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Denial of urinalysis-confirmed opioid use in prescription opioid dependence

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ABSTRACT

Although research has generally supported the validity of substance use self-reports, some patients deny urine-verified substance use. We examined the prevalence and patterns of denying urinalysis-confirmed opioid use in a sample of prescription opioid dependent patients. We also identified characteristics associated with denial in this population of increasing public health concern. Opioid use self-reports were compared with weekly urinalysis results in a 12-week multi-site treatment study for prescription opioid dependence. Among those who used opioids during the trial ($n = 246/360$), 44.3% ($n = 109$) denied urinalysis-confirmed opioid use, although usually only once (78%). Overall, 22.9% of opioid-positive urine tests (149/650) were denied on self-report. Multivariable analysis found that initially using opioids to relieve pain was associated with denying opioid use. These findings support the use of both self-reports and urine testing in treating prescription opioid dependence.

1. Introduction

Many studies have investigated the validity of self-reported substance use by comparing self-reports to urinalysis results (Napper, Fisher, Johnson, & Wood, 2010; Schuler, Lechner, Carter, & Malcolm, 2009; Solbergsdottir, Bjornsson, Gudmundsson, Tyrfingsson, & Kristinsson, 2004). Contrary to concerns that individuals with substance use disorders (SUDs) will underreport substance use, data from these studies generally have shown self-reports of substance use to be valid relative to urinalysis. Nevertheless, some individuals have positive urine results that are inconsistent with their self-reports (Magura, Goldsmith, Casriel, Goldstein, & Lipton, 1987; Myrick, Henderson, Dansky, Pelic, & Brady, 2002). Since clinicians and researchers working with SUD patients often rely heavily on patient self-reports of substance use to track progress, identifying patient characteristics associated with denial of substance use would be useful to assist decision-making regarding the need for objective confirmation of self-report data.

Research comparing SUD patients who deny their substance use to those who never deny using is limited. While those who deny substance use are generally similar to those who admit to use, one study of adults dependent on cocaine found those who underreported cocaine use to be more likely to be employed (Myrick et al., 2002). A study of opioid-dependent adults found that those who underreported substance use were less likely to be dependent on amphetamine or cocaine (Rutherford, Cacciola, Alterman, McKay, & Cook, 2000). In a young adult opioid-dependent sample (mean age = 19.7 years), no background or clinical differences were associated with denial of opioid use (Wilcox, Bogenschutz, Nakazawa, & Woody, 2013).

Little is known about the validity of substance use self-reports among patients with prescription opioid dependence. In recent years, prescription opioid use disorders have become widespread (Substance Abuse and Mental Health Services Administration, 2013). Because those dependent on prescription opioids have been shown to differ from those dependent on heroin with respect to some sociodemographic and clinical characteristics and treatment outcomes (Moore et al., 2007; Sigmon, 2006), factors associated with denial of substance use may also differ in this population. In particular, those dependent upon prescription opioids have a high prevalence of chronic pain; patients seeking treatment for chronic pain have been found to underreport opioid and other substance use (Fishbain, Cutler, Rosomoff, & Rosomoff, 1999; Katz et al., 2003).

The current study examined data from the Prescription Opioid Addiction Treatment Study (Weiss et al., 2011), a large, multi-site randomized clinical trial of varying combinations of buprenorphine–

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naloxone and counseling for prescription opioid dependence. The aim of this exploratory secondary analysis was to determine the prevalence, patterns, and characteristics of denial of urine-confirmed opioid use.

2. Methods

The data reported here were collected as part of the Prescription Opioid Addiction Treatment Study (POATS), a randomized clinical trial ($n = 653$) conducted at ten sites across the United States under the auspices of the National Drug Abuse Treatment Clinical Trials Network. POATS used a two-phase adaptive treatment research design; in phase 1, participants received 2 weeks of buprenorphine–naloxone stabilization, followed by a 2-week taper and 8 weeks of follow-up. Participants who abstained or nearly abstained from opioids in phase 1 completed the study successfully; those who relapsed to opioid use during phase 1 were invited to enter phase 2, which consisted of 12 weeks of buprenorphine–naloxone stabilization, followed by a 4-week taper and 8 weeks of follow-up. In each phase, participants were randomly assigned to receive either (1) Standard Medical Management (SMM) alone or (2) SMM plus individual Opioid Dependence Counseling (ODC).

The primary outcome measure in the trial was success at the end of week 12 of phase 2, defined as abstinence from opioids during the final week of buprenorphine–naloxone stabilization (week 12) and during at least 2 of the 3 previous weeks (weeks 9–11). Of the 360 participants who entered phase 2, approximately half (49.2%) were successful at the end of the 12-week buprenorphine–naloxone treatment. A full description of POATS methods and main outcomes is reported elsewhere (Weiss et al., 2010; Weiss et al., 2011). The criteria for a successful outcome cover the last 4 weeks of buprenorphine–naloxone stabilization treatment in phase 2 (weeks 9–12); because some of our analyses for this report would be confounded by including the 4-week period during which outcome was determined, the current secondary analysis was limited to the first 8 weeks of the 12-week treatment in phase 2.

