Drug and Alcohol Dependence xxx (2014) xxx–xxx

Contents lists available at ScienceDirect

Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep

Who benefits from additional drug counseling among prescription opioid-dependent patients receiving buprenorphine–naloxone and standard medical management?

Roger D. Weiss[a,b,*], Margaret L. Griffin[a,b], Jennifer Sharpe Potter[a,b,c], Dorian R. Dodd[a], Jessica A. Dreifuss[a,b], Hilary S. Connery[a,b], Kathleen M. Carroll[d]

[a] McLean Hospital, Belmont, MA, United States
[b] Harvard Medical School, Boston, MA, United States
[c] University of Texas Health Sciences Center at San Antonio, San Antonio, TX, United States
[d] Yale University School of Medicine, New Haven, CT, United States

ARTICLE INFO

Article history:
Received 5 February 2014
Received in revised form 31 March 2014
Accepted 2 April 2014
Available online xxx

Keywords:
Prescription opioids
Treatment
Counseling

ABSTRACT

Background: In the multi-site Prescription Opioid Addiction Treatment Study (POATS), conducted within the National Drug Abuse Clinical Trials Network, participants randomly assigned to receive individual drug counseling in addition to buprenorphine–naloxone and medical management did not have superior opioid use outcomes. However, research with other substance-dependent populations shows that subgroups of participants may benefit from a treatment although the entire population does not.
Method: We conducted a secondary analysis of POATS data to determine whether a subgroup of participants benefited from drug counseling in addition to buprenorphine–naloxone and medical management, either due to greater problem severity or more exposure to counseling as a result of greater treatment adherence. Problem severity was measured by a history of heroin use, higher Addiction Severity Index drug composite score, and chronic pain. Adequate treatment adherence was defined a priori as attending at least 60% of all offered sessions.
Results: Patients who had ever used heroin and received drug counseling were more likely to be successful (i.e., abstinent or nearly abstinent from opioids) than heroin users who received medical management alone, but only if they were adherent to treatment and thus received adequate exposure to counseling (OR = 3.7, 95% CI = 1.1–11.8, $p = 0.03$). The association between severity and outcome did not vary by treatment condition for chronic pain or ASI drug severity score.
Conclusions: These findings emphasize the importance of treatment adherence, and suggest that patients with prescription opioid dependence are a heterogeneous group, with different optimal treatment strategies for different subgroups.

1. Introduction

Prescription opioid dependence continues to be a significant public health problem in the United States (Substance Abuse and Mental Health Services Administration, 2011). Although research suggests that prescription opioid users differ from heroin users on important prognostic factors (Moore et al., 2007; Sigmon, 2006; Wu et al., 2011) and may have different treatment outcomes (Moore et al., 2007; Nielsen et al., 2013; Potter et al., 2013), most existing studies of opioid dependence treatment have focused primarily on heroin users. To bridge this gap, the Prescription Opioid Addiction Treatment Study (POATS) was conducted as part of the National Drug Abuse Treatment Clinical Trials Network (Weiss et al., 2010). POATS was a multisite, two-phase randomized, controlled trial ($N = 653$) that used buprenorphine–naloxone to treat patients dependent on prescription opioids. All study participants received standard medical management, and half were randomized to receive adjunctive individual opioid dependence counseling. Only 7% of participants met study criteria for successful outcome (i.e., abstinence or near-abstinence from opioids) in the first phase of POATS (a brief buprenorphine–naloxone taper), while 49% were successful at the end of 12 weeks of buprenorphine–naloxone stabilization in the extended treatment phase (Phase 2) of the study.

* Corresponding author at: McLean Hospital, 115 Mill St., Belmont, MA 02478, United States. Tel.: +1 617 855 2242; fax: +1 617 855 2699.
E-mail address: rweiss@mclean.harvard.edu (R.D. Weiss).

http://dx.doi.org/10.1016/j.drugalcdep.2014.04.005
0376-8716/

Results showed that additional counseling did not affect treatment outcome in either the brief or the extended treatment phase (Weiss et al., 2011).

