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Psychosocial functioning and cocaine use during treatment: Strength of relationship depends on type of urine-testing method

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Abstract

Although improvement in psychosocial functioning is a common goal in substance-abuse treatment, the primary outcome measure in most cocaine trials is urinalysis-verified cocaine use. However, the relationship between cocaine use and psychosocial outcomes is not well documented. To investigate this relationship and identify the optimal urine-screen method, we retrospectively analyzed data from two 25-week randomized controlled trials of abstinence reinforcement (AR) in 368 cocaine/heroin users maintained on methadone. Cocaine use was measured thrice weekly by qualitative urinalysis, benzoylecgonine concentration (BE), and an estimate of New Uses of cocaine by application of an algorithm to BE. Social adjustment (SAS-SR), current diagnosis of cocaine dependence (DSM-IV criteria), and depression symptoms (Beck Depression Inventory) were determined at study exit. Cocaine use was significantly lower in AR groups than in controls. Across groups, in-treatment cocaine use was significantly associated with worse social adjustment, current cocaine dependence, and depression at exit. Significant differences were detected more frequently with New Uses than qualitative urinalysis or BE. Nevertheless, the amount of variance accounted for by the urine screens was typically <15%. Cocaine use during treatment, especially when measured with New Uses criteria, can predict psychosocial functioning, but cannot substitute for direct measures of psychosocial functioning.

Keywords

urinalysis; substance dependence; treatment; methadone maintenance; abstinence reinforcement; psychosocial function

1. Introduction

The diagnostic criteria for cocaine dependence in the Diagnostic and Statistical Manual of Mental Disorders Version IV (DSM-IV) focus on the adverse consequences of cocaine use, i.e., disruption of psychosocial functioning, continued use in spite of problems, and tolerance and withdrawal symptoms (American Psychiatric Association, 1994). Severity of cocaine dependence, social adjustment, and depression have been shown to have an important impact on the success of treatment interventions for substance-abuse patients (Hudson et al., 2002; Kampman et al., 2004; Rounsaville, 2004; Teichner et al., 2001).

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Although the amount of cocaine use per se is not included among the DSM-IV criteria for cocaine dependence, the primary measure of treatment efficacy in many clinical cocaine treatment trials is cocaine use, usually determined by qualitative urine cocaine screens. Improvements in psychosocial functioning are used as an outcome measure less frequently. For example, of 29 cocaine treatment trials published between January 2005 and June 2006 identified in a PubMed search under *cocaine treatment* with the limit *clinical trial* selected, all 29 used cocaine use measured by toxicology screens as a primary outcome measure. In contrast, only nine identified a measure of psychosocial functioning as a primary outcome. Urine drug screen results have the advantage of being objective and easily quantifiable, while assessment of psychosocial problems is generally based on self-report, perhaps leading to the perception (whether warranted or not) that these outcomes are less rigorous than biochemical ones. (The existence of this perception can be seen in full-text searches of the literature via scholar.google.com: in conjunction with the word *cocaine*, the phrase *verified by urinalysis* or *verified by urine* appears in at least 88 articles, while *verified by self-report* appears in only 15 articles, of which more than half use it in a context such as “verified by self-report and urine.”) Nevertheless, individual patients' treatment goals usually include improvement in multiple areas of psychosocial functioning, not just decreases in cocaine use.

The degree to which urine drug screen results predict changes in psychosocial functioning during treatment is not clear. This issue was specifically raised in a National Institute on Drug Abuse (NIDA)-sponsored workshop on outcome measures and success criteria in clinical trials; in a section called “Clinical Relevance,” the conclusions were summed up as follows: “Changes observed in urinalysis data have not been correlated with changes in any other outcome variables such as patients' well-being, employment status, or marital status. Until such correlations are established, the clinical usefulness of urine data is limited to validating reported drug use” (Tai, 1997). The question implicit in the NIDA workgroup's conclusion—what do urinalysis data mean in the broadest clinical sense?—has hung unanswered in the literature for at least ten years.

Answering this question requires recognition that “urinalysis data” can take several different forms, including qualitative (positive/negative) results, concentration of the cocaine metabolite benzoylecgonine (BE) from quantitative tests, and New Uses criteria (new uses of cocaine estimated from BE concentration using an algorithm based on pharmacokinetic parameters). Qualitative urinalysis, the most frequently used method, has the drawback that cocaine use can be overestimated if a single occasion of cocaine use results in multiple positive urines (“carryover positives”) (Preston et al., 1997a). Although BE concentrations would seemingly be a very good measure of use, they are unfortunately subject to extreme variability (Delucchi et al., 2002; Delucchi et al., 1997; Jufer et al., 2006; Jufer et al., 2000; Preston et al., 1997c). New Uses, a term referring to the differentiation of new occasions of cocaine use from instances of carryover, as determined by applying an algorithm to BE concentrations, have been shown to have greater sensitivity to differences in cocaine use than either qualitative or quantitative urinalysis (Preston et al., 1997a).

