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CASE REPORT

Pregabalin abuse for enhancing sexual performance: case discussion and literature review

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Pregabalin is a γ-aminobutyric acid analogue that is primarily prescribed in psychiatry for management of generalized anxiety disorder. The belief in its low potential for abuse has placed it in a superior position to other anxiolytic agents. However, more recent, concerns have been raised about the addictive potential of pregabalin. This problem has not received much attention nor has the mechanism of its development. There is also a lack of understanding of the difference in the experience of abusing pregabalin in contrast to abusing other illicit drugs. We report the case of a 55-year-old patient with a background history of multiple psychoactive substances misuse who elaborated on his own personal experience of pregabalin abuse. He consumed a month's supply of this medication over 2 days and realized an enhancement in sexual desire and excitement. This effect should be considered when prescribing pregabalin.

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Key words: Pregabalin, psychological sexual dysfunctions, sexual behaviour, substance abuse detection, substance-related disorders.

Introduction

Pregabalin, [(S)-3-(aminomethyl)-5-methylhexanoic acid], exerts its effect by binding potently to the pre-synaptic α-2-Δ subunit of voltage-gated calcium channels in the central nervous system (Li *et al.* 2011). It inhibits the release of excitatory neurotransmitters and, thus, increases the neuronal γ-aminobutyric acid (GABA) levels. Of note, pregabalin has no demonstrated direct effects on $GABA_A$ or $GABA_B$ receptors, or on GABA uptake or degradation (Selak, 2003; Ben-Menachem, 2004). Psychiatric indications for pregabalin include generalized anxiety disorder (Pande *et al.* 2003; European Medicines Agency 2006; Montgomery *et al.* 2006; Allgulander, 2010) and benzodiazepine misuse (Oulis *et al.* 2008a). In 2005, pregabalin, owing to its presumed low potential for abuse, was placed into Schedule V of the Controlled Substances Act by the United States Deputy Administrator of the Drug Enforcement Administration (Leonhart, 2005).

Although it is well tolerated (Kavoussi, 2006), a range of side effects, often mild and transient and affecting a small proportion of patients (Dobrea *et al.* 2012), have been attributed to the use of pregabalin. Psychiatric adverse effects include psychosis (Olaizola *et al.* 2006), hypomania, confusion, irritability, and memory impairment (Zaccara *et al.* 2011). Neurological adverse effects consist of dizziness (Frame *et al.* 2009), blurred vision (Zaccara *et al.* 2011), incoordination, parathesia, tremor, and sedation (Dobrea *et al.* 2012). Gastric side effects incorporate increased appetite and weight, constipation (Kamel *et al.* 2010), and vomiting. Cardiac side effects consist of peripheral oedema (Page *et al.* 2008) and atrio-ventricular block (Aksaka & Emet, 2012). Reported sexual adverse effects are decreased libido and erectile dysfunction (Taylor *et al.* 2009).

In 2009 and 2010, a few case reports from Germany, United States, and Turkey alerted the clinical community of the potential for abuse of pregabalin (Filipetto *et al.* 2010; Grosshans *et al.* 2010; Yargic & Ozdemiroglu, 2011). In Europe, in summer 2011, about 30 cases of dependence, abuse, or withdrawal symptoms, attributed to pregabalin, and its closely related medication gabapentin, were reported to Swedish and French pharmacovigilance centres and the European Monitoring Centre for Drugs and Drug Addiction (European Monitoring Centre for Drugs and Drug Addiction, 2012). A recent study attempted to compare pregabalin in its therapeutic dosage to oxycodone (Zacny *et al.* 2012). Oxycodone was superior to pregabalin in the ratings of drug liking. However, subjects who abuse pregabalin consume much higher doses (as in the case reports of Filipetto *et al.* 2010; Grosshans *et al.* 2010; Yargic & Ozdemiroglu, 2011) than the dose used by participants in Zacny *et al.*'s study (2012).