2.1. Study population

Participants were 18 years or older and met *Diagnostic and Statistical Manual of Mental Disorders, 4th Edition* (*DSM-IV*; American Psychiatric Association, 2000) criteria for current dependence on prescription opioids. Potential participants were excluded if they used heroin on more than 4 days in the past month, had ever injected heroin, had a lifetime diagnosis of opioid dependence due to heroin use alone, required ongoing pain treatment with prescription opioids, or were currently participating in formal SUD treatment other than self-help groups (see Weiss et al., 2010 for details). Of the 653 participants enrolled in phase 1, 360 entered phase 2. The current study of self-report validity focuses on the 360 participants enrolled in phase 2, since the longer duration of phase 2 offered far more data points to compare self-reports and urine results over time; in addition, length of participation in phase 1 was inconsistent across patients, depending on when they relapsed to opioid use and thus were finished with phase 1.

2.2. Treatments

Participants received sublingual buprenorphine–naloxone at each weekly SMM visit, with doses ranging from 8 to 32 mg/day during stabilization. SMM was medically-oriented addiction counseling delivered to all participants by a physician. In addition, half of the participants were randomly assigned to receive individual ODC by trained substance abuse or mental health professionals. ODC sessions consisted of educational skills training modules on addiction, recovery, and relapse prevention. (See Weiss et al., 2010 for further details about treatment and visit schedules.)

2.3. Assessments

Participants completed a series of assessments at baseline and throughout the study. Sociodemographic and clinical data reported here were collected at baseline. Opioid use data (self-reports and urine tests) were collected at baseline and during weekly visits.

The *Composite International Diagnostic Interview* (*CIDI*; World Health Organization, 1997) was administered at baseline to diagnose SUDs, major depressive disorder, and posttraumatic stress disorder (PTSD). *The Pain and Opiate Analgesic Use History* (Weiss et al., 2010) is a self-report measure developed for this study to assess opioid use history and pain. Opioid craving was assessed with the 3-item, self-rated *Craving Scale*, adapted from the Cocaine Craving Scale (Weiss et al., 2003). The *Addiction Severity Index–Lite* (ASI; McLellan et al., 1992) is a semi-structured interview that measures severity of substance use and related problems. The *Beck Depression Inventory II* (*BDI*; Beck, Steer, & Brown, 1996) is a 21-item self-rated scale used to measure severity of depressive symptoms. The *Fagerstrom Test for Nicotine Dependence* (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991) is a 6-item measure of severity of nicotine dependence. Daily opioid use was assessed weekly during treatment using the *Substance Use Report* (SUR), a self-report measure that uses a calendar technique similar to the Timeline Follow-back (Sobell & Sobell, 1992) to facilitate recall.

The SUR was corroborated at each weekly visit by *urine drug screens* and was used as the primary outcome measure to determine successful outcome (defined above) at the end of phase 2 treatment. Urine samples were screened with the iScreen 9-panel dipstick test for the following opioids, selected for their common use: methadone, oxycodone, propoxyphene, and the Opiate 300 analytes group (morphine, heroin, and codeine), via a qualitative lateral flow chromatographic immunoassay test. The cutoff level for detection was 300 ng/mL for all opioids except oxycodone (100 ng/mL). Agreement between the iScreen test and gas chromatography/mass spectrometry is ≥99% for methadone and opiate 300, 98% for oxycodone, and 94% for propoxyphene (which no participants reported as their primarily used opioid). Negative agreement is ≥94% for methadone and opiate 300, 97% for oxycodone, and 99% for propoxyphene. We did not test for buprenorphine during this time period because it was being prescribed, and we would gain little information (other than complete absence of this medication from the urine) from this test. Consistent with best practices to maximize accurate self-report, participants were assured that urinalysis results would be confidential, were encouraged to be honest in their self-reports, and were made aware that weekly urine samples would be collected for drug testing and that reporting substance use would not affect their study participation (Del Boca & Noll, 2000; Weiss et al., 1998). Results of the urine sample were reviewed with the patient at the next weekly visit; urine results discordant with the previous week's self-report were discussed.

2.4. Data analysis

The current analysis focuses on the subset of participants enrolled in phase 2 ($n = 360$) who used opioids ($n = 246$) during the first 8 weeks of the 12-week treatment according to their self-reports and/or urine results. Participants who were abstinent throughout treatment ($n = 77$) did not have an opportunity to deny use and thus were excluded from the analysis. Participants ($n = 37$) were also excluded if they never denied urine-confirmed opioid use, but more than half of their opioid use data were missing; these participants had too little self-report data to allow for meaningful analysis of patterns of denial and reporting of use.

Denial of use was defined as the presence of a positive urine test for opioids during a week in which no opioid use was reported on the self-report measure. Participants who reported opioid use and never