The objectives of the present study were to address two questions: (1) to what extent urine toxicology results can be linked to changes in psychosocial functioning following treatment for cocaine dependence, and (2) whether some urine measures more consistently predict such changes. Addressing these two questions may have important clinical implications for cocaine treatment trials because urine toxicology measures that are most reliably associated with improvements in psychosocial functioning would be valuable indicators of treatment success. It is unlikely that urinalysis data could substitute for direct assessment of psychosocial functioning, but it would be worth knowing whether some urine measures imply more about psychosocial functioning than other urine measures do.

To address these two questions, we combined data from two recent clinical trials from our laboratory evaluating the efficacy of abstinence reinforcement for treatment of heroin/cocaine abuse (Belendiuk et al., 2006; Epstein et al., 2003). The inclusion/exclusion criteria and study purpose and procedures, including intake assessments, for the two trials (one evaluating monetary vouchers and one evaluating draws for prizes to reinforce abstinence) were similar. Measures of psychosocial functioning were collected as secondary outcome variables to assess the experimental intervention in the two clinical trials. In the present analyses, they were assessed as primary outcome measures. They included a social-adjustment questionnaire, an interview assessing DSM-IV criteria for cocaine dependence, and a depression questionnaire. We hypothesized that the New Uses method would be superior to other urine-testing measures in terms of its association with changes in psychosocial functioning during treatment, but we had no specific hypothesis regarding the magnitude of the association or that there was a direct causal relationship between rate of cocaine use and psychosocial functioning.

2. Methods

2.1 Participants

The data for the present study were collected in two clinical trials conducted at the Intramural Research Program of the National Institute on Drug Abuse (NIDA) in Baltimore, MD between June, 1999 and August, 2005. This research was approved by the local Institutional Review Board for human research. Participants were recruited through advertisements in a variety of local newspapers and television stations selected to ensure exposure to both sexes and all ethnicities. Participants gave informed written consent prior to participation. Participant screening included: medical, psychiatric, and drug-use histories; physical examination; standard laboratory screens; a battery of assessment instruments, including the Addiction Severity Index (ASI) (McLellan et al., 1985) and the Diagnostic Interview Schedule (DIS-IV) (Robins, 1995). Eligibility criteria for enrollment in the study were: age 18–65, cocaine and opiate use (by self-report and urine screen), and physical dependence on opiates. Current DSM-IV diagnoses of heroin or cocaine dependence were not required. Exclusion criteria were: current psychotic, bipolar, or major depressive disorders; current physical dependence on alcohol or sedatives; unstable serious medical illness; estimated IQ below 80 (Shipley Institute of Living Scale) (Zachary, 1986); urologic conditions that precluded urine collection.

2.2 Study Procedure

The study consisted of a 5-week baseline period, a twelve-week experimental (abstinence reinforcement or control) intervention period, and an eight-week post-intervention (return to standard methadone maintenance treatment) period. All participants began methadone treatment upon study enrollment. Throughout the 25-week study, all participants received, without charge, daily methadone (70–100 mg/day) and weekly individual counseling. After the 25-week study period, patients were encouraged to transfer to a methadone-maintenance program in the community; those who chose not to transfer were offered a 10-week gradual methadone taper and referred for aftercare in a drug-free program. Weekly individual counseling continued throughout.

At the end of a 5-week baseline period, participants whose urine specimens tested positive for heroin and cocaine (not necessarily on the same days) on at least four of 15 occasions were randomized to an abstinence reinforcement (AR) or control intervention. Randomization was done by a technician who used a Microsoft Excel macro that stratified randomization by race, sex, employment status, probation status, and frequency of opiate- and cocaine-positive urine specimens during baseline. Group assignment in the clinical trials was unequal to maximize statistical power for pairwise comparisons of interest (Dumville et al., 2006; Woods et al., 1998). Dumville et al. (2006) and Woods et al. (1998) demonstrated that in designs of multiple

treatments where the effect size is expected to be larger for some pairwise comparisons than for others, statistical power may be maximized by assigning a lower proportion of patients to cells involved only in larger-effect pairwise comparisons. We used this rationale in our group assignment. Because of the nature of the intervention, blinding of these conditions was not possible.

During the 12-week intervention, urine specimens from all participants were tested for the presence of cocaine metabolite (BE) with an on-site dip-stick-type drug screen (OnTrak TesTstik, Varian Products); all participants were told the results of these tests during the clinic visit. Participants in the AR condition earned either vouchers with monetary value or opportunities to draw for prizes for each negative cocaine screen. Participants in the control condition received vouchers or opportunities to draw for prizes independent of urine-test results, i.e., noncontingently, according to a schedule matched to earnings of participants in the AR groups. Vouchers were given on the day they were earned (AR groups) or scheduled (noncontingent control groups); accrued vouchers were exchanged for goods and services that were consistent with a drug-free lifestyle and patients' treatment goals, as described previously (Preston et al., 2002). The voucher procedure was modeled after the method developed by Higgins and colleagues (Higgins et al., 1991; Silverman et al., 1996). Draws for prizes were made on the day they were earned (AR groups) or scheduled (noncontingent control groups); prizes were available on site for immediate dispensation. The prize-based-reinforcement schedule was modeled after the method of Petry and Martin (Petry and Martin, 2002). Prior studies have shown that delivery of non-contingent vouchers does not increase drug use (Schroeder et al., 2003).