Recently, a body of evidence in support of the risk of pregabalin abuse is emerging (Schwan *et al.* 2010). It is particularly evident in subjects with a previous diagnosis of alcohol and substance dependence [Canadian Agency for Drugs and Technologies in Health (CADTH) 2012; Skopp & Zimmer, 2012].

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In this case study we discuss the potential for pregabalin abuse. We hypothesize that its direct effect through GABA receptors makes it liable for misuse. We, also, hypothesize that it may enhance the sexual performance at very high doses via potentiating the psychological phases of the sexual response cycle, which is concerned with motivation and desire for sex.

An electronic MeSH (Medical Subject Headings) search of MEDLINE, EMBASE, CINAHL, and PsycINFO databases was carried out. The Boolean operator 'OR' was used to link the following MeSH terms: pregabalin, substance abuse detection, psychological sexual dysfunctions, sexual behaviour, substance-related disorders. Titles and abstracts were screened by one author (M.O.) to identify English-language papers (mainly case reports) reporting pregabalin misuse incidents. A hand search for potentially relevant or unpublished reports was completed. Contact was made with pharmaceutical companies and with interested academics. A bibliographic search for all the references cited by the retrieved articles was performed. Inclusion of the relevant papers was agreed between the authors. We also searched the NHS and HSE policy documents.

Case report

Mr Z is a 55-year-old musician who was attending the outpatient clinic for treatment of paranoid schizophrenia from which he was in remission for the previous 30 years on fluphenazine depot every 3 weeks. He misused a number of psychoactive substances over the years, including cannabis, heroin, and cocaine. He displayed no wish to abstain despite the repeated requests from the treating team. During the 'head shops' era he reported misusing a wide range of products for recreational purposes and to 'self-medicate' a spectrum of generalized anxiety symptoms. Pregabalin 75 mg BD was prescribed for him to help assuage his anxiety and, thereby, lessen the severity of misuse of illicit drugs. He has no relevant medical history.

However, repeated phone calls from his wife indicated that she needed to 'hide' her own supply of pregabalin from him as he 'abused' it. Mr Z, upon clinical review, when no notable mental status abnormalities were reported or observed, he stated that he had taken a month's supply of his prescribed pregabalin over 2 days, that is, 2250 mg/day. This constituted quadruple the maximum licensed pregabalin dose (BCAP 2012). Mr Z said taking such a dose make him feel 'good', in a 'positive form', and 'up-lifted'.

He described this effect as a 'pregabalin high', which, he said was 'very subtle' and 'innocuous'. He reported that it was not like the highs from other illicit drugs, but that it was more of 'a feeling' and 'not as defined'. He did not prefer pregabalin to other substances. In relation to pregabalin he described no tolerance, no loss of control, and no powerful craving. He would not buy it from the street, as 'people need their money's-worth', he explained. When his supply of pregabalin was used, he used for his wife's supply, and often ingesting a considerable amount. If this was not available, he said he was 'tense, brought down, and in a dark mood'. He described no extra withdrawal symptoms.

He went on to elaborate further on the reasons behind abusing pregabalin. He said pregabalin is unique as it is 'aphrodisiac'. It made him sexually aroused. It made him 'in the mood for sex' and 'up for it'. He stated that pregabalin does not initiate the desire, nor enhance his penile tumescence. He, also, experienced no effect of pregabalin on the time to ejaculation, on the ejaculation act itself, or on his erectile function.

Discussion

This is, to our knowledge, the first reported case in Ireland of pregabalin abuse. In Northern Ireland, the Health and Social Board Headquarters in Belfast has issued a letter to make health care professionals aware of the potential for misuse of pregabalin (Health and Social Board Headquarters in Belfast, 2012). However, as far as we know, no specific clinical cases were reported in Northern Ireland. We are attempting to alert the Irish stakeholders, through a comprehensive review of the recent international developments, that govern the prescribing practice of pregabalin.

Our patient had an established background history of multiple psychoactive substance misuse. Such a connection between poly-substance abuse and pregabalin abuse has been reported (Schwan *et al.* 2010) in a number of previous cases, specifically for cannabis and heroin (Pande *et al.* 2003).

