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Predictors of Treatment Outcome in Outpatient Cocaine and Alcohol Dependence Treatment

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Abstract

We examined the ability of several baseline variables to predict treatment outcome in a pharmacotherapy trial that included 164 participants who were both cocaine- and alcohol-dependent and were selected for a randomized, double-blind, placebo-controlled study. Predictor variables included results from the baseline Addiction Severity Index (ASI), initial Urine Drug Screen results, cocaine and alcohol craving and cocaine and alcohol withdrawal symptoms at the start of treatment. Successful treatment was defined as four continuous weeks of self-reported cocaine abstinence verified by urine drug screens. In respect to demographic characteristics, there were no significant differences between patients who achieved four weeks of abstinence from cocaine and those who did not. Baseline variables that most consistently predicted cocaine abstinence included initial urine drug screen (UDS) results, the initial Cocaine Selective Severity Assessment (CSSA) scores, and initial self-reported cocaine use in past 30 days, whereas cocaine craving, cocaine composite scores, alcohol craving, alcohol withdrawal symptoms, and alcohol composite scores did not. The results of this study suggest that cocaine dependence severity in general, and initial UDS results, the CSSA scores and frequency of recent cocaine use in particular, have a significant impact on treatment outcome in the treatment of cocaine-dependent patients with comorbid alcoholism. Initial UDS results and CSSA scores are very useful predictors of treatment outcome and could be used as stratifying variables in outpatient cocaine and alcohol medication trials.

INTRODUCTION

Our intention in this paper is to find predictors of treatment outcome in the outpatient treatment of cocaine-dependent patients with comorbid alcoholism. This could be useful for the development of both pharmacological as well as psychosocial treatments for cocaine dependence and dual alcohol and cocaine dependence. Among the strongest predictors of response to treatment in cocaine-dependent patients are cocaine withdrawal symptom severity and the results of a urine drug screen collected at the treatment entry.¹⁻⁴ The current trial seeks to extend these findings to outpatient treatment of cocaine-dependent patients with comorbid alcohol dependence.

Concurrent dependence on cocaine and alcohol is extremely common and very difficult to treat. In a sample of 298 treatment-seeking cocaine users, 62% had a lifetime history of alcohol dependence.⁵ In an Epidemiological Catchment Area study, 85% of cocaine-dependent patients were also alcohol-dependent.⁶ Use of cocaine with alcohol is common in drug abusers.^{7,8}

Patients who are dually cocaine- and alcohol-dependent tend to have more psychosocial problems compared to patients addicted to alcohol alone⁹ or compared to patients addicted to cocaine alone.^{5,10}

Thus, cocaine-dependent patients with comorbid alcohol dependence represent a distinctly “hard-to-treat” subpopulation of patients with alcohol dependence, which thus far have been relatively unresponsive to standard therapies.^{5,9,10}

High dropout rates are a major problem in the outpatient treatment of cocaine dependence^{11,12} and cocaine–alcohol dependence.¹ Because dropout is so clearly associated with poorer outcomes, some studies have attempted to identify those patient characteristics predictive of early withdrawal from outpatient cocaine treatment.^{12–14} For example, one study has shown that the initial urine toxicology result was a powerful predictor of dropout from a 27 hour per week, four-week outpatient treatment program.¹² This is consistent with the work of Higgins,¹⁴ who found that the presence of cocaine in the initial urine predicted treatment attrition. Other research studies have shown that patients with more severe cocaine withdrawal symptoms were less likely to complete initial abstinence from cocaine in comparison with patients who had less severe cocaine withdrawal symptoms.^{4,15}

Although much is known about predictors of treatment outcome among cocaine-dependent patients, less is known about predictors of treatment outcome among cocaine-dependent patients with comorbid alcoholism. In this trial, we sought to examine predictors of treatment outcome in cocaine-dependent patients with comorbid alcoholism who were participating in an outpatient pharmacotherapy trial. We analyzed data from 164 consecutive cocaine- and alcohol-dependent patients who gave written informed consent for a clinical study of naltrexone for the treatment of cocaine and alcohol dependence. We compared demographics, pretreatment drug and alcohol use data, cocaine and alcohol withdrawal symptoms, and cocaine and alcohol craving symptoms of participants who successfully achieved four weeks of cocaine abstinence to participants who failed to achieve four weeks of cocaine abstinence.