2.3 Urine toxicology

Urine specimens were collected under the observation of laboratory technicians three times per week, usually Mondays, Wednesdays, and Fridays. For a qualitative measure of cocaine use, testing was conducted by enzyme-multiplied immunoassay technique (EMIT; Syva Corp., Palo Alto, California) system that provided qualitative results for benzoylecgonine equivalents (BE) with a cutoff concentration for positive set at 300 ng/ml. Data from the qualitative assays are reported as percentage positive for cocaine and will be referred to throughout the rest of the paper as EMIT results.

For a quantitative measure of cocaine use, BE concentrations were determined by fluorescence polarization immunoassay (FPIA) using TDx Cocaine Metabolite Assay reagents (Abbott Laboratories, Abbott Park, IL) (linear range: 30 to 5,000 ng/ml; specimens with higher concentrations were diluted to concentrations within this range and reanalyzed). Data from FPIA assays are reported as and will be referred to throughout the rest of the paper as BE concentration.

For New Uses, an algorithm was applied to the quantitative BE results to identify whether urine specimens positive by the qualitative screen represented a new use of cocaine or a carryover positive (Preston et al., 1997a). Briefly, criteria for identification of a new occasion of cocaine use were as follows: (1) the urine specimen had a BE concentration greater than 300 ng/ml and more than one-half that of the preceding urine specimen collected at an interval of 24 to 72 hours; (2) BE concentration in the specimen increased to any value over 300 ng/ml, and the preceding urine specimen collected at an interval of 24 to 72 hours was negative; or (3) the urine specimen had a cocaine metabolite concentration greater than 300 ng/ml and the preceding specimen was missing (not collected).

2.4 Psychosocial self-report data collection

DIS-IV diagnoses and ASI results were collected at screening as described above. Social adjustment was assessed with the Social Adjustment Scale – Self-Report (SAS-SR) (Weissman and Bothwell, 1976) at baseline and every two weeks throughout treatment. The SAS-SR has been shown to have good test-retest reliability; its validity has been supported by robust intercorrelations among ratings by participants and interviewers, and it has been used in a wide variety of research and clinical contexts (Brodaty et al., 1991; Garber et al., 1988; Goldman et al., 1992; Kosten et al., 1983; Livingston et al., 1985; Rounsaville et al., 1986; Schneider et al., 1992; Weissman et al., 1978; Weissman et al., 1981; Weissman et al., 2001). It measures adjustment and performance over the past 2 weeks in seven major areas of social functioning using seven individual subscales: work, social and leisure activities, relationship with extended family, parental role, marital role as a spouse, membership in the family unit, and financial status (Weissman and Bothwell, 1976). Each item is rated on a 5 point scale with 1 = no impairment in social functioning and 5 = greatest impairment in social functioning.

DSM-IV diagnoses of heroin or cocaine dependence at study exit were collected using the Substance Dependence Severity Scale (SDSS), a semi-structured clinical interview consisting of items keyed to every criterion of DSM-IV dependence and abuse (Miele et al., 2000). The Beck Depression Inventory (BDI) (Beck and Steer, 1987) was completed at study exit. Participants with BDI scores above 12 were categorized as depressed. The rationale for using this cutoff is based on previous work showing its predictive validity (Lasa et al., 2000).

2.5 Data analysis

Alpha level for all analyses in the study was 0.05 (two-tailed).

Intake measures were analyzed by analysis of variance (ANOVA; for continuous variables) or Pearson χ^2 (for categorical variables) to test comparability among groups. Study retention as a function of treatment group was analyzed with a log-rank test (SAS PROC LIFETEST procedure) of time until provision of the final urine sample.

To assess the relationships between the three urine measures (EMIT, BE, and New Uses) and clinical outcome, we performed a series of analyses as outlined in Table 1. The total number of analyses was large: 13 analyses of primary outcome measures for each of the three urine measures (subsumed under items 1, 2, 3, and 4 in Table 1), with additional analyses assessing individual subscales of the SAS-SR (results of those analyses are shown with items 3A-D). We also evaluated urine cocaine results by experimental treatment group, a secondary outcome measure, using multilevel modeling. These analyses did not reflect psychosocial outcomes, but were included to characterize each type of urine measure in terms of its sensitivity to treatment effects. We did not correct for multiple tests because the outcomes of individual tests were not of interest; we discuss the results only in terms of their overall pattern—that is, which of the three urine measures was most consistently associated with clinical outcomes. Analyses were conducted as follows on an intent-to-treat basis.

