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Cognitive Behavioral Therapy Improves Treatment Outcomes for Prescription Opioid Users in Primary-Care Based Buprenorphine Treatment

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Abstract

To determine whether treatment outcomes differed for prescription opioid and heroin use disorder patients, we conducted a secondary analysis of a 24-week (N = 140) randomized trial of Physician Management (PM) or PM plus Cognitive Behavioral Therapy (CBT) in primary care buprenorphine/naloxone treatment. Self-reported opioid use and urine toxicology analyses were obtained weekly. We examined baseline demographic differences between primary prescription opioid use patients (n = 49) and primary heroin use patients (n = 91) and evaluated whether treatment response differed by assigned condition. Compared to primary heroin use patients, primary prescription opioid use patients had marginally fewer years of opioid use, were less likely to have had a previous drug treatment or detoxification, and were less likely to report injection drug use. Although opioid abstinence only, and treatment retention did not differ by opioid use group, opioid category moderated the effect of CBT on urine samples negative for all drugs. Primary prescription opioid use patients assigned to PM-CBT had more than twice the mean number of weeks of abstinence for all drugs (7.6) than those assigned to PM only (3.6; $p=.02$), while primary heroin use patients did not differ by treatment. Findings suggest that examination of other factors that may predict response to behavioral interventions is warranted.

Keywords

opioid-related disorders; buprenorphine; cognitive behavioral therapy; treatment outcome

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1. Introduction

The rate of heroin dependence in the United States has steadily increased at a rate of .2% per year from 2002 to an estimated 586,000 in 2014 for individuals 12 and older (Center for Behavioral Health Statistics and Quality, 2015). However, rates of prescription opioid dependence (e.g., hydrocodone, oxycodone, morphine) are even higher, with an estimated 1.9 million dependent in 2014. Recent studies have indicated that individuals with prescription opioid use disorder are more likely to be female, white, younger, have more income, and less drug treatment (Cleland, Rosenblum, Fong, & Maxwell, 2011; Wu, Woody, Yang, & Blazer, 2011). Differences between those primarily using prescription opioids versus heroin have been shown among those seeking treatment, including factors predictive of treatment outcomes, such as fewer years of opioid use (Moore, et al., 2007; Rosenblum, et al., 2007; Sigmon, 2006). These findings suggest that primary prescription opioid users may have less severe opioid use disorder or may seek treatment earlier. Among studies evaluating treatment outcomes, prescription opioid patients have been retained in treatment longer and have greater opioid abstinence than patients using heroin (Banta-Green, Maynard, Koepsell, Wells, & Donovan, 2009; Moore, et al., 2007; Nielsen, Hillhouse, Thomas, Hasson, & Ling, 2013; Potter, et al., 2013; Soeffing, Martin, Fingerhood, Jasinski, & Rastegar, 2009).

Although opioid agonist maintenance is the standard of care for both heroin and prescription opioid users, problems with retention and continued drug use are still common. A number of studies, going back to the mid 1980's (Woody, McLellan, Luborsky, & O'Brien, 1987), have examined the added benefit of counseling and other behavioral interventions (e.g., contingency management, directly observed medication adherence). A recent systematic review (Amato, Minozzi, Davoli, & Vecchi, 2011) examined treatment efficacy data of 13 different psychosocial interventions in the context of agonist maintenance treatment for opioid use disorder. The authors concluded that such interventions do not improve treatment outcomes compared to standard agonist maintenance treatment. Recent studies have not been able to detect improved outcomes with additional counseling over physician management alone in the context of primary care and office-based buprenorphine (Fiellin, et al., 2013; Ling, Hillhouse, Ang, Jenkins, & Fahey, 2013; Moore, et al., 2012) and methadone maintenance treatment (Drummond, et al., 2005). These studies evaluated Cognitive Behavioral Therapy (CBT), which despite demonstrated effectiveness with all other substances of abuse and a range of other psychiatric disorders (Butler, Chapman, Forman, & Beck, 2006; Hofmann & Smits, 2008; McHugh, Hearon, & Otto, 2010), did not improve treatment outcomes for opioid dependent patients receiving buprenorphine. However, these studies combined both heroin and prescription opioid dependent populations and did not examine outcomes based on primary opioid of abuse.

To our knowledge, only one study has evaluated treatment outcomes of different behavioral interventions (i.e., different levels of nurse provided psychosocial counseling and directly observed medication adherence) by opioid use type in the context of agonist maintenance (Moore, et al., 2007). Given that CBT has been shown to be effective for other drugs of abuse (e.g., alcohol, cocaine, marijuana, and methamphetamine), CBT may improve treatment outcome compared to physician management alone for prescription opioid abuse while not for heroin. Therefore the current study conducted a secondary analysis from a

randomized trial of buprenorphine//naloxone with and without CBT for opioid dependence (Fiellin, et al., 2013) to evaluate treatment outcomes for prescription opioid and heroin use disorder patients.

