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Evaluation of Ongoing Oxycodone Abuse among Methadone-Maintained Patients

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Abstract

Prevalence of prescription opioid abuse has increased dramatically in recent years in the United States generally, and a similar pattern of increasing prescription opioid use has also been noted among patients seeking treatment for opioid dependence. The current study presents results from an internal quality-assurance project conducted by an outpatient methadone-maintenance (MM) treatment clinic which sought to examine the extent of ongoing oxycodone abuse among patients that might be going undetected with current urinalysis testing methods. One-hundred and five MM patients provided 437 urine samples over a 6-week period. Samples were analyzed using the clinic's usual enzyme multiplied immunoassay test (EMIT) opiate assay (300 ng/ml opiate cutpoint) and a supplemental oxycodone test strip (100 ng/ml oxycodone cutpoint). The EMIT assay identified only 6% (20/437) of samples as positive for oxycodone, while the oxycodone test strip indicated that 19% (83/437) tested positive for recent oxycodone use. Inspection of patient characteristics revealed that oxycodone users were more likely to report a prescription opioid as their primary drug at intake, be in MM treatment for a significantly shorter duration and provide significantly more opioid- and cocaine-positive urine samples. Overall, these data illustrate the potential importance of monitoring for ongoing oxycodone use in MM clinics. While future efforts should examine this question using more rigorous experimental methods, findings from this initial project have implications for clinical issues such as evaluating patient stability in treatment, making medication dosing decisions, and determining patient eligibility for methadone take-home privileges.

1. Introduction

Abuse of prescription opioids, defined here as the intentional use of opioids outside of a physician's prescription for a medical condition (Compton & Volkow, 2006), has increased significantly in the United States over recent years and is quickly becoming a serious public health concern (Birnbaum et al., 2006; Compton & Volkow, 2006; Zacny et al., 2003). In the most recent National Survey on Drug Use and Health, 32 million people reported lifetime abuse of prescription opioids, and over 1.5 million people aged 12 or older reported being currently dependent on or abusing prescription opioids (SAMHSA, 2006). Consistent with these trends

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in the general population, an increasing prevalence of prescription opioid abuse also has been noted among various addiction treatment populations (Brands, Blake, Sproule, Gourlay & Busto, 2004; Carise, et al., 2007; Miller & Greenfeld, 2004; Passik, Hays, Eisner & Kirsh, 2006; Sigmon, 2006). One recent report, for example, sought to determine the prevalence of prescription opioid abuse among 5663 opioid-dependent individuals entering into 72 different methadone-maintenance (MM) treatment programs across the United States (Rosenblum et al., 2007). In that study, 83% of methadone enrollees reported lifetime abuse of prescription opioids and 67% reported abusing prescription opioids within the past 30 days. Overall, the authors from that study concluded that prescription opioid abuse is highly prevalent among patients entering MM treatment.

One of the most frequently abused prescription opioids is oxycodone (Oxycontin® and Percocet®; Cicero, Inciardi & Muñoz, 2005). Prevalence of oxycodone abuse is notable in the United States in general, with approximately 11.2 million people in 2004 reporting lifetime oxycodone abuse (SAMHSA, 2005). High rates of oxycodone abuse were also seen in the above study by Rosenblum and colleagues (2007). In that report, oxycodone was the most commonly abused prescription opioid in that treatment-seeking population, with 89% and 79% of patients who endorsed prescription opioids as their primary drug at treatment intake reporting lifetime and past 30-day abuse of oxycodone, respectively.