2.5.1 SDSS diagnosis of current cocaine dependence at study exit (Table 1, Item 1)—These associations were tested with 3 multiple logistic regressions (SAS PROC LOGISTIC) for each urine measure (i.e., 9 analyses). The dependent variable was current cocaine dependence (negative or positive) at study exit; the main independent variable was the mean percentage of cocaine-positive urines (EMIT) or New Uses, or mean BE concentration during each of the 3 treatment phases (baseline, intervention, and post-intervention). Each analysis controlled for the following potential confounds: sex, race, years of education, and years of use (cocaine, heroin), treatment group (abstinence-reinforcement group or control group), and dropout (coded dichotomously: participants who left before the final week of the

phase in question were coded as dropouts). The term for dropout was included to control for the possibility that dropouts differed in some systematic way from study completers (Hedeker and Gibbons, 1997).

2.5.2 SDSS Social Functioning Item (Table 1, Item 2)—Item 2 in table 1 assesses one SDSS criterion selected *a priori*. This SDSS criterion is particularly relevant in assessing disruption in psychosocial functioning and examines whether important social, occupational/academic, or recreational activities are reduced or given up as a result of cocaine use. Therefore, as a primary outcome measure, we conducted the same logistic regressions on this SDSS item (item 2, table 1).

2.5.3 SAS-SR social adjustment data every 2 weeks throughout treatment (Table 1, Item 3A)—These associations were tested by random-effects mixed-regression models (repeated-measures regression with SAS PROC MIXED) for each of the 3 urine measures (i.e. 3 analyses) (Nich and Carroll, 1997). Random-effects mixed-regression models have been widely accepted in the contingency management literature as appropriate analytical tools for longitudinal data since they were introduced in the late 1980s. They have been shown to compare favorably with traditional repeated-measures approaches. These likelihood-based models use iterative methods that utilize all of the existing data, both on an individual and on a group level, to estimate treatment outcomes over time. They facilitate intent-to-treat analyses by interpolating missing values (for example, due to missed visits or dropouts) (with appropriate penalties reflected in larger standard errors) rather than deleting participants with missing values or coding all missing values identically. They also allow correlations between repeated measurements to be specified; in our case a first-order autoregressive covariance structure was used. This covariance structure allows the correlations of measurements taken further apart to be less than those taken closer to one another, a reasonable assumption for most clinical trials. As in the logistics model described above, a control term for dropout was included (Hedeker and Gibbons, 1997). The dependent variable was the total adjustment score on the SAS-SR social adjustment questionnaire every two weeks throughout treatment; the main regressor variable was cocaine-positive urines (EMIT), BE concentrations, or New Uses. Regressors in the model were summed over 2-week intervals. Each analysis controlled for the potential confounds listed in the analyses of section (1) above. In supplementary analyses, scores on individual subscales of the SAS-SR were analyzed in the same way (for a description of the individual subscales see section 2.4). A first-order autoregressive error structure was used.

2.5.4 SAS-SR social adjustment data at study exit (Table 1, Items 3B-D)—The association between SAS-SR scores at exit and cocaine use during each the study phases was tested by 3 multiple linear regressions (SAS PROC REG) for each urine measure (i.e., 9 analyses). These regressions were conducted identically to the multiple logistic regressions described above for SDSS analyses in section (1). In supplementary analyses, scores on individual subscales of the SAS-SR were analyzed in the same way.

2.5.5 Depression (BDI) at study exit (Table 1, Item 4)—This association was tested by 3 multiple logistic regressions (SAS PROC LOGISTIC) for each urine measure (i.e., 9 analyses). These regressions were conducted identically to the multiple logistic regressions described above for SDSS analyses in section (1). Depression was coded as present if BDI score was greater than 12, absent otherwise. Complementary analyses examined the associations between BDI scores and urine cocaine results.

2.5.6 Urine cocaine results by experimental treatment group (secondary outcome measure, Table 1 Item 5)—For EMIT and New Uses, we used random-effects

mixed-logistic regression (repeated-measures regression with SAS GLIMMIX macro); for BE, we used random-effects mixed-regression models (repeated-measures regression with SAS PROC MIXED). In each analysis, the main between-subjects independent variable was treatment group (AR or Control) and the repeated variable was study phase (intervention and post-intervention). The dependent variable was a summary measure of urine results for each phase (mean log BE concentration or overall percentage of EMIT positives or New Uses, as appropriate). All analyses controlled for the potential confounds listed above, plus baseline cocaine urine results (mean log BE concentration or overall percentage of EMIT positives or New Uses, as appropriate). We controlled for baseline cocaine use because, although as noted below in the Results section, baseline cocaine use was not significantly different across the treatment groups, earlier work has shown that baseline cocaine use is a major predictor of treatment response (Preston et al., 1998). A first-order autoregressive error structure was used.

In all analyses of BE concentrations, values below the laboratory reporting cutoff (300 ng/ml) were coded as 0; because BE concentration data were heavily right-skewed, all nonzero values were log-transformed (Delucchi et al., 1997) to reduce the influence of extremely high values.

