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Longitudinal association between pain severity and subsequent opioid use in prescription opioid dependent patients with chronic pain

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ABSTRACT

Background: Patients with prescription opioid use disorder commonly report relief of chronic pain as the chief reason for first opioid use; indeed, the prevalence of chronic pain is high in this population. Understanding the association between pain severity and subsequent opioid use is crucial for understanding how to manage these conditions simultaneously and has not been examined in this population. The aim of this analysis was to examine the proximal effect of pain severity on opioid use during 12 weeks of buprenorphine-naloxone therapy for patients with chronic pain and prescription opioid use disorder.
Methods: This study is a secondary analysis of a national, randomized, controlled trial of buprenorphine-naloxone plus counseling for prescription opioid dependent patients. The association between past-week pain severity and opioid use in the subsequent week was examined in 148 patients presenting with chronic pain at baseline.
Results: Results from a multivariable logistic regression model showed that greater pain severity in a given week was significantly associated with increased odds of opioid use in the following week over the 12-week treatment, even after adjusting for covariates associated with opioid use (aOR = 1.15, $p < 0.001$).
Conclusions: Despite previous reports of no association between baseline pain and subsequent opioid use, our findings suggest that patients who experience flare-ups of pain during treatment are prone to relapse to opioid use. Future studies may identify those who are at risk to use opioids by carefully monitoring patterns of their pain intensity over time.

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1. Introduction

The presence of chronic pain reported by patients entering prescription opioid use disorder treatment ranges from 42 to 61% in recent studies (Cicero et al., 2008; Green et al., 2009; Rosenblum et al., 2007; Weiss et al., 2011). Understanding the association between pain and opioid use among those with prescription opioid use disorder is important, given the frequent occurrence of chronic pain in this population.

In studies of patients receiving methadone maintenance treatment, pain is often a correlate of more severe clinical problems, at baseline and during treatment. Those with chronic pain are more likely to have major medical problems (Jamison et al., 2000; Trafton et al., 2004), worse psychiatric problems (Barry et al., 2009; Jamison et al., 2000; Trafton et al., 2004), higher unemployment (Trafton et al., 2004), and worse sleep problems (Peles et al., 2006), compared to patients with either no pain or less severe pain. Interestingly, however, although the presence of chronic pain and illicit opioid use have been associated at treatment entry (Ilgen et al., 2006; Trafton et al., 2004), several studies have found no association between baseline pain and illicit opioid use during treatment (Chakrabarti et al., 2010; Fox et al., 2012; Ilgen et al., 2006). Further, a few studies have assessed chronic pain during treatment and

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found no association with opioid use measured at the same time (Barry et al., 2009; Dhingra et al., 2015; Fox et al., 2012). Similarly, the multi-site Prescription Opioid Addiction Treatment Study, led by our group, reported no association between baseline pain and opioid use at the end of treatment among patients with primary prescription opioid dependence (for treatment outcomes, Weiss et al., 2011; for follow-up outcomes, Potter et al., 2015).

This lack of association between chronic pain at treatment entry and opioid use at the end of treatment may be attributable in part to variation in pain severity over the course of treatment; perhaps pain is a stronger predictor of proximal opioid use outcomes than of more distal outcomes. For example, in a 12-month follow-up study of patients in methadone treatment, 38% of patients with clinically significant chronic pain at baseline did not consistently report that level of pain throughout treatment, and another 45% who reported no pain at baseline later reported clinically significant chronic pain (Dhingra et al., 2015). Further, potential variability may have been overlooked due to the measurement of pain as dichotomous rather than continuous, resulting in a loss of sensitivity. Previous studies have focused on the presence or absence of pain, rather than on pain severity. Even when pain was initially assessed on a continuous scale, outcome analyses relied on discrete categories, either any pain or no pain (Jamison et al., 2000; Peles et al., 2006; Weiss et al., 2011); significant pain or not (Fox et al., 2012; Ilgen et al., 2006; Trafton et al., 2004); or significant pain, some pain, and little or no pain (Barry et al., 2009; Chakrabarti et al., 2010; Dhingra et al., 2015). In addition, variability in the experience of pain may be the result of variation in analgesic response to opioid agonist therapy, which has been efficacious in reducing pain overall among patients with opioid dependence (Neumann et al., 2013). However, not all patients report improvement in pain or function (Jamison et al., 2000), suggesting that the agonist analgesic effect is another factor that could affect the pain and opioid use association when considered more distally. Although earlier reports suggest that pain varies over the course of treatment, most studies examining pain and treatment outcome measure the distal association between pain at baseline and end-of-treatment outcomes. Examining the proximal effect of pain on use may control for some factors that could obscure the association between pain and treatment outcome.