Considering the high prevalence of oxycodone abuse among patients entering MM clinics, a reasonable question is whether a subset of patients may continue to abuse oxycodone after becoming enrolled in treatment. Ongoing abuse of opioids and other drugs is not uncommon for a subset of patients receiving opioid treatment (Belding, McLellan, Zanus & Incmikoski, 1998; Stitzer & Sigmon, 2006) and illicit opioid use that persists after enrollment into methadone treatment is a significant predictor of poor treatment outcome (Craig & Olson, 2004; Morral, Belding & Iguchi, 1999; Peles, Schreiber & Adelson, 2006). Despite the clinical importance of detecting illicit opioid use during methadone treatment, however, the urinalysis testing methods used by many methadone clinics may likely be insufficient to detect recent use of prescription opioids like oxycodone. The laboratory methods used for detecting opioid use in clinical settings often are designed to detect morphine and codeine and may have poor sensitivity for some synthetic and semisynthetic opioids, resulting in the high probability of false-negative results in the presence of oxycodone and other similar drugs (Haller et al., 2006). Assays capable of detecting the presence of oxycodone and other prescription opioids in urine are just beginning to become more widely available (Backer, Monforte & Poklis, 2005; Haller et al., 2006), and at least one recent report has advocated for the use of these newer prescription opioid assays in clinical settings (Abadie et al., 2005). Despite this, most methadone clinics and other drug treatment programs in the United States likely have not yet added a specific oxycodone assay to their urinalysis testing methods and may instead rely on general opiate assays that detect a variety of opiates but often have relatively poor sensitivity for oxycodone in particular.

The present report describes a recent effort in one outpatient methadone clinic to explore the extent of ongoing illicit oxycodone use among patients currently receiving MM treatment. The procedures described in this brief report were not intended as an experimental comparison of two toxicology methods; rather, this was simply an internal quality-assurance project which sought to examine whether illicit oxycodone use may be going undetected with the urinalysis methods currently being used in our clinic. Toward this end, the clinic's standard testing methods, which employed an on-site EMIT machine and opioid assay with a cutoff of 300 ng/ml (Syva Co., San Jose, CA), were supplemented with hand-held oxycodone strips with an oxycodone detection level of 100 ng/ml (ACON Laboratories, San Diego, CA). Overall, the knowledge gained from this project might offer some new and important information for other

clinicians and researchers as they evaluate what urinalysis testing methods may be appropriate for their clinical populations and programs.

2. Methods

2.1 Subjects

Subjects were 105 patients who were enrolled in an outpatient MM treatment program during the period that the quality-assurance project was conducted (April 20 – June 5, 2005). Subjects were 31% male, 97% Caucasian and had been in MM treatment for an average of 1.2 years. Forty-two and 52% of patients reported heroin and prescription opioids as their primary drug of abuse at treatment intake, respectively (Figure 1). This information was not available for 6% of patients and their data was not included in these analyses.

2.2 Standard Intake Assessment

All patients had completed a brief intake assessment at the time of treatment intake, which was conducted by trained bachelor's-level clinic staff and included a sociodemographic and drug-history questionnaire assessing demographic variables (e.g., gender, race, age) and measures of opioid and other drug use (e.g., history of IV drug use, amount and duration of opioid use, use of other drugs).

2.3 Standard Urinalysis Testing

As part of the clinic's standard urinalysis monitoring protocol, patients provided 1–3 urine samples per week, with frequency of testing based on patients' status in treatment. Samples were collected under observation of a same-sex laboratory technician, temperature-tested for validity and screened immediately onsite for evidence of opioids, methadone, cocaine, and benzodiazepines using an Olympus AU400 enzyme multiplied immunoassay test (EMIT) analyzer (Dade Behring, Cupertino, CA). The opioid assay (Syva Co., San Jose, CA) uses a cutoff of 300 ng/ml and is intended to primarily detect morphine, morphine-3-glucuronide, and codeine in human urine. While this assay can also detect some prescription opioids like hydrocodone (Vicodin®) and hydromorphone (Dilaudid®) at relatively low concentrations (247 and 498 ng/ml, respectively), as well as other synthetic opiates related to morphine at higher concentrations, oxycodone is only detectable at concentrations (e.g., ≥ 2550 ng/ml) that far exceed those typically seen with oxycodone abuse.