3. Results

3.1 Participant Characteristics

Among the 581 patients enrolled, 82 failed to meet drug-use criteria for randomization, 127 dropped out before being randomized, and four had serious medical or psychiatric events that prevented randomization; the remaining 368 were randomized and were included in the analyses. Demographic characteristics for all 368 randomized participants and for each treatment group are listed in Table 2. Among the 368 randomized participants, all were physically dependent on opiates, and 98% met DSM-IV criteria for current heroin dependence; 68% met criteria for current or remitted cocaine dependence, and another 6% met criteria for cocaine abuse. In addition, 15 out of 368 participants were diagnosed as having a remitted depressive episode, and four were diagnosed as having a current depressive episode. Mean BDI and SAS-SR scores at intake and exit are shown in Table 3. Pearson χ^2 and ANOVA analyses revealed that demographic, ASI, and DIS-IV characteristics at intake did not differ significantly between the abstinence-reinforcement group (N=267) and the control group (N=101). Study retention did not differ between the abstinence-reinforcement group and the control group (log-rank $\chi^2=0.95$, df=1, $p=0.33$).

3.2 Cocaine use

Out of a total of 16,725 urine specimens collected during the study, 11,204 were identified as cocaine-positive by qualitative urinalysis; 3002 (18% of all specimens, 27% of cocaine-positive specimens) were identified as carryover (false) positive urines according to the New Uses method. Concentrations of BE in specimens identified as “positive” by qualitative assay ranged from 300 ng/ml to >2,600,000 ng/ml.

3.3 Urine cocaine screen results as predictors of clinical outcome

Overall, for the clinical-outcome measures (Table 1, items 1–4), the New Uses criteria produced more significant associations (12 of 13) than EMIT (5 of 13) or BE (7 of 13).

3.3.1 SDSS diagnosis of current cocaine dependence at study exit (Table 1, Item 1)—Urine cocaine screen results in participants with and without current cocaine dependence at study exit are shown in Figure 1. There were no significant relationships between cocaine dependence diagnosis at study exit and percent cocaine-positive urines by EMIT during Baseline, Intervention, or Post-intervention. For BE concentrations, there were also no significant relationships during Baseline or Intervention, though there was a significant

relationship during Post-intervention (Table 1). In contrast, relationships with New Use data were significant in all three study phases, with higher rates of New Uses in Baseline, Intervention, and Post-intervention associated with meeting diagnostic criteria at exit (Table 1).

3.3.2 SDSS Social Functioning Item (Table 1, Item 2)—Results for the SDSS item assessing whether important social, occupational/academic, or recreational activities are reduced or given up as a result of cocaine use (as endorsed by participant) were generally similar to results for cocaine dependence diagnosis as a whole (Table 1). Endorsement of this item was significantly associated with higher BE and New Uses in Baseline, Intervention, and Post-intervention. EMIT urine data at Baseline was not significantly associated with endorsement of this SDSS item (Wald $X^2=2.4$, $p=0.12$), but was at Intervention and Post-intervention.

3.3.3 SAS-SR social adjustment data every 2 weeks throughout treatment (Table 1, Item 3A)—In general, lower scores on the SAS-SR (indicating higher social adjustment) were associated with cocaine abstinence, but the three urine measures of cocaine use were differentially sensitive to variations in SAS-SR score (Table 1). EMIT was associated with 2-week SAS-SR scores on only one subscale, Social & Leisure; mean (SD) scores on this subscale were 2.1 (0.2) and 2.3 (0.2) when testing negative and positive for cocaine use, respectively. BE concentration was independently associated with 2 week SAS-SR scores on only one subscale, Financial; an increase of 1 in SAS-SR scores from the Financial subscale was associated with an increase of 0.32 (SD: 1.5) in log-transformed BE concentrations. In contrast, New Uses of cocaine was independently associated with scores on the Overall Adjustment scale as well as on the Financial and Social & Leisure subscales. Mean (SD) Overall Adjustment scale scores were 2.1 (0.2) and 2.3 (0.2) during instances of testing negative and positive for cocaine use, respectively. Mean (SD) Financial subscale scores were 1.9 (0.2) during instances of no New Uses and 2.1 (0.2) when testing positive for New Uses, and mean (SD) Social & Leisure subscale scores were 2.15 (0.2) and 2.3 (0.2) during occasions of testing negative and positive for New Uses, respectively.

3.3.4 SAS-SR social adjustment data at study exit (Table 1, Items 3B-D)—There was no association between exit SAS-SR scores and Baseline cocaine use as measured by any of the three urine measures (Table 1). However, significant associations between cocaine use as measured by New Uses and SAS-SR scores were identified for the Intervention and Post-intervention phases on three SAS-SR scales (Table 1). There were no significant relationships between SAS-SR scores at study exit and mean cocaine use during Intervention and Post-intervention using the other two urine measures.

3.5.5 Depression (BDI) at study exit (Table 1, Item 4)—Overall at study exit, 16% of participants scored 13 or above on the BDI and were classified as depressed. Urine cocaine screen results as a function of depression classification are shown in Figure 2. Depression at study exit was associated with both EMIT and BE urine screen results during intervention and post-intervention phases (Table 1), but not baseline. In contrast, depression at study exit was associated with New Uses results during each of the 3 phases (Table 1). Complementary analyses were conducted with BDI scores expressed numerically rather than dichotomized; similar relationships were found (data not shown).

