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Pain and Continued Opioid Use in Individuals Receiving Buprenorphine-Naloxone for Opioid Detoxification: Secondary Analyses from the Clinical Trials Network

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Abstract

Pain complaints are common among individuals with opioid dependence. However, few studies investigate pain during opioid detoxification, or the impact this pain has on continued opioid use. This secondary analysis utilized data from two Clinical Trials Network (CTN) randomized controlled trials of buprenorphine-naloxone for short-term opioid detoxification to examine the extent to which pain was associated with continued opioid use during and immediately following a 13-day detoxification protocol. At follow-up, more severe pain was associated with a greater number of self-reported days of opioid use during the prior 30 days ($p<.05$), but was not associated with urine toxicology results collected at follow-up. These results, although mixed, have potentially important clinical implications for assessing and addressing pain during opioid detoxification. Pain that is experienced during and immediately following medically monitored detoxification may be associated with continued opioid use. These findings lend further support for continued research on pain among patients with opioid dependence.

Introduction

Pain complaints are common among individuals in treatment for substance use disorders (SUD) as consistently high rates of pain have been observed in patients receiving outpatient addiction treatment (Caldeiro et al., 2008; Ilgen, Trafton, & Humphreys, 2006; Rosenblum et al., 2003) and short-term inpatient detoxification (Ilgen et al., 2006; Larson et al., 2007; Potter, Prather, & Weiss, 2008). In treatment settings in which opioid dependence predominates (e.g., methadone maintenance treatment programs), rates of current pain as high as 80% have been reported (Rosenblum et al., 2003). Indeed, opioid dependence is associated with higher rates of pain than other substance use disorders across a variety of treatment settings (Potter, et al., 2008).

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Because the primary goal of SUD treatment is addressing substance use, pain is understandably not central to the mission of most treatment programs. Addressing pain presents a challenge for SUD treatment providers for a variety of reasons. In the case of chronic pain complaints, clinicians may be understandably hesitant to prescribe opioids to address pain in individuals who are already misusing these drugs (Rosenblum et al., 2003). Indeed, there is concern that patients in SUD treatment may report or over-report pain in an attempt to receive opioids (Caldeiro et al., 2008). Moreover, in the case of detoxification, the use of opioids for a purpose other than treatment of withdrawal conflicts directly with the treatment goal. Acute pain, particularly muscle and joint pain, is a common and well-recognized withdrawal symptom (Polydorou & Kleber, 2008) that may be addressed as part of a general detoxification protocol, but pain is viewed as an expected sign of withdrawal. Although non-opioid medications (e.g., non-steroidal anti-inflammatory drugs) and behavioral approaches to mitigating pain are available, pain is unlikely to garner the attention that it might attract in a general medical or specialty care setting.

A growing body of evidence, however, suggests that pain complicates SUD treatment, in that it is associated with a greater likelihood of continued substance use. Following detoxification treatment, persistent pain was found to be predictive of continued substance use, including alcohol and opioids, 24 months post-treatment in a sample of individuals for whom alcohol, opioids, or cocaine was the primary drug of choice (Larson et al., 2007). Similar findings were reported in outpatient treatment settings among individuals with a non-opioid substance use disorder (Caldeiro et al., 2008). Associations between chronic pain and response to methadone treatment have been inconsistently reported (Friedmann, Lemon, Anderson, & Stein, 2003; Ilgen et al., 2006). Opioid dependent patients with and without pain did not differ in retention, length of treatment, or reduction in illicit opioid or other drug use at 12-month follow-up (Ilgen et al., 2006). The studies referred to above examined chronic or persistent pain, not pain experienced specifically during and immediately following detoxification. Moreover, few of these studies investigated opioid dependent patients exclusively or focused specifically on short-term detoxification outcomes of patients treated with buprenorphine-naloxone (bup-nx), a medication used increasingly for opioid detoxification (Mark, Kassed, Vandivort-Warren, Levit, & Kranzler, 2009).

The National Drug Abuse Treatment Clinical Trials Network (CTN) is a group of 16 university-based regional research training centers linked in partnership to more than 100 community-based treatment programs (CTPs) providing SUD and other health care services. The CTN conducted randomized controlled trials to examine the effectiveness of bup-nx for short-term detoxification from opioids at the community clinic level in outpatient and inpatient (hospitalized) samples (Amass et al., 2004). Together, the studies (Ling et al., 2005) provided strong evidence that a opioid dependent community-based participants receiving short-term bup-nx are significantly more likely to complete their detoxification, be free of illicit opioids at that time, report less subjective withdrawal and craving during a dose taper when compared with participants receiving clonidine (a medication used commonly for detoxification at the time of the trial).

