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Long-term naturalistic follow-up of chronic pain in adults with prescription opioid use disorder

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ABSTRACT

Background: Chronic pain is common in patients with prescription opioid use disorder (OUD), and pain severity has been shown to predict opioid use for those with chronic pain. However, recent research suggests that focusing on pain status (i.e., the presence or absence of chronic pain) at treatment initiation may not reflect the clinical significance of pain over the long-term course of OUD. Reports of variability in chronic pain and its clinical significance over time have yet to be investigated in patients with prescription OUD. The present study examined variability in chronic pain status from entry into prescription OUD treatment through 3.5-year follow-up. Additionally, we examined the association between concurrent chronic pain and opioid use at three follow-up time points.

Methods: This secondary analysis (N = 309) of a national, randomized, controlled trial of prescription OUD treatment used generalized estimating equations to assess variability in the prevalence of chronic pain from study entry to 3.5-year follow-up, and the association between chronic pain status and concurrent opioid use.

Results: Fifty-three percent of participants reported variability in chronic pain status over time. The prevalence of chronic pain decreased from study entry through follow-up (aOR = 0.47, $p < 0.001$). Chronic pain was associated with increased opioid use at each follow-up assessment (aOR = 3.56, $p < 0.001$).

Conclusions: Chronic pain status may vary over time in those with prescription OUD, and chronic pain appears to be associated with concurrent opioid use. The present findings highlight the importance of assessing chronic pain throughout the course of prescription OUD.

1. Introduction

Chronic pain is important to assess in patients with prescription opioid use disorder due to high rates of comorbidity between the two conditions and the potential for pain to increase prescription opioid use (Griffin et al., 2016). In this population, rates of chronic pain ranging between 42% and 61% have been reported (Cicero et al., 2008; Green et al., 2009; Jamison et al., 2000; Rosenblum et al., 2007; Weiss et al., 2011). In the Prescription Opioid Addiction Treatment Study, the largest study to examine patients primarily dependent on prescription opioids, 83.2% of patients with chronic pain at study entry endorsed pain relief as their primary reason for initiation of opioid analgesic use (Weiss et al., 2014).

Several studies have shown that patients seeking treatment for opioid use disorder (OUD) may experience fluctuations in pain over the course of treatment. A study of adults receiving methadone maintenance treatment found that 44.9% of those who denied pain at study entry experienced "clinically significant" (i.e., moderate to severe) past-week average pain during at least one of four assessments over the course of twelve months (Dhingra et al., 2015). Among patients with chronic pain in treatment for prescription OUD, pain severity varied over time and predicted the likelihood of opioid use in the subsequent week (Griffin et al., 2016). Worley et al. (2015), in a study using the same sample, found that greater overall pain variability was associated

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with poor opioid outcomes. These findings, showing the variability and prognostic importance of pain severity, point to the potential utility of assessing pain throughout the course of OUD.

Although previous research has shown fluctuations in pain severity among patients with OUD, no studies have examined variability in pain status itself, i.e., the emergence or resolution of chronic pain in OUD patients over time. Moreover, no previous study has examined the course of pain in OUD patients for longer than one year. Examining participants over time is important as short-term outcomes often differ from longer-term treatment outcomes (Brecht and Herbeck, 2014; Grella et al., 2003; Project MATCH Research Group, 1998). Given that pain may be an initial reason for using opioids (Weiss et al., 2014), the return of pain, onset of new pain, or resolution of chronic pain may be associated with the likelihood of opioid use over time. However, the natural history of chronic pain among patients with prescription OUD over long-term follow-up is currently unknown, as is the clinical significance of the presence of chronic pain on opioid outcomes.

The long-term follow-up study from the multi-site Prescription Opioid Addiction Treatment Study (POATS) presents a unique opportunity to examine the longitudinal association between chronic pain and opioid use following buprenorphine-naloxone treatment for primary prescription opioid dependent patients (Weiss et al., 2015). After participating in the main POATS trial (described in Section 2 below), participants were no longer receiving study treatment; they were assessed at 18, 30, and 42-months following entry into the trial. The aim of the present secondary analysis was to follow the natural course of pain and opioid use in these patients for 3.5 years post-study treatment to understand patterns of chronic pain status among adults with prescription OUD, as well as the association between chronic pain and opioid use over time. We examined stability in chronic pain status by characterizing individual patterns over time (e.g., constant chronic pain throughout all time points vs. fluctuating chronic pain) and testing whether the prevalence of chronic pain changed from entry to the main study to follow-up. Additionally, we examined whether current chronic pain was associated with opioid use throughout long-term follow-up.