3.5.6 Urine cocaine results by experimental treatment group (secondary outcome measure, Table 1 Item 5)—Rates of cocaine use in the AR and control groups are shown in Figure 3. As expected, urine cocaine results did not differ among treatment groups during the baseline phase, prior to random assignment and initiation of the experimental

intervention: percentage of cocaine positive specimens ($F_{1,323}=0.02$, $p=0.88$); percentage of New Uses ($F_{1,323}=0.32$, $p=0.57$); BE concentrations ($F_{1,111}=1.39$, $p=0.24$).

Significant group X phase interactions were found for all three measures: EMIT ($F_{5,833}=21.4$, $p<0.01$); BE ($F_{5,833}=25.8$, $p<0.01$); New Uses ($F_{5,833}=23.5$, $p<0.01$). EMIT and New Uses were significantly lower in the AR groups during the Intervention and Post-intervention phases (Table 1). BE concentration did not significantly differ between treatment groups during Intervention but was significantly lower in the AR groups during the Post-intervention phase.

4. Discussion

In the present study we evaluated the relationship between psychosocial functioning and cocaine use to address the questions (1) to what extent in-treatment cocaine use can be linked to psychosocial functioning following treatment for cocaine dependence, and (2) whether some urine measures of cocaine use more consistently predict such changes. We compared three measures of psychosocial functioning (cocaine dependence, social adjustment, and depression) and three urine toxicology measures of cocaine use (EMIT, a qualitative measure; BE, a quantitative measure; and New Uses, a qualitative measure derived from quantitative BE data). Overall, there were significant associations between psychosocial functioning and urine toxicology results, with greater cocaine use during treatment associated with poorer functioning during treatment and at study exit. Furthermore, regression analyses suggested that the three urine toxicology measures were linked to psychosocial functioning to different degrees: New Uses data from various phases of treatment appeared to be more consistently associated with clinical outcome (12 of 13 associations significant) than either EMIT (5 of 13) or BE (7 of 13). The association between in-treatment cocaine use and psychosocial functioning was particularly robust for New Uses of cocaine during the intervention and post-intervention phases and SDSS and BDI at exit (R-squared values 9–20%). The associations of SAS-SR with New Uses of cocaine were more modest (R-squared values 5–8%).

Our results suggest an affirmative answer to the question posed by Dr. Tai (1997) on the value of urine toxicology results as predictors of changes in psychosocial functioning, i.e., there is a significant association between cocaine use as measured by urine drug screens and psychosocial functioning. This study does not address questions of causation. However, clinical investigators who wish to use urine data as primary outcome measures and regulators who must approve treatments (or approve coverage of treatment by insurance) have some assurance that urine data, at least when analyzed by New Uses criteria, do have implications for psychosocial outcome. Not surprisingly, the association between in treatment cocaine use and psychosocial functioning at exit was strongest for the post-intervention phase. This was particularly apparent for SDSS and cocaine dependence (rows 1A, 1B, and 1C in Table 1). On this measure, the association with New Use data tended to increase across the study, with adjusted R-squares of 5, 9, and 20% in Baseline, Intervention, and Post-intervention.

Nevertheless, the amount of variance accounted for by the urine screens was relatively small, with most R-squared values less than 15% and the highest only 20%. Cocaine use assessed through urine drug screens can predict psychosocial functioning, but cannot substitute for more direct measures of psychosocial functioning.

For simply measuring differences between experimental treatment groups, EMIT and New Uses appeared nearly equal in sensitivity (significant treatment effects detected both during and after treatment), while BE appeared to be slightly less sensitive (significant treatment effects detected only after treatment). This finding suggests that EMIT data should usually be adequate to serve as the primary outcome measure in clinical trials assessing reductions in drug use; clinically significant group differences seem likely to be detected by EMIT without

determination of New Uses. This conclusion is tentative because we are basing it on data from an abstinence-reinforcement intervention that had relatively robust effects. Studies of a treatment with more subtle effects might require the greater sensitivity of an outcome measure such as New Uses. What seems more clear is that BE, with its extreme variability, may be inferior to EMIT as a primary measure of group differences.

Intuitively, one might expect BE to outperform EMIT as a predictor of psychosocial functioning, if only because the quantitative nature of BE seems as if it would permit more sensitive detection of fluctuations in amount of cocaine use. EMIT, when applied to successive urine specimens taken at intervals of only a few days, can overrepresent cocaine use because multiple positives may result from a single use (i.e., “carryover positives”) if the concentration of analytes remains above the EMIT cutoff (Li et al., 1995; Preston et al., 1997b). Yet quantitative urinalysis using BE concentrations has drawbacks of its own, because BE urine concentrations vary widely as a function of individual variability in cocaine metabolism, fluid consumption, frequency of use and time elapsed between cocaine use and urine collection, and wide variations in last cocaine dose (Delucchi et al., 2002; Delucchi et al., 1997; Jufer et al., 2006; Jufer et al., 2000; Preston et al., 1997c). This wide range of BE urine concentrations leads to highly variable, often poorly distributed data (Preston et al., 1997c). Therefore, quantitative BE data may actually be more useful when converted (via the New Uses method) back to qualitative data. This is not a step backwards: qualitative data obtained from the New Uses method more accurately reflect the occurrence of cocaine use than those obtained from EMIT (Preston et al., 1997a). In the present study, out of the 16,725 urines collected, EMIT detected 11,204 total cocaine-positive specimens, and the New Uses method identified 3,002 (27%) of those as carryover false positives. The ability of the New Uses method to eliminate false positives may account for its greater sensitivity to detect real changes in cocaine use that predict changes in psychosocial functioning.

