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BRIEF REPORT

Patterns and correlates of prescribed and non-prescribed pregabalin use among a sample of people who inject drugs in Australia

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Abstract

Introduction and Aims. *Pregabalin is a gamma-aminobutyric acid analogue registered and subsidised for the treatment of neuropathic pain in Australia. Despite pre-clinical evidence of low abuse potential, there are increasing reports of extramedical use and overdose deaths involving pregabalin. This study aimed to describe patterns of pregabalin use among an Australian sample of people who inject drugs (PWID) and identify sociodemographic, substance use and mental/physical health correlates of prescribed and non-prescribed use.* ***Design and Methods.*** *Data were obtained from the 2018 Illicit Drug Reporting System, comprising a cross-sectional sample of 905 PWID recruited from Australian capital cities. Multinomial logistic regression was used to identify correlates of past 6-month prescribed and non-prescribed pregabalin use.* ***Results.*** *One-quarter (25%) of participants reported any past 6-month pregabalin use, with 10% reporting prescribed use and 15% non-prescribed use. Past 6-month use of prescribed benzodiazepines and non-prescribed pharmaceutical opioids were associated with both prescribed and non-prescribed pregabalin use compared to no recent pregabalin use. Pain/discomfort on the day of interview was significantly associated with prescribed pregabalin use. Recent use of non-prescribed benzodiazepines and illicit stimulants and past year non-fatal overdose were significantly associated with non-prescribed pregabalin use (compared to no recent pregabalin use).* ***Discussion and Conclusions.*** *Pregabalin use was relatively common among an Australian sample of PWID. Benzodiazepine and pharmaceutical opioid use were positively correlated with both prescribed and non-prescribed pregabalin use, suggesting that education campaigns regarding the risks of harm associated with concomitant use of these substances are warranted (targeting both health professionals and consumers).* [Sutherland R, Dietze PM, Gisev N, Bruno R, Campbell G, Memedovic S, Peacock A. Patterns and correlates of prescribed and non-prescribed pregabalin use among a sample of people who inject drugs in Australia. *Drug Alcohol Rev* 2020;39:568–574]

Key words: pregabalin, gabapentinoid, injecting, prescription drug misuse, post-marketing product surveillance.

Introduction

Gabapentinoids are gamma-aminobutyric acid analogues that have analgesic, anti-convulsant and anxiolytic properties. The two main gabapentinoids, gabapentin and pregabalin, are primarily used for the treatment of epilepsy and neuropathic pain [1].

Pre-clinical and pre-marketing studies indicate low abuse potential of these substances [2,3]. However, there have been increasing reports of extramedical use (i.e. use outside the bounds of a doctor's prescription [4]) and dependence since market release, particularly among people with a history of substance use disorder (predominantly opioid use disorder [2,3,5]). In Europe, for example, there were 7639 (6.6% of a total 115 616; 2006–2015) and 4301 (4.8% of 90 166; 2004–2015) cases of extramedical use and dependence associated with pregabalin and gabapentin, respectively [5].

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Further, a Swedish study of 191 973 people who were prescribed gabapentinoids from 2006–2013 found that these substances were associated with an increased risk of suicidal behaviour, unintentional overdoses, head/body injuries, and road traffic incidents and offences, with pregabalin associated with higher hazards of these outcomes than gabapentin [1].

In Australia, pregabalin is more frequently dispensed than gabapentin [6]. Pregabalin was registered as a Schedule 4 (prescription only) medicine for the treatment of neuropathic pain and epilepsy in 2005; listed for subsidy on the Pharmaceutical Benefits Scheme in 2013 for neuropathic pain; and in 2016–2017 was the sixth most prescribed subsidised drug in Australia [6,7]. As the prescribing of pregabalin has increased, so too have concerns of pregabalin-related harms. An increase in intentional pregabalin poisonings (375 in 2016; 54% increase per year) and pregabalin-associated deaths (88 in total; 58% increase per year) was observed between 2004 and 2016 in New South Wales, Australia [6]. Similarly, rates of ambulance attendances for pregabalin-related harms increased 10-fold between 2012 and 2017 in Victoria, Australia (0.28 cases per 100 000 vs. 3.32 cases per 100 000, respectively [8]). Co-ingestion of other sedatives (i.e. opioids, benzodiazepines and alcohol) was common across these cases [6,8].