2. Material and Methods

2.1 Participants

For the current study, we evaluated all participants (N = 140) from the Fiellin et al. (2013) study. All patients met Diagnostic and Statistical Manual (DSM)-IV criteria for opioid dependence. Exclusion criteria consisted of current dependence of alcohol, benzodiazepines, or cocaine; danger to oneself or others; psychotic or untreated major depression; inability to speak or comprehend English; or life-threatening medical problems. Women of childbearing age agreed to use contraception and undergo monthly pregnancy monitoring. See Fiellin et al. (2013) for additional details. The research was approved by the Yale University Human Investigation Committee and all patients provided informed consent.

Data from the four weeks prior to intake from the Timeline Followback Substance Use Calendar (Fals-Stewart, O'Farrell, Freitas, McFarlin, & Rutigliano, 2000; Sobell, 1988) was used to classify participants by primary opioid use (prescription or heroin) based on self-reported use 5 days/week. In cases with missing Substance Use Calendar data (n = 12), self-reported days of use in the last 30 from the Addiction Severity Index (ASI; McLellan, et al., 1992) was used. Forty-nine patients met criteria for prescription opioids and 91 for heroin. No participant met criteria for both subcategories (i.e., 5 days/week). Only 15% (3/48) of prescription opioid users reported any recent heroin use, and 17% (6/93) of heroin users reported any recent prescription opioid use.

2.2 Measures

Over the 26 weeks of the study, brief assessments (urine screen and Substance Use Calendar) were collected weekly, while longer assessments, including the ASI, were collected monthly by a trained research assistant. The ASI was used to assess substance use and related problems in seven areas (Medical, Employment, Alcohol Use, Drug Use, Legal, Family/Social Relationships, and Psychiatric (McLellan, et al., 1992). Treatment process variables included mean buprenorphine dose, number of PM visits, number of CBT sessions and CBT session length.

Illicit drug use during treatment was measured by patient self-report (Substance Use Calendar) and urine toxicology testing. Urine samples were collected during weekly research assessments. Urine toxicology analyses were performed using a semi-quantitative homogenous enzyme immunoassay for opioids, oxycodone, methadone, benzodiazepines, amphetamine, methamphetamine, cannabis, and cocaine. For the 26 weeks in treatment, the total number of missing urine screens, urine screens negative for opioids, and urine screens negative for all drugs were calculated for each participant. The maximum consecutive weeks of abstinence from illicit opioids was based on self-report and verified by urine toxicology test results.

Retention variables included study completion and weeks remaining in treatment. Completion was defined as remaining in the study until week 24. Retention was defined as the number of weeks prior to study withdrawal. Participants were withdrawn from the study due to protective transfer, missing medication for greater than 7 days, or missing more than 3 physician management sessions.

2.3 Design and Treatment

The secondary analysis was based on a 26-week (2 week induction/stabilization, 24 weeks of maintenance) randomized clinical trial in a primary-care clinic comparing Physician Management (PM) to Physician Management with Cognitive Behavioral Therapy (PM-CBT) for opioid abuse disorder patients receiving buprenorphine/naloxone treatment (see Fiellin et al. 2013 for more methodological detail). All participants received the buprenorphine/naloxone combination tablet with a two-week induction and stabilization period, followed by a maintenance phase of 24 weeks. During maintenance patients received 16 mg of buprenorphine daily with increases to 20 mg and 24 mg permitted depending on the level of discomfort or evidence of continued illicit opioid use.

Following induction and stabilization, participants were randomly assigned to either PM or PM-CBT based on urn randomization procedure controlling for patient sex, employment status, and achievement of abstinence during induction and stabilization. PM sessions were approximately 15 to 20 minutes and were provided by internal medicine physicians experienced providing buprenorphine. During each session, physicians reviewed the patient's recent drug use, weekly urine toxicology results, and attendance at self-help groups, and provided brief advice and support on methods to achieve or maintain abstinence. Physicians did not have training in CBT. PM sessions occurred weekly for the first two weeks, every other week for the next four weeks, and monthly thereafter.

CBT consisted of up to 12 weekly, 50-minute manual-guided sessions. All sessions were provided by a masters or doctoral level clinician trained to competence in delivery of CBT and provided weekly supervision to maintain fidelity.

2.4 Data Analysis

Univariate comparisons of patients by opioid use group were conducted using chi-square tests for categorical variables and t-tests for interval and continuous variables. Treatment process variables used Analysis of Variance (ANOVA) and controlled for assigned condition. For treatment outcomes, 2 by 2 ANOVA's were used to evaluate opioid use group (primary prescription opioid vs primary heroin), assigned condition (PM only vs. PM-CBT), and the interaction. Retention was examined using Cox Regression survival analysis on weeks in treatment. Post-hoc follow-up comparisons used Bonferroni correction.