METHODS

Participants

Of 313 patients who signed consent and began screening, 164 patients completed detoxification and entered a 12-week trial. The participants were 164 men and women between the ages of 18 and 65 who were seeking treatment for both cocaine and alcohol dependence and were consecutive admissions to an outpatient treatment research study for cocaine-dependent patients with comorbid alcoholism at the University of Pennsylvania. Participants were recruited through advertisements in the local media, and those who met criteria in an intake appointment were referred to treatment in a randomized double blind placebo-controlled naltrexone trial for the treatment of cocaine and alcohol dependence. Participants were paid for participation and received a comprehensive psychiatric and medical evaluation prior to entry into the study, and were both cocaine- and alcohol-dependent at the time of study entry. Informed consent was taken from all participants. The study design was approved by the Institutional Review Board at the School of Medicine of the University of Pennsylvania.

Inclusion and Exclusion Criteria

Participants were included if they

- were between 18 and 65 years old;
- met DSM-IV criteria for both cocaine and alcohol dependence, as measured using the Structured Clinical Interview for DSM-IV Axis I Disorders;¹⁶
- ingested at least \$200 worth of cocaine in the past 30 days and more than 15 standard alcohol drinks on average/week, with at least one day of four or more drinks, as determined by the timeline follow-back (TLFB) adapted to collect both alcohol and cocaine use;¹⁷ and
- successfully completed alcohol detoxification (ie, five consecutive days of abstinence from cocaine and alcohol), measured via self reports and negative urine toxicology screens.

Participants were excluded if they

- were abstinent from cocaine or alcohol for 30 days prior to signing consent form;
- had a current DSM-IV diagnosis of any substance dependence other than cocaine, alcohol, nicotine, or cannabis;
- showed evidence of opiate abuse in the past 30 days, as assessed by self-report and urine drug screen at admission to treatment;
- was currently treated with psychotropic medications, including disulfiram;
- had a history of unstable or serious medical illness, epilepsy, or seizure disorders;
- had a known severe physical or medical illness such as AIDS, active hepatitis, significant hepatocellular injury as evidenced by high bilirubin level;
- showed current severe psychiatric symptoms (eg, psychosis, dementia, acute suicidal or homicidal ideation, mania, or depression requiring antidepressant therapy);
- used an investigational medication in the past 30 days; or
- were female subjects who were pregnant or nursing.

Procedures

Participants who were eligible for the study based on the medical/psychosocial evaluation were asked to complete outpatient detoxification (at least five consecutive days of abstinence from alcohol via self-reports and a cocaine-negative urine toxicology screen). All measures were completed before the participant received any medication or therapy. Participants who successfully completed detoxification from alcohol and cocaine then entered a 12-week double-blind, placebo-controlled trial comparing naltrexone 150 mg daily to placebo. The primary outcome measures included urine drug screens obtained twice weekly and alcohol use measured by self-report using a timeline followback.

Assessments and Predictor Variables

Predictor variables were obtained at treatment entry. Baseline demographics, drug and alcohol use, and drug and alcohol dependence severity were obtained using the Addiction Severity Index (ASI) at the first detoxification visit and prior to treatment.¹⁸ A trained research technician administered the ASI. Cocaine craving was measured using a 100 mm visual analog scale (VAS), which was included as part of the Minnesota Cocaine Craving Scale at the first detoxification visit and prior to treatment.¹⁹ Participants were asked to rate

the strength of their craving for cocaine, on average, over the past week. For alcohol craving, the visual analog scale described above was modified for alcohol. Participants were asked to rate their strength of their craving for alcohol, on average, over the past week, and prior to treatment. Each scale was anchored by “none” and “a great deal.”

