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A pilot study of the accuracy of onsite immunoassay urinalysis of illicit drug use in seriously mentally ill outpatients

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Abstract

Objectives—This pilot study investigated the accuracy of onsite immunoassay urinalysis of illicit drug use in 42 outpatients with co-occurring substance use disorders and serious mental illness.

Methods—Up to 40 urine samples were submitted by each participant as part of a larger study investigating the efficacy of contingency management in persons with co-occurring disorders. Each sample was analyzed for the presence of amphetamine, methamphetamine, cocaine, marijuana, and opiates or their metabolites using onsite qualitative immunoassays. One onsite urinalysis was randomly selected from each participant for confirmatory gas chromatography–mass spectrometry (GC–MS) analyses.

Results—Agreement between immunoassay and GC–MS was calculated. Agreement was high, with 98% agreement for amphetamine, methamphetamine, opiate, and marijuana. Agreement for cocaine was 93%.

Conclusions—Results of this pilot study support the use of onsite immunoassay screening cups as an assessment and outcome measure in adults with serious mental illness.

Scientific Significance—Data suggest that onsite urinalysis screenings may be a helpful assessment tool for measuring clinical and research outcomes.

Keywords

urinalysis; drug use; serious mental illness; immunoassay; accuracy

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Introduction

Research supports the utilization of immunoassay urinalysis of illicit drug use as an assessment and outcome measure that can be used in combination with self- and clinician/collateral-report (1,2) to provide comprehensive assessment of illicit drug use. Agreement between the low-cost immunoassay urinalysis and the gold-standard (but higher-cost) confirmatory gas chromatography–mass spectrometry (GC–MS) is high in adults with drug use disorders (3,4). As a result, immunoassays are widely used for both screening purposes in employment settings (to identify potential positive tests for confirmatory GC–MS confirmation) and outcome measures in addiction treatment settings. When the chain of custody, medical review, and quantitative analyses are not needed, onsite immunoassays provide an inexpensive objective measure of use.

Research investigating the accuracy of drug testing for individuals with co-occurring serious mental illnesses (SMI) and co-occurring substance use disorders (COD) is relatively limited (5). Case reports and other studies have described concerns that onsite immunoassays may be inaccurate in COD populations because of potential false positives associated with prescribed psychotropic medications, such as quetiapine and venlafaxine (6–8). Information supporting the accuracy of onsite drug-testing devices in COD populations is needed because immunoassays might be convenient and low-cost objective measures of treatment outcome.

The aim of this pilot study was to investigate the agreement between immunoassay and GC–MS urinalyses of illicit drugs in a sample of 42 adults with co-occurring illicit psychostimulant dependence and SMI, many of whom also used other illicit drugs and prescribed psychotropic medications. We also investigated the correlation between the number and class of psychotropic medications prescribed and immunoassay accuracy. We hypothesized that the rates of agreement between onsite immunoassays and GC–MS would be high in this sample.

Method

Participants were part of a larger study investigating the effectiveness of a 12-week contingency management treatment for stimulant use in persons with SMI (Overall $n = 181$). The first 42 participants were selected for this sub-study. Participants were recruited from multiple clinical settings (including an urban drop-in center; a court-mandated drug treatment program, a typical outpatient addiction treatment program, and urban and suburban community mental health centers) within a large community mental health and addiction treatment agency. All psychiatric and substance use disorders were made using the MINI neuropsychiatric interview (9). All diagnostic interviews were conducted at study enrollment by trained research staff under the supervision of the first and last author. Forty-two psychostimulant-dependent adults ($n = 31$, 74% males, $n = 11$, 26% females) aged 25–60 years ($M = 43.9$, $SD = 8.9$) were the participants. They were 55% ($n = 23$) Caucasian, 26% ($n = 11$) African–American, and 19% ($n = 8$) other ethnicities. Rates of current substance dependence diagnoses were 95% ($n = 41$) cocaine, 29% ($n = 12$) methamphetamine, 24% ($n = 10$) amphetamine, 15% ($n = 6$) marijuana, 24% ($n = 10$) opiate,