3. Results

3.1 Demographic Characteristics

Table 1 presents baseline demographic, clinical, and treatment process variables by opioid use group. Opioid use groups did not differ by gender, race, or education. Employment

status and years of opioid use approached significance, with prescription opioid users being marginally more likely to be employed and have fewer years of opioid use. The prescription opioid group was less likely to inject opioids and less likely to have prior treatment, including detoxification. In addition, groups did not differ on important treatment process variables of buprenorphine maintenance dose, number of CBT sessions attended, or mean length of attended sessions for those assigned to the CBT-PM condition. However, the number of PM sessions attended approached significance, with the prescription opioid group receiving marginally more sessions than the heroin group.

3.2 Treatment Outcomes

Table 2 presents treatment outcomes by opioid use group (primary prescription opioid vs primary heroin) and assigned condition (PM only vs. PM-CBT). There were no significant main effects or interactions on treatment completion or retention. For the urine screen outcome results there were no main effects of opioid use group or assigned treatment condition. However, there was a significant interaction for the number of urines negative for all drugs. The primary prescription opioid use group differed by assigned treatment condition [$F(1,136) = 4.50$, $p = .04$, Cohen's $d = .35$, Observed Power = 56%], while the primary heroin use group did not [$F(1,136) = 0.94$, $p = .33$, Cohen's $d = .17$, Observed Power = 16%]. There was a similar pattern for the longest consecutive weeks of opioid abstinence, but the interaction only approached significance. Neither the primary prescription opioid use group [$F(1,136) = 2.77$, $p = .10$, Cohen's $d = .28$, Observed Power = 38%], nor the primary heroin use group differed by assigned treatment [$F(1,136) = 1.29$, $p = .26$, Cohen's $d = .20$, Observed Power = 20%].

4. Discussion

The current study evaluated treatment outcomes for patients using primarily prescription opioids or heroin who received primary care-based buprenorphine/naloxone treatment in a randomized clinical trial of CBT (Fiellin et al., 2013). Findings indicated that for patients with primary prescription opioid use, PM with CBT led to better abstinence outcomes for all drugs of abuse compared with PM alone, with an effect size in the small to medium range (Cohen's $d = .35$). CBT did not lead to better outcomes for the heroin dependent patients, consistent with the findings of the parent study (Fiellin, et al., 2013). Given the greater number of heroin dependent patients in the sample, the overall findings appear to mask the effect for patients with primary prescription opioid use.

The primary opioid used was also associated with a number of differences in baseline characteristics. Consistent with other studies (Cleland, et al., 2011; Moore, et al., 2007; Rosenblum, et al., 2007; Sigmon, 2006), those who primarily use prescription opioids had fewer prior detoxification and non-detoxification drug treatment attempts and were less likely to inject drugs. This suggests that primary prescription opioid dependent patients may be more naïve to substance abuse treatment or exhibit less severe dependence than heroin use patients, which may contribute to greater responsivity to CBT. However, contrary to prior findings, opioid use groups did not differ on age, gender or race. This may be due to some prescription opioid users switching to heroin use (Jones, 2013; Tetrault & Butner,

2015), other factors associated with use initiation, or simply the non-random selection of the sample.

There were several limitations of the current study. First, the study did not control for opioid use type in randomization (factors controlled in the urn randomization were gender, employment, and abstinence during induction). Although the groups did not differ in the proportion assigned to each condition, control in randomization would have been preferred. Second, there were fewer patients using prescription opioids compared to heroin, thus reducing the power to evaluate differences, particularly differences in treatment response over time. Third, membership within opioid use group was based solely on self-reported data, which may be biased. Unfortunately, patients who use primarily prescription opioids often use a range of different opioids (Hydrocodone, oxycodone, methadone, etc.). While these can be detected in urines screens, results for some of these opioids do not allow for differentiation of prescription opioid use from heroin due to cross-reactions.

Although the limitations suggest caution, there are research and clinical implications of the current findings. First, replication in a randomized trial is needed in addition to evaluating whether this labor-intensive treatment is cost effective with this population, particularly given that the effect size was in the small to medium range. Second, since patients with primary prescription opioid use improved on some measures with CBT, providers might prioritize CBT or other related counseling to patients with substantial comorbid substance use, or use CBT in a stepped-care approach for patients who do not respond to PM alone. Providing costly interventions, such as individual counseling, in a targeted manner may make other resources available to increase capacity for opioid agonist treatment. Alternatively, automated behavioral interventions can be implemented in opioid agonist settings. Such interventions have a number of advantages, including low cost, consistent delivery, and increased availability, and have been shown to be effective in methadone and buprenorphine/primary care settings (Carroll, et al., 2014; Marsch, et al., 2014; Moore, et al., 2013). Despite the small to medium effect sizes noted here, if effect sizes are similar for automated interventions, they may be a cost effective addition to standard care.