Alcohol withdrawal signs and symptoms were assessed at the first visit and prior to treatment using a modified version of the Selective Severity Assessment (SSA-M). The SSA-M was specifically designed to assist with the outpatient detoxification of alcoholics.²⁰ The SSA-M contains fifteen items, each measured on a 0–7 scale: tremor, paroxysmal sweats, sleep disturbance, clouding of sensorium, quality of contact, agitation, convulsion, temperature, pulse, nausea and vomiting, anxiety, tactile disturbance, auditory disturbance, visual disturbance, and headache. The nurse practitioners treating the participants all had at least three years’ experience using the SSA-M in the treatment of alcohol withdrawal in an outpatient setting. Cocaine withdrawal symptoms were measured at the first visit and prior to treatment by the Cocaine Selective Severity Assessment (CSSA). The CSSA is an 18-item, interviewer-administered measure of the severity of cocaine abstinence symptoms.³ Each of the 18 individual items is scored on a 0–7 scale, with 0 representing no symptoms and 7 representing maximum severity. A total CSSA score is derived by a summation of the individual item scores. The CSSA measures signs and symptoms that commonly occur after abrupt cessation of cocaine use as reported in the literature and observed by clinicians at the University of Pennsylvania Center for the Treatment of Addictions. Signs and symptoms measured include cocaine craving, depressed mood, appetite changes, sleep disturbances, lethargy, and bradycardia. In recent reliability and validity testing, the instrument was found to be a valid and reliable measure of symptoms associated with the abrupt cessation of cocaine use.³ Individual items receiving the highest scores among newly abstinent cocaine-dependent patients in the initial validity testing of the instrument are also the items included in the DSM-IV diagnostic criteria for cocaine withdrawal: depressed mood (dysphoric mood), appetite changes, sleep changes, lethargy (fatigue), and irritability (psychomotor agitation). In the original work,³ the CSSA was found to have excellent interrater reliability and internal consistency. It was found to be specific to cocaine-dependent patients and decreased as patients maintained abstinence over eight days. Initial CSSA scores were correlated with amount and frequency of cocaine use as well as measures of addiction severity from the ASI. Initial CSSA scores predicted poor outcome in treatment.^{2–4} The research technicians who administered the CSSA participated in a 1 h training course on instrument administration and had extensive experience in the administration of the instrument prior to the study. The initial CSSA score was obtained on the first day of detoxification.

This trial evaluated the ability of the selected baseline variables to predict a successful treatment outcome for cocaine use, defined as four weeks of continuous abstinence from cocaine, verified by urine drug screens. In previous cocaine pharmacotherapy trials, a stable period of continuous abstinence from cocaine (3–4 weeks) was found to be predictive of long-term cocaine abstinence.^{15,21,22}

Statistical Analysis

Data analyses were performed with statistical software SPSS version 11.5. Demographics and pre-treatment drug use were compared between patients who achieved four weeks of continuous abstinence from cocaine and those who did not. The two group samples were compared on baseline characteristic using two-tailed t-tests for continuous variables and ² analyses for dichotomous, categorical variables. When necessary, the data were transformed to reduce skew prior to analysis. Predictor variables were first compared individually. Cocaine craving and alcohol craving as measured on the VAS on the first day of detoxification were compared between treatment completers and treatment failures. Cocaine

and alcohol withdrawal severity measured by scores on the CSSA and SSA-M on the first day of detoxification was likewise compared between treatment completers and treatment failures. Finally, logistic regression was used to identify the strongest predictors of treatment success. The dependent measure was cocaine abstinence for four continuous weeks. Individual predictor variables were drawn from demographic variables (see Table 1), baseline cocaine use variables (see Table 2), and baseline alcohol use variables (see Table 2). These were first entered into a logistic regression equation individually. Those variables that were significant predictors individually ($p < 0.05$) were then entered together in a forward stepwise manner to create the final model. A forward stepwise technique was used in which variables were entered in order of significance. This technique was used in this exploratory analysis because we had no preset theory regarding which variables should be included in the final model. The forward stepwise technique allows for the evaluation of the predictive power of each variable as other variables are entered into the equation. Robustness of the model was checked by repeating the regression with 10% of the cases randomly removed and provided a model nearly identical to the model generated with the whole sample. Level of significance was at 0.05.