The instantaneous effects of pregabalin following consumption, as described by Mr Z, mirror those reported in the literature, particularly euphoria (Pande *et al.* 2003; Reedy & Schwartz, 2010; Yargic & Ozdemiroglu, 2011). Of note, previous reports did not fully investigate the actual subjective personal experience of the patients. We endeavour to report the patient's verbatim account to provide the reader with information on the psychological aspects that make pregabalin prone for abuse, such as the feeling of being 'up-lifted' but in an 'innocuous' way. Pregabalin-related euphoria was fleeting and transient. For Mr Z it was definitely not as addictive as other illicit drugs. This is in agreement with the available evidence (Zacny *et al.* 2012). Pregabalin causes an indirect decrease in stimulation of the post-synaptic receptors by binding to the pre-synaptic α-2-Δ subunit of voltage-gated calcium channels (Kavoussi, 2006) in areas like the neocortex, the amygdaloid nucleus, and the hippocampus (Hill *et al.* 1993). On the other hand, drugs like

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oxycodone acts as a direct agonist at μ, κ, and δ opioid receptors within the central nervous system (Chen *et al.* 1991). Although oxycodone is relatively weaker at μ opioid receptors' binding, it still produces more euphoric effects than pregabalin (Zacny *et al.* 2012).

Dramatic withdrawal symptoms were reported in the previous case studies, including abdominal pain (Filipetto *et al.* 2010), sweating, unrest, arterial hypertension, tremor, and intense cravings for pregabalin (Pande *et al.* 2003). However, our patient denied such symptoms. This is in agreement with the recent 'Rapid response report' findings that pregabalin withdrawal effects are relatively weak and unsustainable after long-term use (CADTH, 2012). Only insomnia, nausea, headache, or diarrhoea were described in more recent studies (Schifano *et al.* 2011). Relatively older trials reported no significant withdrawals when pregabalin was stopped (Feltner *et al.* 2003; Pohl *et al.* 2005; Oulis *et al.* 2008a), and it can be argued that the dose used in those trials was lower than the abused doses. Furthermore, the tapering schedules used during discontinuation of pregabalin in these trials are likely to have been more gradual than the abrupt discontinuation following its misuse by our subject.

The ICD-10 diagnostic criteria for abuse have been extended to cover a wide variety of medicaments, especially laxatives, and analgesics. Although pregabalin is prescribed for treatment of anxiety, still it can be classified as an analgesic (Boyle *et al.* 2012; Graversen *et al.* 2012). Attempts to dissuade the person from use of the substance are often met with resistance (ICD 10 Online, 2010). Mr Z consumed dosages of pregabalin that were much higher than those prescribed. Furthermore, he also took his wife's supply of pregabalin and ingested it. Although, criteria for dependence syndrome are not fulfilled in Mr Z's case, his behaviour and symptoms can still be regarded congruent with a diagnosis of abuse of non-dependence-producing substances.

Of critical importance, when examining previous case reports, is the reason that pregabalin was prescribed in the first instance. This includes refractory partial seizures and neuopathic pain syndrome; both are legitimate medical conditions with evidence supporting the use of pregabalin in their control (Boyle *et al.* 2012; Zhou *et al.* 2012). Our patient was prescribed pregabalin mainly for treatment of anxiety. He was self-medicating his anxiety by psychoactive substances. However, a diagnosis of generalized anxiety disorder according to the ICD-10 requires anxiety to be generalized and persistent with variable dominant symptoms that include complaints of persistent nervousness, trembling, muscular tensions, sweating, lightheadedness, palpitations, dizziness, and epigastric discomfort (ICD 10 Online, 2010). It was not clear from the patient's description whether the constellation of these symptoms was present when prescription for pregabalin was commenced. Other psychoactive substances that he was misusing could also cause his anxiety symptoms via diverse mechanisms, including craving and withdrawals (Dijkstra *et al.* 2008). This possibility, during clinical assessment, received sub-optimum exploration. The assumed low potential of abuse (Leonhart, 2005) was most likely one of the reasons for prescribing pregabalin. The alternative option of an antidepressant (Kapczinski *et al.* 2003) such as an SSRI (Rickels *et al.* 2003) or van SNRI (Lenox-Smith & Reynolds, 2003), or even non-pharmacological approaches, (National Institute for Health and Clinical Excellence, 2007) such as CBT and relaxation training, might have been more appropriate in this patient-specific circumstances (Taylor *et al.* 2009).