As part of the study, participants were assessed for presence of pain at a baseline interview conducted shortly before beginning detoxification, providing an indicator of pain before beginning treatment, and at a follow-up assessment conducted 15 days post-detoxification, providing an indicator of pain experienced during the 4 weeks since beginning treatment. This secondary analysis examined the association between pain and illicit opioid use at the end of detoxification and at follow-up (15 days post-detoxification). Specifically, we investigated the following research questions: (1) to what extent does moderate-to-severe pain at baseline (experienced during the preceding 4 weeks) predict treatment success (providing an opioid-free urine sample) at the end of detoxification and continued success

15 days post-detoxification; and (2) to what extent does pain (experienced during the preceding 4 weeks) predict days of opioid use at 15 days post-detoxification.

METHODS

Study Design

Twelve SUD treatment programs participated in one of 2 trials comparing bup-nx and clonidine in an open-label, randomized 13-day detoxification regime, with six programs conducting an inpatient trial (hospital-based) and six programs conducting an outpatient trial. The inpatient and outpatient trials, conducted concurrently, were identical in all respects except for the treatment setting in which the opioid detoxification was provided. In both trials, patients were assigned randomly to bup-nx or clonidine, using a 2:1 ratio in favor of bup-nx. Comprehensive descriptions of the trial designs, eligibility criteria, and trial outcomes are reported elsewhere (Amass et al., 2004; Brigham et al., 2007; Ling et al., 2005; Ziedonis et al., 2009).

Participants

Participants were treatment-seeking adults who were at least 18 years old and in good general health, diagnosed with opioid dependence as defined by the *Diagnostic and Statistical Manual- IV* criteria (*DSM-IV*, 1994), and in need of medical management for opioid withdrawal. The study was approved by all participating sites' Institutional Review Boards. All participants provided written informed consent before engaging in any study procedures.

Of the 344 participants randomized to the two trials (113 to the inpatient trial and 231 to the outpatient trial), we elected to consider only those participants randomized to the bup-nx condition in our analyses because of the dramatic outcome differences observed between the two treatment conditions described above. Based on interim analysis, the NIDA Data and Safety Monitoring Board recommended that the studies be halted before enrolling the number of participants originally proposed because the results favored the bup-nx condition overwhelmingly, and additional participant enrollment would not yield meaningful new information. Analyzing only data from participants assigned to the bup-nx condition ensures that our analyses will be relevant to current clinical practice, which supports the clinical superiority of bup-nx for detoxification. Thus, our current analysis focuses on the 234 bup-nx participants (77 inpatients and 157 outpatients). Of these, 138 (59%) returned to complete the follow-up visit conducted at 15 days post-detoxification.

Measures

SF-36v2—The SF-36v2, which was administered at the baseline and follow-up visits (15 days post-detoxification), is a widely-accepted 36-item, patient-administered instrument examining health-related quality of life (Ware et al., 2007). Each item is rated on a 5-point scale. There are 2 items addressing pain: severity ("How much bodily pain have you had during the past 4 weeks?") and interference ("During the past 4 weeks, how much did pain interfere with your activities?") To address research question 1, moderate-to-severe pain at baseline was defined as having an SF-36v2 score > 4 on the severity item. This was selected because prior research suggests that pain of this degree is clinically relevant in SUD settings, while those with less severe pain are more similar to those with no pain (Potter, Shiffman, & Weiss, 2008).

To address research question 1, the SF-36v2 Bodily Pain scale (BP) was used. The BP, one of 8 available subscales of the SF-36, is comprised of the 2 pain items described above. BP scores may be normalized to a 0 – 100 scale, with a higher score reflecting milder pain-

related problems (Ware et al., 2007). Normalized scores permit comparison of the BP to normative samples available from the test publisher.

Adjective Rating Scale for Withdrawal (ARSW) (Amass, Kamien, & Mikulich, 2000; Bickel, Amass, Higgins, Badger, & Esch, 1997)—This 16-item self-report scale, completed daily, measured subjective severity of opioid withdrawal symptoms at baseline and during treatment. Consistent with Ling et al. (2005), a grand mean was derived based on the multiple ARSW scores collected during the treatment phase. The ARSW grand mean was treated as missing if more than 5 ARSW scores were missing. To address the role of withdrawal symptom severity in opioid use, the ARSW was included in multivariate analyses.