Given evidence of elevated risk of pregabalin extra-medical use among people who use illicit and non-prescribed substances (particularly opioids [9–11]), there is a need to better understand patterns of pregabalin use in this population. This includes obtaining a more nuanced understanding of the profile of pregabalin consumers to guide public health responses. Thus, the aims of this paper are twofold:

1. Examine patterns of pregabalin use (prescribed and not prescribed) among a sample of people who inject drugs (PWID) in Australia.
2. Identify sociodemographic, substance use and mental/physical health correlates of prescribed and non-prescribed pregabalin use among PWID.

Methods

Study design and participants

The Illicit Drug Reporting System is an Australian illicit drug monitoring system that has operated nationally since 2000; one component comprises annual interviews with non-representative sentinel samples of PWID recruited in Australian capital cities (for full protocol details, see [12]). Inclusion criteria comprised being ≥16 years old, ≥monthly injection of illicit/non-prescribed drugs in the 6 months preceding interview and residence in the city of recruitment in the preceding ≥12 months. In 2018, 905 participants were recruited. All information disclosed was confidential and anonymous, with participants reimbursed AU$40 for their time. Ethical approval was granted by the UNSW Sydney Human Research Ethics Committee (HC12086) and jurisdictional ethics committees.

Measures relevant to the current study

Outcome variable. In 2018, participants were asked about their lifetime and past 6-month ('recent') use of prescribed and non-prescribed pregabalin.

Correlates. Participants were asked about their past 6-month use of illicit substances, as well as other prescribed and non-prescribed substances. Among those reporting recent use, average quantity (for illicit and non-prescribed substances only) and routes of administration were also recorded. Participants completed the Severity of Dependence Scale about opioid and methamphetamine use; cut-off scores of ≥5 and ≥4 were considered indicative of possible dependence, respectively [13,14]. Past 6-month binge use (i.e. ≥48 h of use without sleep), past year alcohol problems (using the Alcohol Use Disorders Identification Test scores ≥16 indicative of high-risk consumption [15]) and past year overdose on any psychoactive substance were also examined.

Psychological distress (Kessler 10 [K10]; scores ≥22 indicates high/very high psychological distress [16]) and self-reported mental health problems (including those not formally diagnosed) were examined. Mobility and pain/discomfort on the day of interview were assessed using the European Quality of Life—5 Dimensions questionnaire [17]. These variables are included as correlates given that: (i) pregabalin is used in the treatment of pain; and (ii) depression and suicidal ideation are potential adverse effects of pregabalin [18].

Statistical analysis. Analyses were conducted using SPSS v25. We calculated percentages for categorical data, means for normally distributed continuous variables and medians for continuous data with significant positive skew and/or kurtosis.

To address the second aim, we identified four groups based on self-reported past 6-month pregabalin use: no use, prescribed use only, non-prescribed use only and both prescribed and non-prescribed use. Correlates of pregabalin use were analysed using bivariate and multivariable multinomial logistic regression; the group reporting no pregabalin use was the referent

category (additional results using prescribed pregabalin as the referent category are presented in Table S1, Supporting Information). Consumers using both prescribed and non-prescribed pregabalin were excluded from analyses due to small numbers (n = 7). Correlates that were significant ($P < 0.05$) in bivariate models (for prescribed or non-prescribed use) were entered into the multivariable model to determine independent associations with pregabalin use. Multicollinearity between correlates was tested using variance inflation factors (<2 for all variables). Little's Missing Completely at Random test suggested that missing data for all variables included in the model were missing completely at random (P = 0.628), hence complete-case analysis was used (n = 905).

Results

Patterns of pregabalin use

One-quarter (25%; 225/905) of the sample reported past six-month pregabalin use, at a median frequency of 14 days (i.e. approximately once a fortnight). The percentage of people reporting prescribed and non-prescribed use was 10% and 15%, respectively. Those using prescribed pregabalin reported daily use, while those using non-prescribed pregabalin reported infrequent use (i.e. less than once a month) (Table 1). Swallowing was the main reported route of administration with <1% reporting pregabalin injection.

