# The Trend of Tramadol Vending in Retail Pharmacies and Negative Impact of Abusing Drug on its Purchasers in Mosul City, Iraq

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ABSTRACT—Since 1998 tramadol was introduced to the Iraqi markets as a nonscheduled centrally acting analgesic with low abuse potential. Many patients (or customers on their behalf) purchased the drug from retail pharmacies without medical prescription which may raise a strong need to investigate the suspicion of potential trmadol abuse among those customers who visited those pharmacies in Mosul which is one of the biggest cities in north Iraq.

Methodology: Under the supervision of the pharmacists in ten retail pharmacies (which were selected randomly from different areas in Mosul), a closed-ended questionnaire constructed by the researches and designed to detect the trends of purchasing tramadol from private pharmacies besides the International Neuropsychiatric Intervew version-5(module L), were filled out for every patient or (someone on their behalf) who purchased tramadol from those pharmacies during six months period (June 2012-December 2012). Sociodemographic characters of the purchasers were obtained in this study and subjected to descriptive statistics to make comparison with other studies.

Results: Of 163 patients or (someone purchased the drug on their behalf) who seek tramadol from the pharmacies, 84 (51.53%) purchasers did not have prescription. About 98(60.12%) patients reported abuse or addiction criterias on tramadol after interviewing them through M.I.N.I. international neuropsychiatric interview version- 5. Most of the purchasers were males and females below thirty (73.3%, 74.1% consecutively). Participants who were unemployed (83.9%), singles (92.6%) were aging below thirty. Approximately (60%) of the patients reported a history of addiction or drug abuse. Most of the patients with no prescription(46%) had abuse criteria on tramadol.

Conclusion: Patients who request tramadol from private pharmacies in Mosul seem to have a high potential for drug abuse, dependence, in particular those who do not have prescriptions. The high prevalence of people under 30 years of age seeking tramadol could be a worldwide trend. Construction of detoxification units is highly recommended in Mosul.

Keywords- tramadol, drug abuse, dependence, pharmacy, Mosul, Iraq

# 1. INTRODUCTION

Tramadol is an unscheduled atypical analgesic that acts as an agonist at  $\mu$ -opioid receptors and inhibits monoamine reuptake[1]. It is a centrally-acting analgesic with weak  $\mu$ -opioid agonist properties, and a weak inhibition of norepinephrine and serotonin reuptake[2]. First marketed in the 1970s, tramadol was said to have a low-abuse potential. [3],[4],[5]. The prescription of the drug had begun for management of opioid detoxification, for headache and body pains, and as an alternative to injectable opioids. All subjects reported an experience of euphoria with tramadol use[6]. Preclinical, clinical, and epidemiologic studies prior to 1994 suggested that tramadol has a low abuse potential[7],[8] which led the Drug Abuse Advisory Committee to recommend to the US Food and Drug Administration (FDA) that tramadol be approved as a nonscheduled analgesic(9).

However, its abuse liability and diversion were soon recognized, with several reports on physical dependence.[10,11,12,13,14,15,16]. The largest series of tramadol-dependence was reported from a study in Sweden,[17] comprising of 104 patients, where the majority were women. In another series 97% of the abusers had a history of abuse of other substances.[18]. Association with seizures at therapeutic and toxic doses has been reported. [19] as has been the abuse among occupations like physicians[20] and air force personnel.[21]. Tramadol can suppress opioid withdrawal, and chronic administration can produce opioid physical dependence; however, diversion and abuse of tramadol is low.[1]. Tramadol dependence is very rare but can happen in a patient without substance abuse history[22].

Two Phase IV studies, as well as a post-marketing surveillance study, have evaluated tramadol abuse in the US[19,23]. Studies that have evaluated the psychological dependence and compulsive use of opioids, which are the defining features of dependence/addiction, have reported an abuse rate of 3%–16%, and defined the term "addiction" as an inability to cease use of the drug, compulsive use, continued use despite harm, and craving upon cessation of taking the drug,[22],[24]].

It has been marketed in an unregulated manner as a new generic prescription drug in Iraq during 1998 in retail pharmacies. Recently, it has become one of the most widely dispensed analgesics in Iraq's essential drugs list. Due to the critical security situations and the weak control and supervision on the retail pharmacies in Iraq, many of the drugs were sold without medical prescription, so many of the drug abusers can access their abused drugs easily there. Consequently high rates of tramadol intoxication were reported in the emergency departments in Iraq.

