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Pregabalin dispensing patterns in Amman-Jordan: An observational study from community pharmacies

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ABSTRACT

Objectives: Pregabalin is currently approved for the treatment of epilepsy, generalized anxiety disorder, neuropathic pain and fibromyalgia. Rising attention to the abuse liability of pregabalin causing addictive behaviors is partially based on case reports and published literature of pregabalin used in dosages that override the approved therapeutic range. This study was conducted to provide background data regarding the abuse/misuse of pregabalin from community pharmacy in Jordan.

Methods: A prospective cross-sectional observational study design was used, which was conducted at different community pharmacies in Amman-Jordan. During the study period (November 2016–January 2017), a total 77 requests for pregabalin were observed from 14 pharmacies. A structured interview was conducted with all customers to gather information regarding their demographic and their request of pregabalin.

Results: A total of 77 pregabalin requests from 77 customers in a community pharmacy setting were observed in this study. Spinal disc herniation was the most common complaint for which the customer asked for the medication (n = 27, 35.1%). Self-medication was the most frequent method of requesting pregabalin (n = 44, 57.1%), while a total of 33 customers (42.9%) asked for the product using a prescription. During the observation period the number of customers suspected of abusing pregabalin for non-medical reason was 35 (45.5%). A total of 33 out of the 35 suspected customers (94.3%) asked for the product without a prescription, and 19/35 weren't sold due to suspicion of abuse (54.3%).

Conclusion: The study underscores the need for regulatory efforts to manage pregabalin abuse, through the addition of pregabalin containing products to the controlled drug list which can't be purchased without a prescription. Also, pharmacists and customers must be educated at a community pharmacy level regarding potential hazards of pregabalin abuse.

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1. Introduction

Substance use disorder is a group of behavioral, cognitive and physiological symptoms resulting from applying the substance continuously despite significant negative effects (Kerridge et al., 2017). It may result as a consequence of drug abuse and misuse.

“Misuse” is a broad term which comprises many different forms of problematic consumption where the use of the substance does not follow medical instructions (Bronstein et al., 2011; Casati et al., 2012) while the term “abuse” refer to situation where the substance be used for nontherapeutic purposes to obtain psychotropic effects (Cicero et al., 2007). By definition, any medication can be misused, but only few have the abuse potential, such as those with mind-altering or body-shaping properties (Cooper, 2013).

The risks of addiction to prescription drugs rise when they are used in means other than prescribed (e.g. at higher doses, by other routes of administration, or mixed with alcohol or other drugs) (NIDA, 2014). The most commonly reported prescription medications to be abused worldwide are stimulants such as methylphenidate, central nervous system depressants such as sedatives

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(benzodiazepines) or some anticonvulsants like clonazepam (NIDA, 2014) or pregabalin (Loftus and Wright, 2014).

Pregabalin is an analogue of the gamma-aminobutyric acid mammalian neurotransmitter. They act as inhibitory modulators of neuronal excitability that reduce ectopic neuronal activation of hyperexcited neurons while normal activation remains unaffected (Papazisis and Tzachanis, 2014). Pregabalin is approved for the treatment of partial epilepsy; generalized anxiety disorder; peripheral and central neuropathic pain and fibromyalgia with an accepted dosage range of 150–600 mg/day (Papazisis and Tzachanis, 2014).

In Jordan, like other countries in the region, with the exception of controlled drugs, it is possible to buy any medicine without a prescription. This availability linked with relatively low price products and availability of pharmacies is speculated to lead to abuse of a wide variety of OTC and prescription drugs (Albsoul-Younes et al., 2010). In 2014 a study was conducted by Wazaify et al. to document any change that may have happened in the type and frequency of suspected abuse/misuse of medications that can be bought without prescription from community pharmacies in Jordan (Wazaify et al., 2017a). A recent concerning trend was the abuse of the anticonvulsant drug (pregabalin), which obtained from pharmacies without a prescription and was not been mentioned previously in Jordan (Wazaify et al., 2017a).