2. Methods

2.1. Main trial and follow-up study description

The present study is a secondary analysis of data from both the main trial of POATS (Weiss et al., 2011) and its long-term follow-up (Weiss et al., 2015), sponsored by the National Drug Abuse Treatment Clinical Trials Network. The 10-site main trial was the largest treatment study that has been conducted with those dependent either exclusively or primarily on prescription opioids. This study was a two-phase randomized controlled trial examining optimal lengths of buprenorphine treatment and different intensities of counseling. Buprenorphine doses (8–32 mg) were determined by the study physician based on opioid use, withdrawal, craving, and adverse effects, but not pain. Patients with chronic pain (see below for the definition) were also given a self-help guide to the treatment of chronic pain (Jamison, 1996). However, pain relief was not specifically targeted in either of the counseling conditions although it was discussed as a potential relapse risk factor. Participants were stratified by chronic pain status because it was seen as a potential prognostic factor based on previous research linking pain relief to prescription opioid misuse (Back et al., 2011; McCabe et al., 2013). For more details about main trial study procedures, see Weiss et al. (2010).

The POATS long-term follow-up study was initiated prior to the completion of the main trial to track the natural course of OUD among study participants for 3.5 years after the study treatment. The follow-up study consisted of 45–60-min telephone interviews conducted by trained research assistants. The target dates for each assessment were 18, 30, and 42 months following main trial randomization. (For a full description of the follow-up study, including sample and outcomes, see Weiss et al., 2015.)

Both the main trial and the long-term follow-up study were approved by the Institutional Review Boards at McLean Hospital and the additional nine participating institutions prior to data collection (Weiss et al., 2011, 2010).

2.2. Measures

Chronic pain status was assessed at main study entry and at each follow-up time point. First, participants were asked the initial question on the Brief Pain Inventory (BPI), a well-validated assessment of pain severity (Cleeland, 1991; Tan et al., 2004): “Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today? (Do not include pain associated with alcohol or drug withdrawal.)” If participants answered yes to this question, they were then asked about the duration of the pain. Those who reported pain for at least 3 months met criteria for chronic pain, as defined by the International Association for the Study of Pain (Merskey and Bogduk, 1994). The BPI also provided data on pain location and severity.

The Composite International Diagnostic Interview (World Health Organization, 1997) was used to diagnose substance use disorders and two co-occurring psychiatric disorders (i.e., posttraumatic stress disorder and major depressive disorder) in all participants at study entry. Opioid use was assessed at all three follow-up time points using the Addiction Severity Index (McLellan et al., 1992). Participants were asked about past 30-day use of heroin, methadone (only illicit use was included in the present analyses), and “other opiates/analgesics.” A dichotomous variable was created at each follow-up time point to indicate any use of opioids (yes/no). Of note, in creating this variable, agonist medication (i.e., buprenorphine or methadone) prescribed to treat OUD was not coded as opioid use. By contrast, we did not distinguish between use of opioids as prescribed for pain versus illicit or not-as-prescribed use. All participants enrolled in the study had met DSM-IV criteria for opioid dependence at study entry and had been given permission from their prescribing physician (if there was one) to discontinue opioid use. Thus, prescription opioids were not indicated as continued treatment for pain in this population.

Additional background characteristics and clinical history were assessed using questionnaires designed for this study (see Weiss et al., 2011, 2010).

2.3. Data analysis

Participants were included in the present analyses only if we had data from at least two of three follow-up time points (N = 309), to ensure that group categorizations would not be based on majority missing data. (All subjects had data from study entry.) To assess variability in chronic pain status, we grouped participants into the following categories: 1) No chronic pain reported at study entry or any follow-up time point, 2) Chronic pain reported at all available time points, 3) No chronic pain reported at study entry but chronic pain at one or more follow-up time points, 4) Chronic pain reported at study entry but no follow-up time points, or 5) Chronic pain at study entry and at least one but not all follow-up time points. Next, we examined whether the prevalence of participants meeting criteria for chronic pain changed from study entry to follow-up, using a generalized estimating equations (GEE) approach. Chronic pain status at entry to the main study was used as the reference for comparing change over time. GEE was chosen to account for the correlation among the repeated binary outcomes for participants followed longitudinally; further, this method allows for the inclusion of all available follow-up data on participants.