One limitation of our study, noted above, is that we performed a large number of statistical tests without correcting the error rate. Accordingly, we have not attempted to interpret or discuss any of the outcomes of the individual associations we found. The measures of psychosocial assessment were chosen based on the original study design, not specifically for the present analyses; we selected them for these analyses because they were the most appropriate measures available. Further studies are needed to assess a wider range of psychosocial function. Another limitation is that the sample in the present study consisted primarily of heroin-dependent individuals who also had cocaine-use disorders. Most treatment-seeking cocaine abusers in the Baltimore, MD area also use illicit opiates (NIDA, 2006). Future studies should assess whether the present findings also apply to primary cocaine users. The present study showed a significant relationship between in-treatment cocaine use and psychosocial measures at study exit; future research should examine the durability of this relationship, for example during follow-up periods after treatment.

The core of the present findings lies in the overall pattern of associations, which consistently pointed to the New Uses method as the most reliable predictor of psychosocial functioning. While it is unlikely that urinalysis data could substitute for direct assessment of psychosocial functioning, the New Uses method implies more about psychosocial functioning than other urine toxicology measures do.

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Figure 1.

Results of three urine-testing measures of cocaine use expressed mean percentage of specimens cocaine-positive by qualitative urinalysis (EMIT) (top panel), percentage of specimens identified as New Uses (middle panel), and BE concentration (ng/ml) (bottom panel) during baseline, intervention, and post-intervention maintenance phases by classification of current cocaine dependence by DSM-IV criteria at study exit (total number of participants, N=368). Asterisk indicates significant differences ($p<0.05$) between groups.

Figure 2.

Results of three urine-testing measures of cocaine use expressed mean percentage of specimens cocaine-positive by qualitative urinalysis (EMIT) (top panel), percentage of specimens identified as New Uses (middle panel), and BE concentration (ng/ml) (bottom panel) during baseline, intervention, and post-intervention maintenance phases by depression classification at study exit (BDI score 13 or above = depression) (Lasa et al. 2000). Asterisk indicates significant differences ($p < 0.05$) between groups.

Figure 3.

Results of three urine-testing measures of cocaine use expressed mean percentage of specimens cocaine-positive by qualitative urinalysis (EMIT) (top panel), percentage of specimens identified as New Uses (middle panel), and BE concentration (ng/ml) (bottom panel) during baseline, intervention, and post-intervention maintenance phases by treatment group: Abstinence Reinforcement (N=267) and Control (N=101). Asterisks (one - $p < 0.05$; two - $p < 0.01$) indicate significant differences between groups.

Data analyses testing the associations between three measures of cocaine use during treatment and psychosocial functioning and treatment group.

Table 1

Outcome Measure: Item	Period tested	Dependent Variable	Main Independent Variable	Analysis	Cocaine Use Outcome Measure			
					EMIT (%) cocaine positive	BE concentration	New Uses	
1. Current diagnosis of exit cocaine dependence at	1A	Baseline	SDSS at exit	urine screen results	Logistic regression	n.s.	n.s.	Wald X ² =6.6, p<0.05 adjusted R-square: 5% Wald X ² =14.0, p<0.01 adjusted R-square: 9% Wald X ² =24.5, p<0.01; adjusted R-square: 20%
	1B	Intervention	SDSS at exit	urine screen results	Logistic regression	n.s.	n.s.	
	1C	Post Intervention	SDSS at exit	urine screen results	Logistic regression	n.s.	Wald X ² =9.3, p<0.01; adjusted R-square: 17%	
2. Endorsement of interference with social functioning by cocaine use (DSM criterion)	2A	Baseline	SDSS item at exit	urine screen results	Logistic regression	n.s.	Wald X ² =4.9, p<0.05; adjusted R-square: 3% Wald X ² =8.4, p<0.01; adjusted R-square: 5%	Wald X ² =6.6, p<0.05 adjusted R-square: 7% Wald X ² =8.9, p<0.01 adjusted R-square: 12%
	2B	Intervention	SDSS item at exit	urine screen results	Logistic regression	Wald X ² =6.8, p<0.01; adjusted R- square: 7% Wald X ² =7.4, p<0.01; adjusted R- square: 14%		
	2C	Post Intervention	SDSS item at exit	urine screen results	Logistic regression		Wald X ² =14.7, p<0.01; adjusted R-square: 11%	Wald X ² =8.1, p<0.01; adjusted R-square: 15%
3. Social adjustment	3A	Use throughout treatment	SAS-SR (every 2 weeks)	urine screen results - every 2 weeks	Repeated- measures regression	Overall score: ns; Social & Leisure subscale: F (1,230) = 9.1, p<.01	Overall score: ns; Financial subscale: F(1,95) = 5.6, p<.05	Overall score: F (1,264) = 7.5, p<.01; Financial subscale: F (1,256) = 4.4; p<.05; Social & Leisure subscale: F (1,263) = 6.0, p<.05
	3B	Baseline	SAS-SR at exit	urine screen results	Linear regression	n.s.	n.s.	Overall score and Family Unit and Financial subscores: R- squares 6–8%; Overall score: t=2.3, p<0.05;
	3C	Intervention	SAS-SR at exit	urine screen results	Linear regression	n.s.	n.s.	