The dose consumed by our patient was 2250 mg/day, but doses of up to 7500 mg/day Grosshans *et al.* 2010 have been reported. No significant physical consequences were reported in the literature, even on such high doses. Pregabalin is reported to be safe on overdose. In ~100, who overdosed on pregabalin, it was not associated with unexpected adverse events or medically important consequences (Baldwin & Ajel, 2007). A recent report by Aksaka & Emet (2012), indicated an atrioventricular block incident upon pregabalin overdose. Unfortunately, the exact dose was not reported, nor the serum pregabalin level. A case report was published of a 16-year-old child with a pregabalin serum level of 27 μcg/ml after ingestion of 2700 mg for recreational purposes. The child developed transient generalized tonic–clonic seizure activity. He was discharged in full remission (Reedy & Schwartz, 2010). Serum levels for up to 43 μcg/ml were reported. In adults, no specific toxicity syndrome was described at serum levels of 29 μcg/ml (Spiller *et al.* 2008; Miljevic *et al.* 2012). It is worth noting that for subjects taking therapeutic doses of pregabalin, the serum level ranged between 2.8 and 8.2 μcg/ml (Berry & Millington, 2005). Pregabalin serum levels were not available in our patient at the time of abuse.

What is unique in our patient is the reporting of sexual enhancing effect for pregabalin. Although abused recreational substances may enhance sexual performance by decreasing inhibition, anxiolytics, and opioids are notorious for depressing sexual desire (El-Bassel *et al.* 2003; Saddock, 2005). Furthermore; Mr Z confidently attributed a sexual enhancement effect to pregabalin and not to the other illicit drugs he continued to take over decades. Mr Z had no prior comorbid diagnosis of sexual dysfunction. This makes the possibility of indirect enhancement of sexual arousal, through euphoria or reduced anxiety, less likely.

Would pregabalin be a promising alternative in the treatment of disorders of sexual desire? A relatively recent case study described the usefulness of pregabalin in ameliorating sexual adverse effects of Citalopram

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(Oulis *et al.* 2008b). In a case series, a temporal association between commencing pregabalin and increased libido was also reported (Bucur & Jeczmien, 2011). This may seem counter-intuitive, as pregabalin can and has caused reduction in libido and erectile dysfunction (Hitiris *et al.* 2006). Furthermore, the sexual dampening effect of pregabalin has been used in a therapeutic way. A recent case report described significant improvement for a woman with persistent genital arousal disorder when she was treated with pregabalin (Philippsohn & Kruger, 2012). The question of whether pregabalin causes or treats sexual dysfunction is open to debate. This case study highlights the potential legitimacy of sexual enhancing effects of pregabalin, at least at higher doses.

Our patient, on close questioning, described the benefit of pregabalin to be at the late stages of the desire phase and the early stages of the excitement phase. Thus, pregabalin seems, predominantly, to potentiate the psychological phases of the sexual response cycle, which is concerned with motivation and desire for sex (Saddock, 2005).

Several limitations are noted in this case report. Reporting Mr Z's single case provides little basis for scientific generalisation. Nonetheless, it does create an objective clinical stand for further scientific exploration.

Conclusion

We report a first case in Ireland of pregabalin abuse in a 55-year-old male. Pregabalin abuse, albeit less severe than illicit drugs abuse, is a genuine problem that has a range of clinical and legal implications. Clinicians have to be cautious before prescribing pregabalin for patients with substance misuse problems. Our case support that pregabalin could have sexual enhancement effect, especially of the psychological phase of the sexual response cycle and at higher doses. The need for more rigorous and focused research is required particularly with respect to the effect of different doses of pregabalin upon the sexual cycle.

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Conflicts of Interest

None.

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