2.4 Supplemental Oxycodone Testing

In addition to the standard EMIT testing described above, all urine samples collected between April 20 and June 5, 2005 also were tested for oxycodone using a TMS Labs Urine 1- Drug Card (ACON Labs, San Diego, CA), a qualitative test strip with a more sensitive oxycodone detection level of 100 ng/ml. The oxycodone test strip is a lateral flow chromatographic immunoassay with a high specificity to oxycodone (i.e. low cross-reactivity with other opioids) and a high agreement (97%) with gas chromatography-mass spectrometry testing (ACON Laboratories product insert).

3. Data Analyses

Comparisons between patients who submitted at least one oxycodone-positive sample during the study and those who were continuously negative for oxycodone were performed using 2-sample *t* tests for continuous measures (e.g., durations and amount of drug use) and chi-square tests for categorical variables (e.g., gender, race, history of IV use). Statistical analyses were performed using SPSS statistical software, with statistical significance based on $p = .05$.

4. Results

Each subject provided an average of four (range 1–14) urine specimens during the 6-week sampling period. Of the total 437 urine samples tested, 85 samples (19%) tested positive for recent oxycodone use with the oxycodone test strip. Inspection of clinical records determined that seven of these oxycodone-positive samples were from patients who had a clinic-verified legitimate oxycodone prescription for a concurrent medical problem and therefore were not included in subsequent data analyses. Thus, our supplemental oxycodone strip testing identified a total of 78 of 430 (18%) urine samples as positive for illicit oxycodone. Of these, only 19 samples had been identified as positive by the EMIT opioid assay, suggesting that the clinic's standard testing methods had detected only 24% of those identified as positive with the oxycodone test strip.

Closer inspection of individual patient data revealed that oxycodone-positive samples had been submitted by a subset of 27 patients (26% of the total sample of 105 patients), while 78 patients (74% of patients) tested continuously negative for oxycodone. For those patients who did test positive at least once during the sampling period, 45% of their urine samples on average tested positive for recent oxycodone use (range 7%–100%). Also of interest was that oxycodone use during methadone treatment was more common among patients who had reported a prescription opioid (versus heroin) as their primary drug of abuse at treatment intake (Figure 1). More specifically, 35% of primary prescription opioid users submitted at least one oxycodone-positive sample during the 6-week period compared to 17% of primary heroin users ($p < .05$).

With the exception of the above-noted difference in their preferred primary opioid of abuse, oxycodone-positive and oxycodone-negative patients generally did not differ in terms of intake demographic characteristics (Table 1). Several significant differences were found on treatment status variables at the time of the study. For example, oxycodone users had been in treatment for a significantly shorter period of time ($p = .03$) and they provided more opioid- and cocaine-positive urine samples ($p < .01$) during the study period than oxycodone-negative patients. No differences were found in rates of benzodiazepine-positive samples or in methadone dose between the two patient groups at the time this project was conducted.

5. Discussion

Regular monitoring of drug use, typically via urinalysis testing, is an important component of drug abuse treatment and provides objective biochemical evidence of patients' success and difficulty with drug abstinence during treatment (Hawks & Chiang, 1986; Katz & Fanciullo, 2002). In the United States, federal regulations require outpatient treatment programs to provide adequate drug abuse testing; however, the individual program can choose the specific drugs to be tested for depending on local patterns of abuse and compliance with state and accreditation standards (Bailes & Lowery, 2006). Despite the increasing prevalence of prescription opioid use, and particularly oxycodone use, in recent years in the United States, the current guidelines used by most opioid treatment programs for accreditation do not yet specify that urine samples be tested for oxycodone (CSAT, 2005).