Primary prescription opioid use disorder is an important problem, but little research has been conducted on pain among those who primarily abuse prescription opioids with minimal or no heroin use. Investigating the extent to which pain influences these patients' ability to abstain from illicit opioid use over the course of treatment is crucial for understanding how to manage these disorders simultaneously. The first large, multi-site, randomized controlled trial to study treatment of prescription opioid dependence provides an opportunity to address this issue. The aim of this analysis was to examine the proximal effect of pain severity on opioid use during 12 weeks of buprenorphine-naloxone therapy for patients with prescription opioid dependence and chronic pain. In particular, we sought to determine whether pain severity in a given week was associated with opioid use in the following week, after adjusting for opioid use in the previous week (i.e., the week in which the pain data were collected). This study is novel in examining the association between a continuous measure of pain severity and opioid use at weekly time intervals over 12 weeks in patients with prescription opioid dependence and chronic pain.

2. Methods

The current secondary analysis uses data from the Prescription Opioid Addiction Treatment Study sponsored by the National Drug Abuse Treatment Clinical Trials Network; the parent study was a national, 10-site randomized controlled trial (N = 653) comparing different durations of buprenorphine-naloxone treatment (a 4-week treatment phase followed for some participants with an extended, 12-week treatment phase) and different intensities of counseling (standard medical management with or without additional opioid dependence counseling) to treat patients with prescription opioid dependence (for details, see Weiss et al., 2010b). Following approval by the Institutional Review Boards at the participating sites, participants were recruited upon entry for treatment of prescription opioid dependence. Manual-based standard medical management (Fiellen et al., 1999) consisted of medically-oriented addiction counseling delivered to all participants by a physician. In addition, half the participants were randomly assigned to receive individual opioid dependence counseling, also manual-based (Pantalon et al., 1999), by trained substance abuse or mental health professionals; these counseling sessions were more frequent and covered a wider range of issues in greater depth during longer sessions. Manuals can be found as Supplementary Material. Treatment fidelity was excellent: all sessions were audiotaped, with 99% rated by independent reviewers as acceptable. All participants identified with chronic pain at baseline were monitored for pain at each medical management visit and were encouraged to use a self-guided behavioral pain management manual (Jamison, 1996); the impact of pain on recovery from substance dependence was addressed for those participants assigned to opioid dependence counseling. However, participants were not specifically treated for pain as part of the study.

Buprenorphine doses of 8–32 mg/daily were set by study physicians based on opioid use, craving, withdrawal, and adverse effects; pain was not an indication to alter dose. Participants were instructed to take the medication once per day. Treatment attendance was quite strong: 85.8% of participants attended ≥60% of standard medical management sessions, designated a priori as adequate; this did not vary by treatment condition. Further, 68.9% of participants assigned to opioid dependence counseling (n = 74) attended an adequate number of these sessions.

Study participants met DSM-IV criteria for current opioid dependence and were ≥18 years old. Because this was the first large-scale trial to examine patients dependent exclusively or primarily on prescription opioids, key exclusion criteria included past-month heroin use on >4 days, a lifetime diagnosis of opioid dependence due to heroin alone, or a history of heroin injection (Weiss et al., 2010a). We also excluded those who needed to continue opioid use for pain management (as determined by the physician treating the participant prior to study entry), as well as those with current unstable psychiatric illness or on-going formal SUD treatment (for details, see Weiss et al., 2011).

2.1. Measures

Chronic pain was defined as pain beyond the usual aches and pains, lasting ≥3 months, in accordance with the International Association for the Study of Pain (Merskey and Bogduk, 1994), and excluding pain from opioid withdrawal. At baseline, 42% of participants met this definition of chronic pain; the current analysis is limited to those who initially reported chronic pain and participated in the 12-week buprenorphine-naloxone treatment phase ("extended treatment;" N = 148), which was offered to participants who relapsed to opioid use during an initial 4-week opioid taper ("brief treatment") or during the 8-week post-taper follow-up period.

The *Brief Pain Inventory-Short Form* (BPI-SF; Cleeland and Ryan, 1994; Keller et al., 2004) was used to measure physical pain. Originally developed for cancer pain, it is widely used to assess nonmalignant acute and chronic pain (Tan et al., 2004). The BPI-

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