Table 1. *Patterns of pregabalin use among a sample of people who inject drugs, 2018*

	n = 905
Any pregabalin use	
Lifetime use, % (n)	41 (368)
Lifetime injection, % (n)	2 (19)
Recent use[a], % (n)	25 (225)
Recent injection[a], % (n)	0.7 (6)
Median days of use[a] (IQR; n)	14 (3–180; 225)
Lyrica main brand[a], % (n)	99 (218)[b]
Prescribed pregabalin use[c]	
Lifetime use, % (n)	16 (147)
Lifetime injection, % (n)	1 (8)
Recent use[a], % (n)	10 (93)
Median days of use[a] (IQR; n)	180 (60–180; 93)
Non-prescribed pregabalin use[c]	
Lifetime use, % (n)	26 (238)
Lifetime injection, % (n)	1 (11)
Recent use[a], % (n)	15 (139)
Median days of use[a] (IQR; n)	4 (1–14; 139)
Average quantity used per day[a], mg[d] (IQR; n)	
All consumers	250 (75–300; 121)
<Monthly use	200 (7.5–300; 68)
≥Monthly, <weekly use	300 (150–900; 27)
≥Weekly, <daily use	300 (150–900; 19)
Daily use	150 (10–300; 7)
Both prescribed and non-prescribed pregabalin use	
Lifetime use, % (n)	2 (17)
Recent use[a], % (n)	0.8 (7)

[a]Within the past 6 months. [b]Four participants did not know the main brand they had used and were excluded from analysis. [c]Includes those who had used both prescribed and non-prescribed pregabalin. [d]The maximum recommended dose of Lyrica is usually 300 mg/day (100 mg three times a day). IQR, interquartile range.

Correlates of pregabalin use

In the adjusted analyses, past six-month use of prescribed benzodiazepines and non-prescribed pharmaceutical opioids were positively correlated with recent use of prescribed and non-prescribed pregabalin, when compared to no recent pregabalin use (Table 2). Pain/discomfort on the day of interview was significantly associated with prescribed pregabalin use, while recent use of non-prescribed benzodiazepines and illicit stimulants, as well as past year non-fatal overdose, were significantly associated with non-prescribed pregabalin use (compared to no recent pregabalin use).

Discussion

Pregabalin use was relatively common among this Australian sample of PWID. Lifetime use (41%) was lower than reported elsewhere (e.g. 56% of detoxification patients in Germany) [19], while recent use (25%; 10% prescribed, 15% non-prescribed) was comparable to studies conducted in Germany, Israel and the USA (range: 7–22% of opioid consumers [9–11]).

Recent use of prescribed benzodiazepines and non-prescribed pharmaceutical opioids was associated with both prescribed and non-prescribed pregabalin use. Although the reasons for use of these substances among our sample are unknown, it is possible that pregabalin is being used to alleviate symptoms of withdrawal from opioids and/or benzodiazepines [5,9]. Furthermore, while data were not collected on concomitant use of these substances specifically, this use pattern is concerning given the elevated overdose risk associated with combined use of opioids and pregabalin [6,8,20]. For example, a recent study in Canada which examined mortality data from 1997 to 2016 found that concomitant exposure to pregabalin and opioids almost doubled the odds of opioid-related death when compared to opioid exposure alone [20]. Proposed mechanisms for this increased risk include:

Table 2. *Correlates of pregabalin use among a sample of people who inject drugs, 2018*