Outcome Measure: Item	Period tested	Dependent Variable	Main Independent Variable	Analysis	Cocaine Use Outcome Measure		
					EMIT (%) cocaine positive)	BE concentration	New Uses
3D	Post Intervention	SAS-SR at exit	urine screen results	linear regression	n.s.	n.s.	Family Unit subscale: $t=2.7$, $p<0.01$; Financial subscale: $t=2.4$, $p<0.05$ Overall score and Family Unit and Financial subscale: R- squares 5–7%; Overall score: $t=2.0$, $p<0.05$; Family Unit subscale: $t=2.5$, $p<0.01$; Financial subscale: $t=2.3$, $p<0.05$
4. Depression at exit 4A	Baseline	BDI at exit ($>12=\text{depr}$)	urine screen results	logistic regression	n.s.	n.s.	Wald $X^2=7.6$, $p<0.01$; adjusted R-square: 5% Wald $X^2=13.6$, $p<0.01$; adjusted R-square: 9%
4B	Intervention	BDI at exit ($>12=\text{depr}$)	urine screen results	logistic regression	Wald $X^2=6.4$, $p<0.05$; adjusted R- square: 4%	Wald $X^2=6.6$, $p<0.05$; adjusted R-square: 4%	
4C	Post Intervention	BDI at exit ($>12=\text{depr}$)	urine screen results	logistic regression	Wald $X^2=8.7$, $p<0.01$; adjusted R- square: 7%	Wald $X^2=6.1$, $p<0.05$; adjusted R-square: 4%	Wald $X^2=14.9$, $p<0.01$; adjusted R-square: 14%
5.* Treatment Group: Control / Abstinence Reinforcement							
5A	Intervention	urine screen results	treatment group	repeated- measures regression	AR lower: F (1,322) = 4.7, $p < .05$	n.s.	AR lower: F (1,322) = 12.7, p < .01
5B	Post Intervention	urine screen results	treatment group	repeated- measures regression	AR lower: F (1,322) = 5.2, $p < 0.05$	AR lower: F (1.91) = 6.96, $p <$ 0.01	AR lower: F (1,322) = 5.1, p < 0.05

* Analyses in 5A and 5B did not reflect psychosocial outcomes, but were included to characterize each type of urine measure in terms of its sensitivity to treatment effects.

Table 2
Mean (SD) intake demographic characteristics and retention

	All Participants	By experimental treatment	
		Non-contingent Controls	Abstinence Reinforcement
N	368	101	267
Age (Years)	37.8 (7.7)	37.5 (8.0)	37.9 (8.2)
Heroin Use (Years)	10.3 (7.7)	9.4 (6.0)	10.6 (8.2)
Cocaine Use (Years)	8.0 (5.8)	7.8 (6.0)	8.0 (6.5)
Days Heroin Use *	29.4 (3.8)	29.8 (1.0)	29.2 (3.3)
Days Cocaine Use *	18.5 (9.6)	16.5 (10.0)	19.2 (9.8)
Estimated IQ	92.6 (7.7)	93.2 (8.0)	92.4 (8.2)
Years of Education	11.4 (1.9)	11.4 (2.0)	11.4 (1.6)
Retention (weeks)	22.6 (7.7)	23.0 (5.0)	22.3 (6.5)
Completed 25 weeks	48.6%	51.4%	47.5%

* - number of days used in last 30 before admission

Table 3

Mean (SD) SAS-SR Scale and Beck Depression Index scores at Intake and Exit in 368 participants.

	Intake	Exit
Beck Depression Index	21.9 (7.7)	9.99 (13.4)
SAS-SR - Social Adjustment Scale-Self-Report		
Overall Adjustment	2.41 (0.6)	2.08 (0.6)
Work	2.42 (1.0)	2.19 (1.2)
Social and Leisure	2.73 (0.8)	2.43 (0.8)
Parental	1.63 (1.2)	1.43 (0.8)
Marital	2.18 (1.0)	1.96 (1.0)
Extended Family	2.06 (0.8)	1.76 (0.8)
Family Unit	2.31 (1.0)	2.11 (1.2)
Financial	3.43 (1.5)	3.01 (2.1)