The goal of the present study was to explore the extent of ongoing illicit oxycodone abuse during treatment among a convenience clinical sample in a local outpatient methadone program. As part of an internal quality-assurance project in our clinic, we supplemented our standard urinalysis testing with a hand-held oxycodone test strip. We found that approximately 18% of the urine samples provided tested positive for recent oxycodone use, most of which had previously gone undetected with the clinic's conventional urinalysis testing methods. While certainly the majority of samples tested negative for oxycodone, these findings were

still somewhat unexpected, particularly considering that our clinic's standard urinalysis procedures are quite rigorous (e.g., specimens are collected under same-sex observation, temperature- and adulterant-tested for validity, analyzed onsite immediately using sophisticated EMIT technology). That said, these data are consistent with a recent report evaluating ongoing oxycodone abuse in an adolescent substance abuse treatment program (Levy, Sherritt, Vaughan, Germack & Knight, 2007). Overall, these results suggest that at least a subset of patients may engage in illicit oxycodone use during treatment, much of which may go undetected with the typical testing methods used in many clinics. Considering the increasing prevalence of oxycodone abuse and the importance of having accurate urinalysis data available to guide clinical and medical decision-making during treatment, clinics may wish to consider including oxycodone assays in their urinalysis testing methods. Effective monitoring of illicit drug use during treatment can significantly influence methadone treatment outcomes (Morrall et al., 1999; Villafranca, McKellar, Trafton & Humphreys, 2006; Wasserman, Korcha, Havassy & Hall, 1999), and objective urinalysis testing offers more accurate information than patient self-report (Chermack et al., 2000).

Our data also revealed that patients who continued to abuse oxycodone were more likely to have endorsed prescription opioids as their primary drug of abuse upon entry into treatment. This may suggest that these patients were simply continuing to abuse their primary drug of abuse, particularly if use during the early days of treatment went undetected by clinic urinalysis procedures. Considering this finding, methadone clinic staff may want to particularly consider this subset of their patient population when making decisions about urinalysis testing. An evaluation of clinical characteristics also revealed that oxycodone-positive patients had been in treatment for a significantly shorter period of time than oxycodone-negative patients. Although there was no significant difference in methadone dose level, this finding could imply that oxycodone-positive patients had not yet been fully stabilized in treatment. Furthermore, it is reasonable to expect that continued illicit opioid abuse, even at low levels, could impede clinic efforts to evaluate and make appropriate dose adjustments for the patient. Examination of urinalysis data also showed that oxycodone users provided significantly more opiate- and cocaine-positive samples than non-oxycodone users. This finding provides additional evidence that oxycodone-positive patients were less stable in treatment than the oxycodone-negative patients.

This study focused on identifying the extent of ongoing oxycodone use among patients receiving outpatient methadone treatment. Our choice of oxycodone was based on several factors. First, local data suggested that oxycodone was the most commonly diverted opioid in Vermont (Office of National Drug Control Policy, 2003). Second, while our clinic's standard EMIT opioid assay likely offered reasonable detection of other prescription opioids, like hydrocodone (Vicodin®) at 247 ng/ml and hydromorphone (Dilaudid®) at 498 ng/ml, its oxycodone cutoff was at a level too high to be clinically useful (i.e., 2550 ng/ml). Third, a handheld oxycodone test-strip with a sensitive (100 ng/ml) cutoff was readily available, relatively inexpensive, and easy to use by staff. As a result, we found that the addition of an oxycodone test to our clinic's urinalysis methods was helpful in identifying previously-undetected illicit opioid use. That said, since rates of abuse of prescription opioids or other pharmaceuticals can vary greatly among different geographical regions, it would be important for clinics to independently evaluate the incidence of such drug use in their particular area and patient population and then use this information to develop urinalysis testing methods that are appropriate for their needs.

The clear limitation of this study is that it was an uncontrolled, internal quality-assurance project conducted in a single clinic. Additional self-report data on recent opioid use was not collected from patients for comparison to urinalysis results, and urine specimens were not sent out for confirmation with chromatographic methods such as gas chromatography-mass

spectrometry. Indeed, as noted previously, this project was not intended as a rigorous comparison of two toxicology methods and there was no experimental manipulation. Rather, we simply sought to explore the degree to which oxycodone use may be going undetected with the standard urinalysis methods being used in a non-research, community-based methadone clinic. The knowledge gained from this project was intended to guide internal policy decisions about future urinalysis monitoring procedures in our clinic. However, our experience with this project may provide helpful information to other clinics throughout the country, including both opioid treatment programs as well as clinics treating other forms of drug abuse. Certainly any level of illicit opioid use that goes undetected has the potential to undermine treatment efforts and success in any treatment setting.