and 57% ($n = 24$) alcohol. All participants carried an SMI diagnosis, including recurring major depressive disorder ($n = 8$, 19%), bipolar disorder ($n = 13$, 31%), schizophrenia ($n = 4$, 10%), or schizoaffective disorder ($n = 17$, 40%). Sixty-three percent ($n = 26$) of the sample reported that they were currently taking psychotropic medications, with 36% ($n = 15$) taking multiple psychotropic medications. Self-reported psychotropic medications included atypical antipsychotics ($n = 20$, 47%), selective serotonin reuptake inhibitors ($n = 9$, 21%), selective serotonin-neuroepinephrine reuptake inhibitors ($n = 2$, 5%), antiseizure/mood stabilizers ($n = 6$, 14%), lithium ($n = 1$, 2%), anxiolytics ($n = 2$, 5%), methadone ($n = 1$, 2%), and prescription opiates ($n = 2$, 5%).

Each participant received up to 40 immunoassay urinalyses as part of their involvement in the parent study. Urine samples were collected and screened for drug use using Integrated EZ Split Key[®] Cup (Innovacon, Inc., San Diego, CA, USA). This device includes an internal thermometer used to assess the temperature of the sample. This onsite testing device employs an immunoassay for drugs and metabolites using the following cutoff levels: amphetamines (*D*-amphetamine = 1000 ng/mL), methamphetamine (*D*-methamphetamine = 1000 ng/mL), cocaine (benzoylecgonine = 300 ng/mL), opiates (morphine = 2000 ng/mL), and tetrahydrocannabinol (THC) (THC-COOH = 50 ng/mL).

The procedure for conducting these onsite immunoassays involved the participant providing a urine sample in the testing cup. Samples were immediately provided to trained research assistants who verified their acceptable temperature (90–100°F) of the urine using an internal thermometer. If the sample temperatures were abnormally high or low, they were discarded and another sample with an acceptable temperature was gathered. The research assistant then inserted a “key” into the testing device to begin the immunoassay test. After 5 min, the research assistant determined the test results by examining the presence of one (positive test) or two lines (negative test) on each drug-testing strip displayed on the side of the testing device. These results were then recorded. No adulterant tests were conducted as part of immunoassays.

One immunoassay from each participant was randomly selected for confirmatory urinalysis. These samples were prepared for transportation in sealed packaging and sent through overnight courier to Redwood Toxicology (redwoodtoxicology.com) for GC–MS. The cutoff levels of detection for GC–MS were identical to immunoassays. Creatinine levels of each GC–MS sample were calculated. Agreement between immunoassay and GC–MS was assessed for each drug of abuse (true negatives + true positives/total number of samples). The magnitude of agreement beyond chance was evaluated using the Cohen's kappa coefficient for each drug. Kappa coefficients could not be calculated for methamphetamine and amphetamine agreement because no immunoassay tests for these drugs were positive. Adjusted kappa coefficients were also calculated to control for the relatively infrequent number of positive tests, using the prevalence-adjusted bias-adjusted kappa coefficient as described by Sim and Wright (10). Sensitivity and specificity of immunoassays were also calculated. The association between the class of psychotropic medication, SMI diagnosis, and inaccurate immunoassay test result (i.e., disagreement between immunoassay and GC–MS result) was calculated using chi-square tests and the association between creatinine

levels and inaccurate immunoassay was assessed using a point-biserial correlation. The cutoff for statistical significance was set at an alpha of $p < .05$.