Studies of other substance-dependent populations have shown that, although a treatment may not have an effect on the population as a whole, it may benefit certain subgroups of participants (Anton et al., 2008). Thus, although additional counseling did not improve outcome for the POATS population overall, certain subpopulations of prescription opioid-dependent patients receiving buprenorphine–naloxone pharmacotherapy and standard medical management may have benefitted from the additional counseling offered in POATS.

When considering which subgroups of participants might have better outcomes with additional counseling, we focused on two potential sources of variability: (1) participant characteristics and (2) adherence to treatment, resulting in adequate exposure to the intervention. For participant characteristics, we examined severity of drug problems, because some previous research has demonstrated that patients with more severe drug problems may benefit from more intensive treatment (Hser et al., 1998; McKay et al., 2002; Tiet et al., 2007). Although problem severity among individuals with substance use disorders (SUDs) has been defined in a number of ways, including chronicity of dependence (Carroll et al., 1993) and pre-treatment quantity or frequency of drug use (Brewer et al., 1998; Laffaye et al., 2008; Saxon et al., 1996), the Addiction Severity Index (ASI; McLellan et al., 2006) drug composite score is a commonly used, well-validated measure of severity of drug dependence (Crits-Christoph et al., 1999; Farabee et al., 2013; Rosenheck et al., 2011). Additionally, for our study population of individuals dependent on prescription opioids, two other potential markers of response in this population were examined: (1) a lifetime history of heroin use, because of its association with poorer outcome in POATS (Weiss et al., 2011) and (2) chronic pain, due to its high prevalence rate among opioid-dependent individuals (Potter et al., 2008; Rosenblum et al., 2003) and its association with greater severity of SUD symptoms (Rosenblum et al., 2003; Trafton et al., 2004).

In addition to severity, another potential reason for varying effectiveness of a treatment intervention among subgroups of an overall patient population is treatment adherence, resulting in differential exposure to the treatment. Not surprisingly, patients who are adherent to a treatment regimen and thus receive an adequate amount of a treatment intervention are more likely to benefit from it (Fareed et al., 2009; Montoya et al., 2005). Past research has shown that individual and group therapy are more effective for SUD patients who attend more treatment sessions (Fiorentine and Anglin, 1996; Lydecker et al., 2010; Montoya et al., 2005); thus, it is likely that level of attendance of treatment sessions among POATS patients may have been related to treatment outcome among patients who received adjunctive opioid dependence counseling.

We therefore conducted a secondary analysis of data from POATS to determine whether a subgroup of participants benefited from drug counseling in addition to buprenorphine–naloxone and standard medical management, either due to greater problem severity, more exposure to counseling as a result of greater treatment adherence, or the interaction of these variables.

2. Methods

Data were collected as part of a multi-site, randomized, controlled trial examining different intensities of counseling in the context of different lengths of buprenorphine–naloxone treatment for patients with prescription opioid dependence (for details of the parent study, see Weiss et al., 2011). Treatment-seeking participants met DSM-IV criteria for current opioid dependence, and were at least 18 years of age. Key exclusion criteria included a requirement of ongoing pain management with opioids, currently unstable psychiatric illness, or concurrent formal substance use disorder treatment (other than mutual-help groups; see Weiss et al., 2011 for details).

We included participants with a very limited history of heroin use to increase generalizability of our study results to typical treatment-seeking prescription opioid-dependent populations, while ensuring that we were examining a new population of participants who either exclusively or predominantly used prescription opioids. We thus excluded individuals with heroin use on ≥4 days in the past month, a lifetime diagnosis of opioid dependence due to heroin alone, or a history of ever injecting heroin.