Urine drug screening—For the purposes of our analyses, urine drug screening results collected at the end of detoxification and at follow-up (15 days post-detoxification) were considered. Urine drug screening results were coded qualitatively as positive or negative for metabolites of illicit opioids (cutoff = 300 ng/ml). As in Ling et al. (2005), missing urines were treated as opioid positive. Urine samples were collected before dispensing bup-nx. All urine specimens were monitored by staff using drug test cups with temperature controlled monitoring. Test cups were provided by the Northwest Toxicology via the Center for Toxicology in Utah, which served as the central laboratory contractor for this protocol.

Addiction Severity Index-Lite (ASI-Lite) (McLellan et al., 1992)—An abbreviated version of the ASI was administered prior to randomization to characterize the study sample along demographic, medical, employment, alcohol, drug, legal, and psychiatric domains. For the present analysis, the number of self-reported days of opioid use at follow-up was included in the analysis as an indicator of treatment outcome. Because of the non-normal distribution, the variable was log-transformed prior to its use in analyses.

Procedures

After providing informed consent, but prior to randomization, participants completed a 2-3 hour baseline screening assessment. The baseline assessment included demographic characteristics, ARSW, ASI-Lite, SF-36, and urine drug screening. Eligible participants meeting all inclusion and exclusion criteria were invited to participate in the trials. For up to 13 consecutive days, randomized participants received daily study medications and participated in protocol-prescribed counseling sessions in addition to the treatment-as-usual psychosocial intervention provided at each clinical site. The study measures described above were collected regularly during this time.

Following induction, participants randomized to the bup-nx arm received daily doses for 13 days with a starting dose on day 1 of 4mg/1mg bup-nx, escalating in a step-wise manner to 16 mg/4 mg bup-nx on day 3 and tapering to 2 mg/0.5 mg bup-nx by days 12 and 13. After completing detoxification, participants completed a follow-up assessment at 15 days post-detoxification; assessments at that visit included the ASI-Lite, SF-36v2, and urine drug screening. The ASI-Lite and SF-36v2 captured information about behaviors during the past 4 weeks (the period of time since the beginning of detoxification.) The urine drug screen results were for the day of the follow-up visit.

Statistical Analysis

Because the primary analyses (Ling et al., 2005) demonstrated a substantial difference in treatment outcome between the inpatient and outpatient treatment arms, all multivariate analyses were adjusted for treatment setting (inpatient or outpatient) as well as age, sex, and ARSW (opioid withdrawal) scores.

After reviewing participant descriptive characteristics, we examined outcomes at two points in time: end of detoxification and at follow-up (15-days post-detoxification). To address outcome at the end of detoxification, we examined treatment "success" at the end of detoxification (day 13) between those with and without moderate-to-severe pain at baseline (n=234). As in Ling et al. (2005), treatment "success" was defined as completing the detoxification and providing an opioid-free urine sample on the last day of detoxification. As a secondary measure, we examined potential differences in treatment retention between those with and without moderate-to-severe physical pain by comparing the number of days from randomization to dropout or completion of detoxification. The Kaplan-Meier method was used to estimate the distribution of the time to dropout. Completion of detoxification was treated as a censored observation.

To address outcome at follow-up (15 days post-detoxification), logistic and linear regression were used. Using logistic regression, we examined whether BP scores at follow-up were associated with treatment "success" at follow-up (completing the detoxification and providing an opioid-free urine sample on the last day of detoxification). Accordingly, individuals who did not attend the follow-up visit were counted as treatment "failures", and the full sample of 234 participants was included in the analysis. Finally, linear regression was used to examine whether follow-up BP scores were associated with total days of opioid use at follow-up. This model included the 138 participants (59%) who completed the post-detoxification follow-up visit.

RESULTS

Table 1 presents a brief summary of the sample characteristics. The sample was predominantly male (68.4%) and most were over 35 years old (59.1%). At baseline, pain during the past thirty days was reported by 78.9% of the sample, of whom 67.4% reported moderate-to-severe physical pain. At follow-up (15 days post-detoxification), pain was reported by over two-thirds of the 138 participants (68.1%) who completed this assessment, of whom 52.2% had moderate-to- severe pain during this time. Baseline BP score was 61.1 (SD =26.8). Relative to the general U.S. population, this BP score was below that observed in the general U.S. population, indicating more severe pain and pain-related functional interference. Follow-up BP score was 68.8 (SD=26.8). In contrast to baseline, follow-up BP scores were consistent with the general U.S. population norm, indicating that clinically meaningful improvements in pain were obtained overall (Ware et al., 2007). However, as noted above, 35.5% of participants reported moderate-to-severe pain at follow-up.