RESULTS

Demographics

Of the 164 participants, 76% had a high school education or some college education and 76.2% were African-American. The mean age was 39.10 years (SD 6.99) for total sample (age range 23–55), 39.03 years (SD 7.45) for males, and 39.29 years (SD 5.81) for females ($t = 0.22$, $df = 162$, $p = 0.83$). With respect to demographic characteristics, there was no significant difference between treatment completers and treatment failures.

Baseline Alcohol and Cocaine Use

According to Table 1, baseline measures of alcohol dependence differed little between those who attained sustained abstinence from cocaine (cocaine abstainers) and those who did not (cocaine nonabstainers). Out of the eleven baseline alcohol use variables tested, only one variable, alcohol treatments per lifetime, was significantly different. Cocaine abstainers had significantly more treatments compared to cocaine nonabstainers ($t = 2.08$, $df = 160$, $p = 0.039$). The severity of alcohol withdrawal symptoms and the severity of alcohol craving were not significantly different between the two groups.

Baseline measures of cocaine dependence severity varied in a number of variables between cocaine abstainers and nonabstainers. Out of the eleven baseline cocaine use variables examined, four differed significantly between the two groups of patients. Cocaine nonabstainers had significantly more days of cocaine use ($t = 2.36$, $df = 160$, $p = .019$), significantly higher number of drug treatments per lifetime ($t = 2.27$, $df = 160$, $p = .025$), and significantly higher cocaine withdrawal scores ($t = 2.54$, $df = 161$, $p = .012$). The number of negative self-reported cocaine use verified by cocaine-negative urines was significantly lower in cocaine nonabstainers compared to cocaine abstainers ($\chi^2 = 37.61$, $df = 1$, $p < 0.001$).

Prediction of Treatment Outcome

To find which variables best predict sustained abstinence from cocaine, we entered each individual demographic and drug and alcohol use variable (see Table 1) into a separate logistic regression equation. All variables that were significant predictors of cocaine abstinence are shown in Table 2. These predictor variables were then entered into a single logistic regression equation in a forward stepwise manner. Those variables that remained significant predictors of cocaine abstinence in the final model were days of cocaine use in

the past 30 days (Wald coefficient = 7.99, df = 1, odds ratio = 0.926, 95% confidence interval = 0.877–0.977), the CSSA score (Wald coefficient = 5.82, df = 1, odds ratio = 0.970, 95% confidence interval = 0.946–0.994), and initial urine drug screen (Wald coefficient = 27.91, df = 1, odds ratio = 0.045, 95% confidence interval = 0.014–0.142). This model had a model χ^2 of 59.19, $p < 0.001$, and percent correctly predicted 78.3%.

DISCUSSION

Among cocaine-dependent patients with comorbid alcoholism, it was the severity of cocaine dependence, specifically the initial urine drug screen, the self-report of cocaine use, the severity of cocaine withdrawal symptoms, and the frequency of recent cocaine use that best predicted sustained abstinence from cocaine. Patients who attained sustained abstinence from cocaine differed from patients who did not achieve abstinence in only one of alcohol use variables, compared to four cocaine use variables. In cocaine use variables that were significantly different, cocaine nonabstainers had signs of more severe cocaine dependence. Furthermore, when each demographic and drug use variable was entered individually into a regression equation to predict sustained abstinence from cocaine, none of alcohol use variables proved to be a significant predictor. On the other hand, three of cocaine use variables proved to be significant predictors of sustained cocaine abstinence: the urine drug screen, the severity of cocaine withdrawal symptoms, and the frequency of recent cocaine use. Thus, the results of this study reinforce and extend the previous findings, that cocaine dependence severity adversely affects treatment outcome.^{3,4}

This trial included outpatient participants who were dependent on both cocaine and alcohol, and most participants reported mild to moderate alcohol withdrawal symptoms. Participants who experienced more intense alcohol severity were referred to an inpatient center. Therefore, care must be taken not to generalize these findings to all cocaine- and alcohol-dependent patient populations.