In 2014 a formal statement about the restriction of pregabalin products dispensing in Jordan appeared (JFDA, 2014). This was due to the occurrence of spontaneous reports which was observed by the Jordan Food and Drugs Administration (JFDA) pharmacovigilance center regarding pregabalin abuse containing products. Pregabalin containing products were placed on the list of restricted drugs use that require a medical prescription to dispense it. This list includes drugs with abuse liability, but not competent to be under scheduled controlled drugs (JFDA, 2014). But unfortunately, it is still possible to get such medications easily without fearing of legal accountability.

In 2017 another announcement was released in Jordan to emphasize the obligation on not to supply samples of drugs containing this substance or grant quantities of incentives on the quantities sold of this medicine (JFDA, 2017). Despite this announcement the pregabalin products still can be sold without a prescription and without fear of any legal accountability. So efforts are needed to support the addition of this drug to the controlled drug list (which can't be purchased without prescription in Jordan). In order to support this requirement, we aimed in this observational study to provide background data regarding the abuse/misuse of pregabalin products in a community pharmacy setting in Jordan. Up to the researchers' knowledge, this is the first study of its kind in Jordan to address this issue.

2. Methods

2.1. Study design, setting and subjects

The study was designed as a prospective cross-sectional observational study that was conducted at different community pharmacies in Amman, the capital of Jordan. Two researchers interviewed all customers of a number of community pharmacies asking for pregabalin products during the observational period (November 2016–January 2017). Customers verbally consenting to be interviewed.

A convenience sampling technique was used to select the involved pharmacist. This was based on the feasibility, geographical proximity to the researchers housing, and upon consenting to participate by the pharmacy manager of each community pharmacy. Researchers took every effort to cover most socioeconomic regions

in Amman (Dahiyat AlRasheed, Al-Jandaweel, Sweifieh, Sweileh, Khalda, Jbeiha, Sahab, Wadi-Alseir, Khrbet Alsouq, and Arjan).

2.2. Data collection instrument

Researchers used a pre-tested and pre-piloted data collection form which was adopted from Wazaify et al. 2017 study (Wazaify et al., 2017b). The method used in this study was a structured interview with all customers presented at the time of the survey. The data collection form was designed to gather customers information in an anonymous way without mentioning any information belonging to customers or pharmacists.

Information obtained in the interview include: (1) customers' demographic data including (age, gender and academic qualification, site of recruitment and shift of recruitment), (2) pharmacies and pharmacists information (pharmacy location, chain or independent pharmacy, pharmacists age, gender, and experience), (3) the name of pregabalin product, quantity, indication and duration of use, (4) the way of asking for the medication (prescription, customers' request (self-medication), or pharmacist dispenses), and (5) pharmacist response with the abuser customers and the signs that led the pharmacists and the researchers to suspect them, for example (the pattern and repeated requests, customers's appearance (if he confused or related to his face), pharmacists' familiarity with customers and the quantity requested).

2.3. Data collection procedure

A predetermined schedule was designed in order to observe each community pharmacy for one week. Data collection took place over November 2016–January 2017 through 14 pharmacies at different regions of Amman. Data were filled by the researchers after informing the pharmacists within pharmacies that the aim of this research was to measure the pregabalin drug misuse/abuse among customers in community pharmacies. To minimize the observers' effect (i.e. Hawthorne effect), the researchers noticed the interaction between customer and pharmacist standing beside the pharmacist on the dispensing counter, wearing lab coats. A collaboration was made between the researchers and the main pharmacists to detect the abuser customers. The data collection form was filled immediately after observations and any additional information thought to be important to the research was written at the end of the data collection form. Each researcher was the only observer in each community pharmacy.

2.4. Ethical consideration

This study was approved by Jordanian Ministry of health (Reference number: MOH REC170012). In addition, verbal consents were obtained from all pharmacists to use their demographic data. Written and signed consent forms were obtained from the pharmacy managers for their acceptance for the study to be conducted in their pharmacies.

2.5. Statistical analysis

All data were coded and entered into the Statistical Package for Social Sciences (SPSS) database (version 22) for statistical analysis (IBM Corporation, Armonk, NY, USA). Descriptive data were summarized as counts and percentages for categorical variables and mean and SD for continuous variables.

Univariate statistical analysis including chi square and Fisher exact tests were used to detect factors affecting pregabalin products selling among abuser patients. A p-value less than .05 was considered significant throughout the analysis.

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