Results

GC-MS tests identified cocaine use in 26% of participants ($n = 11$), followed by marijuana (10%, $n = 5$), and opiates (7%, $n = 3$). Methamphetamine and amphetamine use was rare (2%, $n = 1$). The average creatinine level of samples was within an acceptable range, 99 mg/dL (SD = 71 mg/dL). One sample was observed to be below the acceptable cutoff level for creatinine (<20 mg/dL), suggesting the possibility that this sample was diluted. Results indicated high levels of agreement between immunoassay and GC-MS urinalyses (Table 1). Agreement between immunoassay and GC-MS was 98% ($n = 41$) for methamphetamine, amphetamine, marijuana, and opiates. Agreement between cocaine use occurred in 93% ($n = 39$) of samples. Unadjusted kappa coefficients of agreement ranged from .81 (cocaine) to .88 (THC). Disagreement occurred in a total of 7 of 215 (3%) comparisons (43 samples, 5 comparisons/sample). False negatives ($n = 5$, 71%) were more common than false positives ($n = 2$, 29%). Immunoassay sensitivity and specificity were high (80–100%), with exception of the sensitivity of amphetamine and methamphetamine, where no immunoassays indicated use. There was no association between inaccurate immunoassay results and patient characteristics (e.g., ethnicity, gender, age, or diagnosis) or creatinine levels. Neither the type nor the number of psychotropic medications prescribed was associated with GC-MS immunoassay disagreement.

Discussion

Results of this pilot study support the accuracy of low-cost onsite immunoassay screening tests for drug use in adults with co-occurring drug dependence and SMI, most of whom were prescribed psychotropic medications. When errors did occur, they were more likely a result of underidentification of use rather than false positive results, as 71% (i.e., 5 of 7) of inaccurate immunoassay results were false negatives.

When legal chain of custody and confirmatory testing is not required, onsite urinalysis provides an inexpensive and accurate clinical tool for assessing recent drug use in persons with COD. A positive urinalysis at treatment intake is one of the most robust predictors of subsequent drug use during treatment (11). Therefore, onsite drug testing at treatment intake can provide valuable treatment planning information, identifying those at highest risk of relapse.

Onsite drug testing can also be used as a tool to monitor drug abstinence and treatment outcomes. This is particularly important in COD populations, as research supports the underidentification of drug use even in settings where clinicians are providing integrated COD treatment and have frequent patient contact (2). Use of urinalysis in clinical practice allows for early identification of relapse, as well as the prevention of subsequent use, and possible exacerbation of psychiatric symptoms. Immunoassay urinalyses also allow for implementation of evidence based interventions, such as contingency management, which rely on frequent monitoring and reinforcement of abstinence.

Study results may be limited by selection of a sample composed of psychostimulant-dependent adults and recruitment from multiple treatment sites at one urban community mental health center. It is important to note, however, that the diagnostic and demographic composition of this sample is typical of those served at community mental health centers. Furthermore, the majority of the sample was dependent on another drug or alcohol, in addition to psychostimulant dependence. Other weaknesses include the relatively small number of samples collected and absence of tests of other drugs of abuse (e.g., benzodiazepines). Because adults with SMI who have CODs may use drugs less frequently than those without a psychiatric disorder (12), and the window of detection or urine test is relatively brief for most drugs tested (2–3 days after use), we observed relatively low rates of drug use in this study. Future studies should include larger sample sizes and investigate onsite testing devices in COD populations with higher rates of drug use. Studies in other settings are also important as onsite drug test cups are increasingly being relied upon in many medical, psychiatric, and emergency settings.

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Agreement between the results of immunoassay and confirmatory GC-MS urinalyses of illicit drug use in 42 adults with drug dependence and serious mental illness.

Table 1

GC-MS results											
		Cocaine		Methamphetamine		Amphetamine		Marijuana		Opiates	
Immunoassay result		-	+	-	+	-	+	-	+	-	+
-		30	2	41	1	41	1	37	1	38	0
+		1	9	0	0	0	0	0	4	1	3
Immunoassay performance											
Accuracy rate (%)		93		98		98		98		98	
Sensitivity (%)		82		0		0		80		100	
Specificity (%)		97		100		100		100		97	
Kappa coefficient		.81*		N/A		N/A		.88*		.84*	
Kappa coefficient adjusted for prevalence and bias		.90*		N/A		N/A		.95*		.91*	

Notes: GC-MS, gas chromatography-mass spectrometry; N/A, not applicable; not possible to calculate kappa coefficient.

* Statistical significance at $p < .001$.