### 2. OBJECTIVES

- 1. To explore the trends and negativities of vending tramadol to the customers attending the retail pharmacies in Mosul city
- 2. To highlight the potential risk of tramadol abuse and dependence among people who seek for tramadol for themselves or on the behalf of other patients from the retail pharmacies.
- 3. To point out many demographic variables in correlation with age of customers purchasing tramadol from retail pharmacies.

## 3. MATERIALS AND METHODS

## Design

Observational cross-sectional study

### **Setting**

Ten private sector pharmacies in different areas of Mosul city in Iraq, were randomly selected and invited to participate in the study

## **Participants**

One hundred sixty three participants attending ten private pharmacies requested the drug (tramadol) with or without medical prescription, were asked to respond to the interview questions from the period 1/6/2012 till 31/12/2012

## Tools and data collection

A structured closed-ended questionnaire containing seven questions constructed by the researchers was designed to explore the trends of purchasing tramadol from retail pharmacies, concentrating on possessing medical prescriptions, seeking for the sources from which the participants got the drug before, the duration of tramadol consumptions, the kind of tramadol preparation used, the purpose of its consumption, abuse or addiction on other drugs in its customers. This questionnaire was used for the first time in Iraq through this research and not previously validated. The participants were then subjected to the MINI International Neuropsychiatric Interview version-5, the Arabic copy, module (L) to point out any potential risk of tramadol abuse or dependence among tramadol customers. The M.I.N.I. was designed as a brief structured interview for the major Axis I psychiatric disorders in DSM-IV and ICD-10. Validation and reliability studies have been done comparing the M.I.N.I. to the SCID-P for DSM-III-R and the CIDI (a structured interview developed by the World Health Organization for lay interviewers for ICD-10). The results of these studies show that the M.I.N.I. has acceptably high validation and reliability scores, but can be administered in a much shorter period of time (mean  $18.7 \pm$ 11.6 minutes, median 15 minutes) than the above referenced instruments. [26,27]. It can be submitted by a physician or layman. The patient demographic information (including sex, marital status, employment) in relation to age, were studied and taken into account. The lists of the structured questionnaire and the interview were completed by the pharmacies staff (pharmacist's assistant, male nurses, trained in pharmacology) under the supervision of pharmacists and responded to them verbally by the participants. Patient information were obtained anonymously during a private consultation in the pharmacies after a written consent from the respondents, besides confidentiality of both customer and pharmacy's names were kept on. The questionnaire and the M.I.N.I data were collected and analyzed using SPSS software.

## 4. RESULTS

The responses to each category of the structured questionnaire were summarized in tables (2), while answers which confirm the suspicion of the risk of abuse or dependence on tramadol were summarized in table (3). The demographic characters were shown in table (1). Participants whose ages were below thirty were 120 out of 163, most of them were males(73.3%),unemployed(83.9%), singles(92.66%). Although a high percent of the divorced and widowed women were above thirty years old (86.6%, 100% consecutively), the result was insignificant the small number of participants. In short, of 163 purchasers of tramadol from Mosul private sector pharmacies, 84(51.53%) didn't have prescription,

(47.23%) got tramadol from drug dealers in the past, while most of the customers (77.91%) had taken tramadol frequently and (60.1%) of the customers gave a history of abusing other drugs, (77.3%) took tramadol tablets(table 2). About 74.2% used tramadol to relieve the pain of the physical diseases they complained of while 25.6% used it for psychological relief(table 2). The striking result of tramadol abuse and dependence among its customers was heightened in tablet (3), where (60.1%) of the participant were found to have abuse (37.4%) or dependence (22.6%) on tramadol.

### 5. DISCUSSION

Iraq was almost devoid from drug addiction before 2003. Recently there is increasing numbers of addicted people due to the bad insecure situation in the country, high percentage of unemployment, and the weak control on the Iraqi boarders besides the negligible supervision on dealing and dispensing of drugs with high abuse potential in the retail pharmacies. There is an increment in the purchase requisition of tramadol from private pharmacies in Mosul city due to its availability there and its consideration as anon-scheduled drug in Iraq besides the over prescription of this drug to relieve pain in many medical specialties, which is a similar worldwide trend as the drug is easily available and widely prescribed for pain management,[24,25] as well as the leniency and connivance practiced by some of the pharmacist assistants in the private pharmacies in vending the potentially addicted drugs. The medical registrations and the reports of the emergency departments in Mosul revealed an increment in tramadol intoxication in adolescents and young adults (thirty six patients presented to the emergency department complaining of tramadol intoxication in 2011, whose ages range were between 17-28 years old ), such results highlight increasing risk potential of tramadol abuse among teenagers and young age groups

The results of this study and responses to the questionnaire categories besides the responses to the (L) module questions of the Mini international neuropsychiatric interview, submitted to the respondents, were comparable to a similar Iranian study [28]. This is the first study which was performed in Iraq on the trend of dispensing tramadol in private pharmacies and the potential of abuse and dependence of this substance among its purchasers.