Outcomes at End of Detoxification

As described above, we first examined treatment success for individuals with and without moderate-to-severe physical pain at the end of detoxification (n=234). Logistic regression analyses indicated that individuals with moderate-to-severe pain were significantly more likely to complete treatment successfully (aOR = 2.24, CI = 1.15– 4.37) than those without this degree of pain (see Table 2). Treatment setting was associated with treatment success (aOR=6.2, CI = 3.0–12.7) such that inpatient detoxification predicted treatment success at the end of detoxification. There were no significant associations between treatment success and age, sex, or ARSW scores. Thus, those who entered treatment with moderate-to-severe physical pain were more likely to complete treatment successfully. Review of the data suggested that, in large part, this was attributable to high retention rates for inpatient participants with moderate-to- severe pain. This finding was confirmed in survival analyses such that participants with moderate-to-severe pain at baseline remained in treatment longer (Mantel-Cox = 6.7, df = 1, $p < .01$).

Outcomes at End of Detoxification

We then examined the association between follow-up BP scores and treatment success and days of opioid use at follow-up. Not surprisingly, treatment setting again predicted outcome (aOR=3.82, CI = 1.6–9.1) such that inpatient detoxification predicted treatment success at follow-up as it had at the end of detoxification. However, there was no significant association between moderate-to-severe pain and treatment "success" as there had been at the end of detoxification (described above). Again, there were no significant associations between treatment success and age, sex, or ARSW scores. As with the end of detoxification analyses reported above, we examined whether moderate-to-severe pain was associated with attending the follow-up visit, and we found was no significant association.

Finally, we examined the relation between follow-up BP scores and days of opioid use at follow-up (15 days post-detoxification) in the 138 participants who completed follow-up interviews. As shown in Table 3, BP score at post-detoxification was associated significantly with days of opioid use such that more pain and pain interference during the past 4 weeks was associated with a greater number of days of illicit opioid use ($b=-0.09$, $p < 0.05$) after adjusting for age, sex, ARSW, baseline BP, and inpatient treatment setting. There was no association between days of opioid use and ARSW scores, age, or sex. As with the treatment success outcome, inpatient setting was associated with fewer days of opioid use in the past 4 weeks ($b=1.07$, $p<0.001$).

DISCUSSION

This secondary analysis investigated the role of pain on illicit opioid use during opioid detoxification treatment. Consistent with prior reports, pain was a common problem reported by the majority of participants at baseline and follow-up. Overall, results regarding the role of pain in predicting treatment outcome were mixed. Moderate-to-severe pain at baseline was associated with treatment success (urine toxicology results) at the end of detoxification. It is possible that individuals experiencing more pain prior to entering treatment, perhaps related to withdrawal symptoms experienced during the month prior to detoxification, were more motivated to stay in detoxification.

However at follow-up, there was no association between moderate-to-severe baseline pain and urine drug screen results. While this could represent a true negative finding, some methodological features of both the main study and our analytic strategy may have contributed to this result. As in the original study, we adopted a conservative approach in which individuals who did not complete the follow-up visit were assumed to have an opioid-positive urine result. Thus, a sizable number of participants were deemed opioid-positive because of failure to attend this follow-up interview, but, we found no association between attending the follow-up visit and pain status.

In contrast to the above, at follow-up, more pain (as measured by the BP) was associated with more days of opioid use. This finding was observed after adjusting for baseline BP and self-reported opioid withdrawal symptoms during detoxification. This is consistent with previous research suggesting that pain worsens SUD outcomes, including those for opioid dependence (Caldeiro et al., 2008; Larson et al., 2007). It is important to note that the BP includes two elements of pain (intensity and interference) rather than just pain intensity as with the moderate-to-severe pain measure. Thus, our findings suggest that continued research regarding the role of pain on substance abuse treatment outcomes is warranted.