				Bivariate, no pregabalin use (n = 678) vs.		Multivariate, no pregabalin use (n = 678) vs.	
	No use (n = 678)	Prescribed use only (n = 86)	Non-prescribed use only (n = 133)	Prescribed use only (n = 86) RRR (95% CI; P-value)	Non-prescribed use only (n = 133) RRR (95% CI; P-value)	Prescribed use only (n = 86) ARRR (95% CI; P-value)	Non-prescribed use only (n = 133) ARRR (95% CI; P-value)
Demographics							
Mean age (SD)	43.7 (9.3)	42.3 (8.8)	40.3 (8.9)	0.98 (0.96, 1.01; 0.180)	**0.96 (0.94, 0.98; <0.001)**	0.99 (0.96, 1.03; 0.695)	0.99 (0.97, 1.02; 0.571)
Male, %	68	66	62	0.94 (0.58, 1.51; 0.791)	0.77 (0.52, 1.13; 0.177)	—	—
Aboriginal and/or Torres Strait Islander, %	19	11	26	0.51 (0.25, 1.05; 0.067)	1.50 (0.97, 2.31; 0.070)	—	—
Unemployed, %	86	86	91	1.01 (0.53, 1.92; 0.988)	1.64 (0.87, 3.09; 0.123)	—	—
Stable accommodation, %	78	76	70	0.87 (0.51, 1.47; 0.596)	**0.65 (0.43, 0.99; 0.042)**	1.49 (0.77, 2.87; 0.234)	0.74 (0.44, 1.23; 0.242)
Drug use (past six months), %							
Heroin use	52	64	59	**1.65 (1.04, 2.63; 0.034)**	1.32 (0.91, 1.93; 0.148)	1.30 (0.74, 2.30; 0.363)	0.77 (0.47, 1.27; 0.307)
Prescribed OST use	42	54	55	**1.59 (1.01, 2.49; 0.044)**	**1.66 (1.14, 2.41; 0.008)**	1.54 (0.89, 2.66; 0.124)	1.22 (0.76, 1.96; 0.418)
Non-prescribed OST use	22	35	34	**1.89 (1.17, 3.06; 0.009)**	**1.81 (1.20, 2.72; 0.004)**	1.49 (0.82, 2.70; 0.189)	0.70 (0.41, 1.20; 0.192)
Prescribed pharmaceutical opioid use	10	20	8	**2.30 (1.27, 4.14; 0.006)**	0.82 (0.42, 1.59; 0.549)	1.26 (0.61. 2.64; 0.534)	0.74 (0.33, 1.67; 0.467)
Non-prescribed pharmaceutical opioid use	26	46	49	**2.44 (1.54, 3.88; <0.001)**	**2.69 (1.84, 3.94; <0.001)**	**2.39 (1.37, 4.14; 0.002)**	**2.75 (1.70, 4.47; <0.001)**
Prescribed benzodiazepine use	25	54	34	**3.52 (2.23, 5.57; <0.001)**	**1.58 (1.06, 2.36; 0.025)**	**3.02 (1.76, 5.19; <0.001)**	**2.03 (1.23, 3.35; 0.006)**
Non-prescribed benzodiazepine use	24	31	55	1.42 (0.87, 2.32; 0.157)	**3.85 (2.62, 5.66; <0.001)**	1.15 (0.63, 2.10; 0.642)	**3.82 (2.34, 6.26; <0.001)**
Stimulant use	76	80	92	1.28 (0.73, 2.25; 0.381)	**3.51 (1.85, 6.67; <0.001)**	1.70 (0.80, 3.62; 0.166)	**3.25 (1.39, 7.60; 0.007)**
Drug-related harms, %							
SDS opioid score ≥ 5 (past six months)	57	57	53	1.01 (0.64, 1.59; 0.976)	0.84 (0.58, 1.23; 0.380)	—	—
SDS methamphetamine score ≥ 4 (past six months)	38	38	34	1.00 (0.63, 1.59; 0.998)	0.84 (0.57, 1.24; 0.381)	—	—
AUDIT score ≥ 16 (past year)	15	14	14	0.90 (0.47, 1.72; 0.754)	0.94 (0.55, 1.59; 0.805)	—	—
Binged on an illicit substance (past six months)	55	63	71	1.40 (0.88, 2.22; 0.155)	**2.07 (1.38, 3.11; <0.001)**	1.42 (0.77, 2.63; 0.259)	1.16 (0.68, 1.96; 0.588)
Overdose (past year)	18	31	36	**2.09 (1.24, 3.50; 0.005)**	**2.54 (1.65, 3.91; <0.001)**	1.47 (0.81, 2.67; 0.202)	**2.31 (1.38, 3.87; 0.002)**

(Continues)

Table 2. (Continued)

				Bivariate, no pregabalin use (n = 678) vs.		Multivariate, no pregabalin use (n = 678) vs.	
	No use (n = 678)	Prescribed use only (n = 86)	Non-prescribed use only (n = 133)	Prescribed use only (n = 86) RRR (95% CI; P-value)	Non-prescribed use only (n = 133) RRR (95% CI; P-value)	Prescribed use only (n = 86) ARRR (95% CI; P-value)	Non-prescribed use only (n = 133) ARRR (95% CI; P-value)
Mental/physical health, %							
K10 score ≥ 22 (past month)	54	47	47	0.75 (0.48, 1.19; 0.225)	0.75 (0.51, 1.01; 0.137)	—	—
Self-reported mental health problems (past 6 months)	42	54	55	**1.64 (1.03, 2.61; 0.038)**	**1.73 (1.18, 2.53; 0.005)**	1.12 (0.65, 1.92; 0.691)	1.44 (0.90, 2.31; 0.134)
Mobility problems (day of interview)[a]	24	42	21	**2.21 (1.38, 3.55; 0.001)**	0.85 (0.54, 1.34; 0.476)	1.28 (0.72, 2.29; 0.403)	0.82 (0.46, 1.48; 0.515)
Pain or discomfort (day of interview)[a]	50	81	53	**4.15 (2.35, 7.32; <0.001)**	1.12 (0.77, 1.63; 0.555)	**3.34 (1.76, 6.34; <0.001)**	1.13 (0.70, 1.85; 0.615)