Finally, the association between chronic pain status and concurrent opioid use (i.e., at the same time point) was examined across the long-term follow-up assessments. These analyses used a GEE approach to fit a logistic regression model for the repeated binary outcomes (past-

month opioid use: yes or no). The following covariates were included in the model: age, gender, employment, treatment condition, and opioid agonist/partial agonist treatment of opioid dependence (hereafter referred to as agonist treatment). The demographic characteristics were chosen because of their known associations with variability in the pain experience (Cassou et al., 2002; Keogh and Herdenfeldt, 2002; Macfarlane et al., 1997). Trial treatment condition was included to account for any delayed effects from the main trial. Opioid agonist treatment was included due to the potential for reductions in both pain and opioid use experienced by those on maintenance medication. Data were analyzed using SPSS version 25.

3. Results

3.1. Sample description

Long-term follow-up study participants (N = 309) were 18–58 years old at main study entry, with a mean age of 33.3 (sd = 9.8). Ninety percent of participants were white, with 7–20 years of education, mean = 13.0 (sd = 2.0). The sample was 45.0% female, 65.0% employed full-time, and 50.8% never married. Utilization of prior professional interventions for opioid dependence was reported by 33.3%, with 22.0% having ever attended self-help groups. Lifetime heroin use was reported by 22.0% of study participants. Regarding route of administration, 81.9% had used opioid analgesics by a non-standard route of administration such as intranasal use or crushing. The most common first source of prescription opioids was a legitimate prescription (52.1%), typically taken for physical pain (62.5%). Although most had no other substance use disorders besides prescription opioid dependence, 15.9% had an additional past-year substance dependence diagnosis; the most common substances were marijuana (6.1%) and sedative-hypnotics (5.5%), followed by alcohol (3.9%), cocaine (3.2%), and other stimulants (2.9%). Current major depressive disorder was diagnosed in 21.7% of participants, and current posttraumatic stress disorder was diagnosed in 12.0%. Overall, 49.5% had a current psychiatric disorder other than substance use disorder.

At entry to the main trial, 43.4% of the participants met criteria for chronic pain. Among these, 41.8% reported constant, rather than intermittent pain. Nearly all reported pain lasting one year or more (93.3%); 52.2% reported experiencing pain for at least 4 years. Pain was predominantly located in the spine (70.9%) and lower extremities (54.5%). The mean Pain Severity score (range 0–10) at study entry was 4.5 (sd = 2.1). Using cutoff scores derived from analysis of functional interference from pain (Jensen et al., 2001; Serlin et al., 1995), 1.6% of participants with chronic pain reported no pain at study entry, 35.6% reported mild pain (1–4), 48.8% reported moderate pain (5–6), and 14.0% reported severe pain (7–10).

Follow-up participants could utilize opioid agonist treatment through community providers following the end of the main trial. At month 18, 31.5% of participants reported current opioid agonist treatment. This percentage rose to 37.2% at month 30 and 37.8% at month 42.

3.2. Variability in chronic pain status over time

Participants' chronic pain status was variable from study entry across the long-term follow-up (Table 1). Among those with at least two follow-up time points (N = 309), only 11.0% of participants reported chronic pain at all time points. Of note, among those reporting chronic pain at any time point, only 17.5% met criteria for chronic pain at all time points. Approximately half (51.7%) of the participants experienced variability in chronic pain status, including 19.4% of participants who did not have chronic pain at study entry but met criteria at least once during follow-up. By contrast, 15.5% of the participants experienced chronic pain at study entry but not at any follow-up time point, while the remaining 16.8% also reported chronic pain at study entry and follow-up but not at all follow-up time points. Examining prevalence of chronic pain at each time, a greater percentage of participants met criteria for chronic pain at entry to the main trial (n = 134; 43.4%) than at Month 18 (n = 80; 33.2%), Month 30 (n = 86; 28.3%), or Month 42 (n = 78; 26.4%). Results from a logistic regression analysis, fitted using generalized estimating equations, confirmed that the percentage of participants meeting criteria for chronic pain decreased significantly from study entry to each long-term follow-up time point (OR = 0.47; Table 2).

Table 1
Patterns of chronic pain status from entry to the main study through long-term follow-up (N = 309).

