,(2005).In contrary to the study done by Ahmadi et al.,(2012) who reported that suicide was the most common cause of tramadol intoxication, recorded in (55.1%) of cases.

A Palestinian study by Al-Afifi et al., (2011) noticed a huge increase in prescription drug abuse, especially tramadol (strong analgesic opioid sedative). The study concluded that there is a worrying increase in prescription drug abuse as well as a sharp shift from traditional drugs to prescription drugs, especially tramadol.

The oral route of intake was recorded in all cases of the present study as being more prevalent easily administered form.

In the present study, history of tramadol addiction was observed. Co- ingestion of other drugs or agents was recorded in 63(16%) of admitted tramadol patients .Benzodiazepines, cannabis and opiate were the commonest co-ingestions with tramadol, which significantly increase the risk of intoxication as reported in similar studies Clarot et al., (2003) and De Decker et al., (2008). PSS was significantly higher among patients presented with Co-ingestion of drugs.

The combination of tramadol and other drugs can cause threatening or even fatal side effects. Both benzodiazepines, opiates and tramadol are central nervous system depressants, and these agents slow down brain activity and function which can lead to confusion, loss of consciousness , brain damage , respiratory depression .Combining alcohol and tramadol also increases the chance of overdosing on either or both. Tramadol and alcohol also increase depression and can cause suicidal thoughts or actions (Shadnia et al., 2008).

Associated trauma was recorded in the present study with tramadol intoxication. Tramadol could induce dizziness, confusion, drowsiness, seizures, and respiratory depression. Any of these toxic effects can negatively affect the performance and good judgment. Tramadol abuse overdose is highly associated with accidental fall, self-unintentional induced injuries and act of violence (Bachs et al., 2009).

In the present study, The most frequent clinical manifestations on presentation were coma, seizures, Constricted pupil, nausea and vomiting

Although tramadol is a novel analgesic which is used in the management of moderate to severe pain, there are some studies on toxicity in overdoses due to different mechanisms like opioid-dependent gamma-aminobutyric acid inhibitory pathway Rehni et al., (2008) or histamine (H1 receptor) involvement Rehni et al., (2009) which could cause tramadol-induced seizures .Neurotoxicity of tramadol is speculated to be related to the reuptake inhibition of serotonin and norepinephrine rather than its opioid effects. Patients will be at risk of seizure as an adverse effect (Sansone and Sansone, 2009).

In the present study, antidotes treatment with naloxone accounted for 9.8% of cases. Naloxone is an opioid antagonist, which is recommended for taramdol overdose has controversial effects. Some studies indicated that administration of naloxone markedly attenuate tramadol-induced seizurogenic activity (Yang et al., 2010), but other studies indicate that naloxone may increase seizure or did not modify tramadol seizurogenic effects (Omrani et al., 2007).

In the present study, mechanical ventilation was needed in 20%of the ICU cases. Serious potential consequences of overdose with ULTRAM (tramadol hydrochloride) are central nervous system depression, respiratory depression and death. Some deaths have occurred as a consequence of the accidental ingestion of excessive quantities of tramadol alone or in combination with other drugs. In treating an overdose, primary attention should be given to maintaining

adequate ventilation along with general supportive treatment (Rosenthal, 2010). Animal trials demonstrated that tramadol increased the apneic threshold and decreased the total CO_2 sensitivity (Teppemaet al., 2003). Naloxone completely reversed these effects, whereas pretreatment with naloxone preserved more than half of the expected ventilatory depression in these animals. Human studies confirmed that tramadol 100 mg p.o. reduced the ventilatory CO_2 response by 30%, acting at the respiratory integrating centers Stamer et al., (2008).

Regarding the period of hospitalization, most of admitted cases (87.4%) were hospitalized for shorter than 48 hours, while only 4.6% cases (severe ICU cases) were hospitalized for 4-7days. This agrees with Ahmadi et al., (2012) who reported that the duration of hospitalization for 94 % of cases were shorter than 48 hours.

Death occurred in 14 cases (0.9%) of the presented cases. The main cause of death was acute respiratory failure in 11 cases, and myocardial ischemia in 3 cases. This agrees with that reported by Ahmadi et al., (2012) who reported that mortality rate of tramadol poisoning was 0.97%. Mortality reports after tramadol poisoning and overdose have been seldom reported. The mortality of acute poisoning depends on a number of factors such as nature of poison, dose consumed, level of available medical facilities and the time interval between intake of poison and arrival at hospital (De Decker et al., 2008).

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الملخص العربي

دراسة إكلينيكية لحالات التسمم الحاد بالترامادول بمركز علاج السموم جامعة عين شمس عام ٢٠١٢

هبه محمد حلاوة[1]

الخلفية: يمثل التسمم بالترامادول خطرا متزايدا في المجتمع المصري بصورة ملفته للنظر في السنوات الأخيرة. رغم أن مشكلة الإدمان ليست بجديدة على المجتمع المصري إلا أن انتشار تعاطي الترامادول بشكل كبير و الممارسات الغير قانونيه المصاحبة لتداوله جعلت منه عقار سهل الحصول عليه ورخيص الثمن.

الهدف من هذه الدراسة إلقاء الضوء على مشكلة التسمم بالترامادول و تحديد نمط التسمم به خلال عام ٢٠١٢. وكذلك تحليل بيانات التسمم بالترامادول ومتابعتها في تقارير سنوية لمواجهة تحديات هذه المشكلة.

المرضى والطريقة: تمت هذه الدراسة على ١٥٨١ مصابا تم استقبالهم في مركز علاج السموم خلال الفترة من ١ يناير حتى ٣١ ديسمبر من عام ٢٠١٢ . تم تحليل البيانات إحصائيا ووصفيا.

النتائج: أغلبية المرضى (54.6%) في الفترة العمرية من١٩ إلى ٣٠ سنه بأغلبية الذكور الذين يمثلون ٧٩,٨ % من إجمالي عدد الحالات. أغلبية المرضى المحتجزين (56.6%) من ذكور مدمني الترامادول، يليهم محاولات انتحار باستخدام الترامادول في (٢٦,٦%) من المرضى المحتجزين. سجلت الدراسة تناول أدويه أخرى في ١٦% من حالات الترامادول التي تم احتجازها و التي أدت إلي زيادة السمية بدرجة ملحوظة. كانت أكثر العلامات المرضية شيوعا الغيبوبة في (٥٢%) من الحالات المحتجزة، التشنجات في (٥,١٧%) وضيق حدقة العين في (٣٠%). الفشل التنفسي وجد في (12.6%) من الحالات المحتجزة. سجلت الوفيات في ١٤ حالة (0.9 %) من إجمالي حالات الترامادول. كان السبب الرئيسي للوفاة هوا لفشل التنفسي الحاد .

1 قسم الطب الشرعي والسموم الإكلينيكية كلية الطب جامعة عين شمس