Further, these results support that physical pain is experienced by a sizable proportion of individuals entering detoxification. Although pain is a known withdrawal-related symptom, it may be important to assess and address pain reported during and immediately following

detoxification more vigorously and explicitly as it may be a risk factor for relapse. Moreover, given the relative lack of awareness of pain in SUD treatment settings and the potential for participants with pain to be seen as difficult and "medication (or drug)-seeking" (Merrill, Rhodes, Deyo, Marlatt, & Bradley, 2002; Modesto-Lowe, Johnson, & Petry, 2007), it is understandable that pain might not be at the forefront of the treating clinician's attention. Assessing and addressing pain is encouraged increasingly in most health care settings including behavioral health care settings, for example the Joint Commission (Lanser & Gesell, 2001) and Veteran's Health Administration (Veterans Health Administration National Pain Management Strategy, 1998). The findings discussed above, although exploratory, add to the literature because this research focuses on a detoxification sample using bup-nx for detoxification, and directs attention to pain experienced during and immediately following detoxification.

These results have limitations. As with all secondary data analyses, this was exploratory work intended to generate future hypothesis-driven research. Our sample only included individuals who received a 14-day detoxification using bup-nx, and results should not be generalized to detoxification using other medications and schedules. The high attrition rate from baseline to follow-up limited the sample available for analysis at follow-up. While we did not observe a differential attrition rate between those with and without moderate-severe pain, our analyses are limited by the fact that only 59% of participants randomized returned for the follow-up visit. Thus, interpretation of these results must be made with caution. Finally, because pain was not a primary focus of the original study, our ability to assess pain was somewhat limited. While the SF36v2 BP captures two important components of pain (intensity and interference), this is not a comprehensive measure of pain. In addition, pain was only assessed at baseline and follow-up. As a result, we were unable to discriminate pain experienced during detoxification from pain experienced after detoxification. Similarly, we were unable to distinguish acute pain from chronic pain or to isolate the reason for the pain (e.g., withdrawal pain). This is important because different types of pain may have different implications for substance abuse treatment outcomes. For example, the pain that participants reported at baseline might have resulted from pre-existing chronic pain problems (with various etiologies), opioid-related withdrawal pain, a combination of these two, or some other reason.

Despite these limitations, the results suggest potentially important clinical implications regarding pain management during the detoxification process that warrant continued research. This is, to our knowledge, the first report describing pain and its association with SUD outcome among individuals receiving bup-nx for opioid detoxification in a controlled clinical trial. As such, our findings extend previous reports indicating that persistent pain is associated with negative SUD treatment outcomes and confirm the importance of examining co-occurring physical pain in SUD populations (Caldeiro et al., 2008; Ilgen et al., 2006; Larson et al., 2007).

Research on co-occurring pain and substance use disorders is relatively new, To advance our understanding of the potential clinical implications of pain on substance abuse treatment, comprehensive and systematic pain assessment that goes beyond pain severity to include etiology, course, and functional impairment is critical. It is important that we better understand the role of pain, acute and chronic, in maintaining substance use. Finally, we need to determine the extent to which currently available pharmacological and psychosocial treatments for substance use disorders are effective in individuals with co-occurring pain.

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Table 1

Sample Characteristics

Variable	TOTAL[a] (n=234)
Male	69.3%
Age	
<35	42.0%
35–44	31.2%
45–54	24.7%
55–64	2.2%
Outpatient treatment	67.1%
ARSW (withdrawal symptoms)	16.6(16.7)
BP Score – Baseline	61.1(26.8)
BP Score – Post-detoxification[b]	68.8(26.8)
Post-detoxification opioid use (past 30 days)[b]	8.8(10.3)

[a] Mean(SD) or %

[b] n=138

Table 2

Adjusted Odds Ratios (aOR) and 95% Confidence Interval (CI) for Factors Associated with Treatment Success (present at follow-up and opioid-free urine sample) at End of Detoxification (n=234)

	aOR (95% CI)
Treatment Setting	
Outpatient	1.00
Inpatient	6.2** (3.0, 12.7)
Sex	
Male	1.00
Female	0.66 (0.33, 1.34)
Age	1.0 (0.70, 1.43)
ARSW	1.21 (0.98, 1.50)
Pain (at baseline)	
No pain	1.00
Mod-Sev pain	2.24* (1.15, 4.37)

* p<.05

** p<.001

Table 3

multiple Regression Analysis for Factors Associated with Days of Opioid Use at Follow-up (n=138)

	B	R^2
Treatment Setting (inpatient)	1.07**	
Sex	.19	
Age	.10	
ARSW	.09	
BP baseline	.03	
BP follow-up	−.09*	.23

* p<.05

** p<.001