Chronic pain status during 3.5 years	% (N)
Denied chronic pain at all times	37.2% (115)
Reported chronic pain at all times	11.0% (34)
Denied chronic pain at study entry but reported it ≥ once during follow-up	19.4% (60)
Reported chronic pain at study entry but not at any follow-up time	15.5% (48)
Reported chronic pain at study entry & 1 but not all follow-up times	16.8% (52)

Table 2
Logistic regression model, fitted using generalized estimating equations, examining chronic pain status at follow-up compared to pain status at main study entry (N = 309).

	Estimate	Odds ratio	95% confidence interval	p-Value
Month 18	−0.43	0.65	0.49–0.86	0.003
Month 30	−0.66	0.52	0.38–0.70	< 0.001
Month 42	−0.76	0.47	0.35–0.63	< 0.001

3.3. Association between chronic pain status and opioid use at each follow-up time point

The association between chronic pain and concurrent opioid use during the long-term follow-up study was examined using logistic regression models adjusted for time and for receipt of concurrent opioid agonist treatment (Table 3). The model was also adjusted for fixed variables: demographic characteristics at study entry and treatment condition (i.e., standard medical management alone or combined with opioid drug counseling during the initial brief treatment phase, since not all participants entered the subsequent extended treatment phase of the main trial). Chronic pain status was significantly associated with concurrent opioid use over the long-term follow-up study: odds of

Table 3
Logistic regression model, fitted using generalized estimating equations, examining the association between current chronic pain status and concurrent opioid use across long-term follow-up: 18, 30, and 42 months following randomization to buprenorphine-naloxone treatment for prescription opioid dependence (N = 309).

Variable	Estimate	Odds ratio, adjusted	95% confidence interval	p-Value
Chronic pain	1.27	3.56	2.45–5.16	< 0.001
Time	−0.17	0.84	0.71–0.99	< 0.05
Opioid agonist treatment	−1.72	0.18	0.12–0.27	< 0.001
Treatment condition[a]	−0.12	0.89	0.61–1.30	0.55
Entry to the main study				
Male	0.17	1.18	0.80–1.75	0.41
Age	−0.01	0.99	0.97–1.01	0.36
Employed full-time	−0.83	0.92	0.61–1.39	0.69

[a] Standard medical management alone vs. combined with opioid dependence counseling.

opioid use were more than 3.5 times greater for those with chronic pain compared to those without (OR = 3.56, $p < 0.001$), even when adjusting for relevant covariates. At each follow-up time point, demographic characteristics at study entry and main-trial treatment condition were not significantly associated with opioid use. Opioid use decreased during the long-term follow-up study (adjusted OR = 0.84, $p < 0.05$). Consistent with Weiss and colleagues (2015), the odds of opioid use decreased among participants receiving agonist treatment.

4. Discussion

In this large, multi-site study of patients dependent on prescription opioids, 51.7% of the study participants experienced variability in chronic pain status from main study entry through follow-up, including 19.4% of participants who met criteria for chronic pain at a follow-up time point but not at study entry. Overall, the rate of chronic pain decreased by approximately half from entry to the main study through long-term (3.5-year) follow-up of buprenorphine-naloxone and counseling treatment for prescription opioid use disorder. These findings indicate that the presence or absence of chronic pain at treatment entry may not be indicative of pain status over time in those with prescription OUD. Previous research in patients without OUD seeking treatment for chronic pain suggests that even though pain intensity may vary, pain status (i.e., presence or absence of current chronic pain) typically remains constant (Jamison et al., 2009; Kongsted et al., 2017; Noble et al., 2010). Even among those receiving evidence-based pain treatment, the effects of interventions are typically small to moderate, and chronic pain rarely remits completely (Noble et al., 2010; Skelly et al., 2018). By contrast, this sample of patients with prescription OUD exhibited considerable variability in chronic pain status (i.e., presence or absence) over a 3.5-year follow-up: chronic pain status varied for 51.8% of participants. These findings suggest that the course of chronic pain in those with prescription OUD may follow a different route from that of patients presenting at pain clinics, indicating the importance of ongoing assessment of chronic pain over time in this population.

Additionally, chronic pain status was associated with a 3.5 times greater likelihood of concurrent opioid use, even when controlling for the presence or absence of opioid agonist treatment. Multiple previous studies have failed to find an association between chronic pain and concurrent opioid use in patients receiving opioid agonist treatment (Barry et al., 2009; Fox et al., 2012). However, previous samples have primarily included heroin users, who tend to present with greater severity and worse opioid outcomes compared to those with primary prescription OUD (Moore et al., 2007; Nielsen et al., 2013; Potter et al., 2010). Further, previous studies have been conducted largely in participants continuing to receive agonist treatment, which applies to a subset of the follow-up participants in the current sample. To our knowledge, the present study is the first to examine pain and opioid use over the course of long-term follow-up from buprenorphine-naloxone treatment for prescription OUD.