POATS consisted of two phases. In Phase 1 (brief treatment), participants were inducted onto buprenorphine–naloxone, stabilized for two weeks, tapered during the next two weeks, and followed for eight additional weeks. Those who abstained or nearly abstained from opioids during that 12-week period completed the trial as Phase 1 successes. Those who relapsed to opioids were invited to enter Phase 2 of the study (the extended-treatment phase), consisting of 12 weeks of buprenorphine–naloxone, a four-week taper, and an eight-week post-taper follow-up. In each phase, participants were randomized to receive either (1) standard medical management (SMM) alone or (2) SMM plus individual opioid dependence counseling (ODC). In Phase 1, randomization was stratified by (1) the presence of lifetime history of heroin use and (2) current chronic pain. In Phase 2, randomization was stratified by Phase 1 treatment condition. At SMM visits, buprenorphine–naloxone was dispensed, and brief medically-oriented counseling was conducted by a buprenorphine-certified physician, who reviewed medication side effects and withdrawal symptoms, and encouraged abstinence, mutual-help group attendance, and medication adherence. SMM visits, which lasted 15–20 min, took place twice during the initial week of the extended treatment phase, then weekly for the following 11 weeks. In addition, half the subjects were randomly assigned to receive opioid dependence counseling (ODC) in longer (45–60 min) and more frequent visits: twice a week for six weeks, then weekly for six weeks in the extended treatment phase. ODC, conducted by a trained substance abuse or mental health professional, employed relapse prevention strategies, encouraged abstinence, and focused more intensively on high-risk situations and interpersonal stresses. Assignment to additional ODC was not related to outcome in either phase. Because so few participants were successful in Phase 1, this report focuses on the second phase (extended treatment) of the parent study.

2.1. Measures

A series of standardized assessments was administered to all participants. The Composite International Diagnostic Interview was used to diagnose opioid dependence. The Pain and Opiate Analgesic Use History, developed for this study, was administered at baseline to assess opioid use history. Severity of problems was measured by the Addiction Severity Index (ASI) drug composite score, the presence of lifetime heroin use, and the presence of current chronic pain. The ASI (McLellan et al., 2006, 1985) is a widely used, multidimensional interview, which assesses the severity of addiction-related problems. Chronic pain was defined by the Brief Pain Inventory (Keller et al., 2004) as "pain beyond the usual aches and pains, not including withdrawal pain" for at least 3 months.

The Substance Use Report, corroborated by weekly urine drug screens, was administered weekly during treatment and every two weeks during follow-up. This was the primary measure to determine outcome in Phase 2 of the study: "successful outcome" was defined as urine-confirmed self-report of abstinence from opioids during the final week of buprenorphine-naloxone treatment (week 12) and during ≥2 of the 3 weeks prior (weeks 9–11).

For analysis, "adequate adherence," and thus an adequate "dose" of treatment, was defined at the beginning of the trial as attending at least 60% of offered sessions (see Section 3.2.2 for more details). Although definitions of the level of attendance at which patients can be considered to have completed treatment vary (Najavits et al., 1998; Wolitzky-Taylor et al., 2012), treatment completion has often been defined as between 60% and 80% of sessions attended (Brady et al., 2001; Hien et al., 2012; Outlaw et al., 2012).

2.2. Statistical analysis

Subjects for this report include the 360 patients randomized in Phase 2 of the main study. Chi square tests assessed the associations between dichotomous variables. A series of logistic regression models examined the effects of severity, Phase 2 treatment, treatment adherence, and the interaction between severity and treatment on opioid use outcomes at the end of the 12-week buprenorphine-naloxone treatment, adjusted for the stratification variable, Phase 1 treatment condition.

3. Results

3.1. Sample description (n = 360)

Most participants (90.6%) were white and 41.9% were female. Mean age was 32.5 years (sd = 9.7), and mean education was 12.9 years (sd = 2.2). Half (50.0%) were never married, and most (60.3%)

Please cite this article in press as: Weiss, R.D., et al., Who benefits from additional drug counseling among prescription opioid-dependent patients receiving buprenorphine–naloxone and standard medical management? Drug Alcohol Depend. (2014), http://dx.doi.org/10.1016/j.drugalcdep.2014.04.005