Finally, meta-analyses have indicated that behavioral interventions do not improve treatment outcome for opioid use disorder in the context of opioid agonist treatment (Amato, et al., 2011). However, the current findings suggest that outcomes may be dependent on opioid use type. Thus, additional examination of factors that may predict response to behavioral interventions is warranted.

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Table 1

Baseline demographic, clinical and treatment process characteristics of opioid use groups

	Primary Prescription Opioid n =48	Primary Heroin n =93	Statistical test value, p
Age, years, mean, SD	32.4 (9.5)	34.4 (9.6)	t(139) = 1.12, p=.24
% Male (n)	71% (34)	75% (70)	X2(1) =0.32, p=.57
% White (n)	94% (45)	88% (80)	X2(1) =1.10, p=.29
% Hispanic (n)	6% (3)	11% (10)	X2(1) =0.77, p=.38
% Full-time employment (n)	51% (24)	34% (32)	X2(1) =3.61, p=.06
% High school education or greater (n)	87% (40)	83% (77)	X2(1) =0.40, p=.53
% Never Married (n)	62% (30)	67% (62)	X2(1) =0.24, p=.62
Years of opioid use, mean, SD	6.6 (5.8)	8.8 (6.6)	t(127) = 1.87, p=.06
Current Route of Administration			X2(1)=54.1, p <.001
% injection drug use (n)	2% (1)	47% (44)	
% intranasal (n)	61% (28)	53% (49)	
% ingest	37% (17)	0	
% Prior attempted detoxification	24% (11)	63% (52)	X2(1)=17.0, p<.001
% Prior treatment (not detox)	49% (22)	74% (61)	X2(1) =7.75, p=.005
Days of use of other substances in previous 30 days, mean, SD			
Alcohol	2.6 (4.8)	3.1 (5.9)	t(127)=0.49, p=.63
Cocaine	1.2 (2.6)	1.4 (2.7)	t(127)=0.48, p=.63
% Assigned to CBT (n)	47% (23)	52% (47)	X2(1) =0.09, p=.77
<u>Process Variables*</u>			
Buprenorphine Dose, mean, SD	17.5 (2.7)	18.3 (3.1)	F(1,128)=2.16, p=.14
Number of PM visits, mean, SD	5.3 (2.2)	4.6 (2.4)	F(1,128)=2.98, p=.09
Number of CBT sessions, mean, SD	7.3 (3.0)	6.8 (3.3)	F(1,66)=0.48, p=.49
CBT session length, mean, SD	43.9 (6.4)	42.9 (5.2)	F(1,66)=0.42, p=.52

Table 2

Treatment outcomes of opioid use groups by assigned treatment condition.

	Primary Prescription Opioid n =48		Primary Heroin n =93		Assigned Treatment F(df), p	Opioid Use F(df), p	Assigned Treatment* Opioid Use F(df), p
	PM-CBT (n = 23)	PM only (n = 26)	PM-CBT (n = 47)	PM only (n = 44)			
Completed Treatment	48% (11)	54% (14)	44% (20)	43% (20)	Wald(1)= 0.01, p=.99	Wald(1)= 0.13, p=.72	Wald(1)= 0.30, p=.59
Weeks in Treatment*	19.4 (6.9)	19.4 (6.2)	17.3 (7.2)	18.2 (7.0)	Wald(1)= 0.01, p=.97	Wald(1)= 0.26, p=.61	Wald(1)= 0.18, p=.67
Number of missing urine screens	0.78 (1.17)	0.64 (0.95)	0.74 (0.85)	0.61 (0.80)	F(1,137)=0.74, p=.39	F(1,137)=0.05, p=.83	F(1,137)=0.00, p=.98
Number of urines negative for opioids	12.0 (8.4)	9.7 (8.1)	9.2 (8.5)	10.4 (8.2)	F(1,137)=0.16, p=.69	F(1,137)=0.50, p=.48	F(1,137)=1.37, p=.24
Longest consecutive weeks of opioid abstinence	8.9 (7.8)	5.7 (6.5)	5.7 (5.8)	7.3 (7.2)	F(1,137)=0.44, p=.41	F(1,137)=0.43, p=.51	F(1,137)=3.83, p=.05
Number of urines negative for all drugs	7.6 (7.9)	3.7 (5.4)	5.1 (6.5)	6.4 (7.0)	F(1,137)=0.01, p=.94	F(1,137)=1.17, p=.28	F(1,137)=4.92, p=.03

Note: Evaluated with Cox Regression