The study was strengthened by its use of a large, national sample with a confirmed diagnosis of OUD and by a standardized procedure we developed to ensure that patients either exclusively or predominantly used prescription opioids rather than heroin (Potter et al., 2010). At study entry, participants commonly cited pain as a primary reason for initiation of opioid use, and, to a lesser extent, for continued use of prescription opioids (Weiss et al., 2014). Among patients with chronic pain, during the course of the main trial, pain severity in a given week predicted the likelihood of opioid use in the ensuing week (Griffin et al., 2016), providing an indication that pain may be causally related to opioid use in this population. The findings of the current study extend our previous work to suggest that chronic pain status also fluctuates over time and that chronic pain status is correlated with opioid use, regardless of whether participants reported chronic pain at study entry. In light of these findings, adding psychosocial treatments for those experiencing pain episodes over the course of treatment for OUD may be useful. Treatments including Cognitive Behavioral Therapy (Wachholtz et al., 2011) and Acceptance and Commitment Therapy (Bailey et al., 2010) have been shown to reduce pain-related disability and increase participation in valued activities that could counter the desire to use opioids. An integrated approach to the management of co-occurring OUD and chronic pain may be most effective at addressing the treatment needs for both conditions (Wacholtz et al., 2011). Such an approach also accounts for potential bidirectional associations between pain and opioid use (see next paragraph): addressing both conditions simultaneously may reduce the likelihood that increased pain will exacerbate opioid use and vice versa.

Several limitations warrant consideration. Regarding pain variability, our assessment of chronic pain status may not have accounted for variability in the day-to-day pain experience of those with a pain condition. In particular, a minority of chronic pain patients experience pain episodically (Kongsted et al., 2017), indicating that they do not have daily pain. Although the present study used the definition of chronic pain provided by the International Association for the Study of Pain (Merskey and Bogduk, 1994), our findings suggest that the experience of pain can be variable. Assessing for past-week or past-month pain may provide a more thorough examination of pain status, whereas the present assessment may have ruled out those with episodic yet still chronic pain. Regarding the association between pain and opioid use, our analyses did not account for temporal precedence; thus, causal claims cannot be made. The association between pain and opioid use could be bidirectional. In particular, pain may decrease following reductions in opioid use due to diminished opioid-induced hyperalgesia (Athanasos et al., 2019) or diminished opioid tolerance (Jamison and Mao, 2015). For some individuals with chronic pain and OUD, then, a significant benefit of their cessation of opioid use could be an improvement in their pain. Future research should examine the proximal effect of pain and pain severity on opioid use throughout long-term follow-up from opioid agonist treatment, such that causal associations between pain and opioid use can be better understood. Finally, the level of pain severity reported was generally moderate. By contrast, those who seek treatment in pain clinics report higher average pain severity, with mean scores in the moderate to severe range (Nicholas et al., 2019). Thus, our findings may not be generalizable to those with OUD who seek pain treatment, whereas the present sample reported chronic pain but sought treatment for OUD.

The present study is the first to examine variability in chronic pain status and its association with opioid use in long-term follow-up from opioid agonist treatment for prescription OUD. Our findings suggest that those with prescription OUD can experience considerable variability in their experience of chronic pain, unlike typical reports from people with chronic pain without OUD. Our data suggest that assessing pain over time may be useful, even in patients who do not initially report chronic pain. Further, chronic pain was associated with opioid use at each follow-up time point, highlighting the importance of ongoing assessment of chronic pain over time in those receiving treatment for prescription opioid use disorder.

Contributors

Dr. Weiss designed the original study. Dr. Griffin, Dr. Weiss, and Ms. McDermott designed this secondary analysis. Dr. Griffin, Ms. McDermott, and Dr. Fitzmaurice performed the data analyses. Ms. McDermott and Dr. Griffin wrote the initial manuscript. Dr. McHugh, Dr. Jamison, Dr. Fitzmaurice, and Mr. Provost participated in the conceptualization of the paper and reviewed and critically edited ongoing drafts. All authors contributed to and approved the final manuscript.

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Conflict of interest

Dr. Weiss has served as a consultant to Janssen Pharmaceuticals and GW Pharmaceuticals. All other authors report no potential conflicts of interest.

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