Note: No pregabalin use is the reference category; – indicates that the variable was not included in the multivariate model as not statistically significant ($P < 0.05$) at bivariate level; significant findings bolded. Those who had used both prescribed and non-prescribed pregabalin (n = 7) excluded from analysis. Opioid substitution therapy (OST) use = any methadone, physeptone, buprenorphine and buprenorphine-naloxone use; pharmaceutical opioid use = any fentanyl, morphine, oxycodone and/or tapentadol use; stimulant use = any methamphetamine, cocaine and/or non-prescribed pharmaceutical stimulants use; ARRR, adjusted relative risk ratio; AUDIT, Alcohol Use Disorders Identification Test; CI, confidence interval; K10, Kessler Psychological Distress Scale; RRR, relative risk ratio; SDS, severity of dependence scale. Overdose was defined as 'a situation where you feel professional assistance would have been helpful'. [a]Taken from the European Quality of Life—5 Dimensions questionnaire which asks participants to rate their 'mobility' and 'pain/discomfort' on the day of interview. The five response options (e.g. I have no pain or discomfort; I have slight pain or discomfort; I have moderate pain or discomfort; I have severe pain or discomfort; I have extreme pain or discomfort) were collapsed to produce a binary variable.

(i) the additive effect of opioids and pregabalin in depressing respiration; and (ii) pregabalin-induced reversal of tolerance to the respiratory depressant effect of opioids [20,21]. It is therefore important that consumers are made aware of the potential risks of combining opioids and other central nervous system depressants, and for a risk assessment to be undertaken prior to prescribing pregabalin.

Past year non-fatal overdose (from any drug) was independently correlated with non-prescribed pregabalin use, but not with prescribed pregabalin use (although there was an association in the unadjusted analyses). It is possible that people reporting non-prescribed pregabalin use are engaging in riskier patterns of substance use (higher rates of non-prescribed benzodiazepine and stimulant use were also reported in this group), thus resulting in higher overdose risk. These multiple risk factors suggest that harm reduction messages regarding the risks of concomitant opioid and sedative use should also be targeted towards PWID more broadly.

Pain/discomfort on the day of interview was positively correlated with prescribed pregabalin use, but not with non-prescribed pregabalin use (although baseline rates of pain/discomfort were high). This suggests that PWID may be using non-prescribed pregabalin for a range of reasons other than to manage pain, such as intoxication, euphoric and dissociative effects, as has been reported in other studies [2].

Using data from a sentinel population of PWID, we have established a detailed profile of the characteristics of those who use pregabalin, delineating between prescribed and non-prescribed use. We did not collect information on whether participants who reported prescribed use were engaging in other forms of extramedical use (e.g. selling or diverting their medication, dose escalation, doctor shopping [4]) and this is an area that requires further research. Although we relied upon retrospective self-report data, which can sometimes be limited by recall and social desirability bias, evidence points to sufficient validity and reliability of self-reported illicit drug use [22].

Conclusion

Pregabalin use was relatively common among an Australian sample of PWID, with evidence of both prescribed and non-prescribed use. Benzodiazepine and pharmaceutical opioid use were positively correlated with both prescribed and non-prescribed pregabalin use, suggesting that education campaigns regarding the risks of harm associated with concomitant use of these substances are warranted, and should be targeted towards both health professionals and consumers.

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Conflict of Interest

AP, RS and SM have received an untied educational grant from Seqirus for a post-marketing study of tapentadol. AP and RB have received an untied educational grant from Mundipharma for a post-marketing study of oxycodone and PMD and RB have received an untied educational grant from Indivior for a study of buprenorphine depot. GC has received an untied educational grant from Indivior to examine attitudes to opioid agonist therapy treatment among people living with chronic pain. PMD has received investigator-driven funding from Gilead sciences for work related to hepatitis C. All other authors have no conflicts of interest to declare. No pharmaceutical grants were received for this study.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Table S1: Correlates of pregabalin use among a sample of people who inject drugs, 2018 (prescribed pregabalin consumers as the referent category)