As noted previously, it is possible that the rates of oxycodone-positive samples in this project may differ from those in other clinics across the country. The state of Vermont has experienced several-fold higher rates of prescription opioid abuse than other regions of the United States (Office of Applied Studies, 2006). This may suggest that the rates of oxycodone use during MM treatment that we identified are higher than what might be found in other parts of the country. That is, in areas of the country where prescription opioid abuse is less prevalent, testing for oxycodone use during treatment may be less of a concern. On the other hand, compared to federal regulations requiring that patients in maintenance programs be tested at least 8 times per year (Federal Register 42 CRF Part 8, 2001), patients in our clinic submit urine samples 2–8 times per month (24–96 times per year), depending on their status in treatment. If frequent urinalysis monitoring is associated with a reduction in illicit drug use during treatment, it is possible that clinics employing less frequent testing may find they have high rates of ongoing oxycodone use, as patients in these clinics could be engaging in drug use that is going undetected and unaddressed.

In summary, our aim in this brief report was to share the clinical knowledge we gained over the course of conducting this internal, quality-assurance project in our clinic. Our data suggest that a subset of patients continues to use illicit oxycodone during methadone maintenance treatment, and that this form of opioid use may likely go undetected by the standard urinalysis testing methods used in many clinics. This information may be useful to guide clinical and programmatic decisions by other opioid and non-opioid treatment programs throughout the country, though decisions about the scope of urinalysis testing should be influenced by the patient population, geographic location, local patterns of drug use and other factors unique to the individual clinic. Overall, we believe that effective detection and clinical management of oxycodone and other prescription opioid use will continue to be an important issue in the treatment of opioid-dependent patients.

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Percent of Patients Reporting a Prescription Opioid or Heroin as their Primary Drug of Abuse, and Relationship to Providing ≥ 1 Oxycodone-Positive Sample

Figure 1.

Bars represent total percent of patients who reported either a prescription opioid or heroin as their primary drug of abuse at treatment intake. Gray area represents percentage of primary prescription opioid users and heroin users who provided ≥ 1 oxycodone-positive urine sample during the 6-week sampling period. Primary prescription opioid abusers were significantly more likely to provide an oxycodone-positive sample than primary heroin abusers (35% versus 17%, respectively; $p < .05$), as indicated by an asterisk (*).

Table 1

Demographic and Drug-Use Characteristics

	Oxycodone-Positive (n=27)	Oxycodone-Negative (n=78)	p-value ^a
Characteristics at Treatment Intake			
% Male	64	42	0.77 ^b
% Caucasian	95	80	0.08 ^b
Completed Education (yrs)	11.49 ± 2.63	12.36 ± 3.13	0.21
Age at Treatment Intake (yrs)	26.12 ± 8.64	28.23 ± 8.51	0.95
Length of Regular Opioid Use (yrs)	7.22 ± 6.68	8.34 ± 10.22	0.53
Number of Past Opiate Treatment Episodes	4.13 ± 3.39	5.27 ± 5.79	0.23
% Primary IV Users	52	70	0.11 ^b
% Ever Used IV	75	79	0.71 ^b
Treatment Status at Time of Study			
Length of Time in Treatment (yrs)	.75 ± .72	1.17 ± .97	0.03
Methadone Dose (mgs)	82.38 ± 36.16	97.07 ± 42.09	0.10
% Opiate-Positive Urine Samples	16	2	<0.01^b
% Cocaine-Positive Urine Samples	19	6	<0.01^b
% Benzodiazepine-Positive Urine Samples	7	8	0.93 ^b

Note: values represent mean ± SD unless otherwise indicated.

^aP-values based on two-sample t-tests unless otherwise indicated.

^bP-values based on chi-square test.