Most of the people seeking tramadol from retail pharmacies in Mosul were adolescent or young adults, most of them showed criteria of drug addiction, a result which is consistent with previous studies [28,29,30] which reported tramadol intoxication in youngsters. The young age profile of the patients identified as being addicted on tramadol might be related to worldwide decrease in the prevalent age of individuals with drug abuse [28,29,30,31,32].

The main explanations for this results are the effect of the critical and bad security situations and its stressful related events which had a negative impact on the daily life in Mosul city, especially in this particular age group and the motivation to use this substance with their peers, the weakness of the familial observation and follow up for these youngsters besides the prevailing unemployment and low income. The dilemma of unemployment in Iraq, particularly in youths may motivate them to drug abuse as a self- medication for the consequent stress, a result which is consistent with the report of the Independent drug monitoring unit [33].

Most of the attendees who purchased the tramadol from those pharmacies were male but a significant number of females reported addiction symptoms in this study, most of them were below thirty and singles, a results which is consistent with a Korean study which revealed that single women are at risk of drug abuse more than married women [34]. There is a significant number of married customers of tramadol in this study specially women. Who admitted abuse of tramadol besides other drugs. Studies have shown that interpersonal relationships may have contradictory effects for women who are addicts, they can be a source of support, they can also contribute to ongoing addiction problems [34].

The regulations of the ministry of health in Iraq prohibited dispensing any drug, including tramadol in the pharmacies without valid medical prescription. Even though many patients can access to tramadol from retail pharmacies without prescription because of the weak governmental supervision on the dispensing regulation of drugs in these pharmacies. A small minority of the patients can't renewed their medical prescription of tramadol because they were financially poor, even though the majority of the customers in the current study who might have illegal access to tramadol from the pharmacies proved to have symptoms and signs of drug use disorder and used consumed the drug frequently, some of them claimed that they got tramadol from drug dealers previously.

Most of the patients preferred oral preparations of tramadol due to its low price and availability, although most of the patients who consumed the parenteral preparation of tramadol proved to have symptoms of substance use disorders in the current study.

The significant high result of abuse and dependence on tramadol in the participants of this study is a percussive result which must attract attention to the potential abuse and dependent effect of tramadol.

An important observation in this study, that many participants demonstrated denial of abuse and dependence symptoms and refusal to reply to questions submitted to them fearing of falling in a conflict with the law, a dilemma tackled through reassurance and observance of confidentiality.

## 6. CONCLUTION

In conclusion, those customers who purchased tramadol from retail pharmacies in Mosul were at high risk of abusing tramadol, especially those who hadn't medical prescriptions. Many patients accessed tramadol from retail pharmacies without prescriptions due to the weak governmental supervision on the dispensing regulations of addictive drugs in retail pharmacies. The increment in the abuse of tramadol and other addictive drugs may be related to insecure environment in Mosul besides the prevailing unemployment, The young age profile of the patients seeking for tramadol (most of them were proved to have abuse or dependence on tramadol) might be related to the worldwide decrease in the prevalent age of individuals with opioid addiction. There is no public education in Iraq about the danger of abusing tramadol, the over prescription of the drug by physicians may increase the risk of abuse and dependence on this drug in the general population. There is no center for detoxification and management of drug use disorders in Mosul city although there is increased reports of tramadol intoxication, especially in youngsters. This point requires further attention from the policy makers and the health directorate in Mosul city to plan for constructing such an important project which could be helpful in managing such a problem, especially among young patients, if synchronized with ongoing public education about the danger of tramadol use disorder and legislate a law to regard tramadol as a scheduled drug and a consequent strict dispensing of it.

# Limitation of the study

- 1. Many of purchasers of tramadol refused to participate in the study fearing that it will lead them to punishment or breaking out of confidentiality.
  - 2. Denial & refusal to answer some of the questions correctly by the participants.
- 3. The structured closed-ended questionnaire has been directly constructed by the researchers and not previously validated.

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