CONCLUSIONS

The results of the current clinical trial suggest that cocaine dependence severity in general, and initial urine drug screen results, CSSA scores, and frequency of recent cocaine use in particular, have a significant impact on treatment outcome in the treatment of cocaine-dependent patients with comorbid alcoholism. Initial urine drug screen results and CSSA scores are very useful predictors of treatment outcome and should be used as stratifying variables in outpatient cocaine and alcohol medication trials.

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TABLE 1

Alcohol and cocaine use variables, expressed as means (standard deviation)

Variable	Cocaine clean for four weeks		t	p
	Completers [n = 57 (34.8%)]	Failures [n = 107 (65.2%)]		
Alcohol use variables				
Days of alcohol use (in past 30 days)	15.89 (8.35)	16.27 (8.17)	0.28	0.78
Days of alcohol use to intoxication (in past 30 days)	13.96 (8.10)	15.09 (8.42)	0.82	0.41
Days of alcohol problem (in past 30 days)	12.47 (11.50)	14.46 (11.33)	1.04	0.30
Dollars spent on alcohol (in past 30 days)	168.33 (248.77)	150.91 (286.30)	0.38	0.71
Alcohol treatments (lifetime)	1.49 (1.76)	2.34 (2.81)	2.08	0.039
Years of alcohol use (lifetime)	19.18 (8.79)	19.95 (7.85)	0.58	0.56
Years used to intoxication (lifetime)	16.82 (8.87)	16.6 (8.15)	-0.16	0.87
ASI composite score for alcohol	0.57 (0.20)	0.62 (0.17)	1.62	0.11
Alcohol interviewer severity score	5.91 (2.13)	6.45 (1.37)	1.90	0.059
Alcohol craving score	8.92 (9.25)	9.01 (7.97)	0.06	0.95
Alcohol withdrawal score	4.35 (4.08)	5.05 (4.21)	1.01	0.31
Cocaine use variables				
Days of cocaine use (in past 30 days)	10.35 (7.06)	3.37 (8.14)	2.36	0.019
Days of drug problem (in past 30 days)	13.71 (11.02)	15.70 (11.06)	1.08	0.28
Dollars spent on drugs (in past 30 days)	630.36 (736.94)	618.11 (782.98)	0.10	0.92
Drug treatments (lifetime)	1.56 (1.57)	2.48 (2.82)	2.27	0.025
Years of cocaine use (lifetime)	11.96 (7.02)	12.30 (6.18)	0.31	0.76
ASI composite score for drugs	.24 (.08)	.25 (.06)	1.30	0.20
Cocaine craving score	11.22 (8.39)	10.66 (9.83)	0.36	0.72
Cocaine withdrawal score	22.38 (14.75)	29.36 (17.65)	2.54	0.012
Cocaine interviewer severity score	6.57 (1.53)	6.85 (1.20)	1.24	0.22
Negative self-reported cocaine use, verified by cocaine-negative urine	93%	43.9%	37.61(²)	< 0.001
Other variables				
ASI composite score for medical problems	0.26 (0.35)	0.30 (0.37)	0.65	0.51
ASI composite score for employment problems	0.59 (0.31)	0.65 (0.29)	1.30	0.19
ASI composite score for legal problems	0.16 (0.25)	0.11 (0.20)	1.39	0.17
ASI composite score for family problems	0.24 (0.27)	0.29 (0.26)	1.05	0.30
ASI composite score for psychiatry problems	0.31 (0.25)	0.33 (0.24)	0.51	0.61

TABLE 2

Individual predictors of completers

Variable	Model χ^2	<i>p</i>	Percent of subjects correctly identified	Wald coefficient	95% confidence interval, lower r bond-upper bond
CSSA score	6.51	0.014	66.3	6.04	0.954-0.995
Days of cocaine use (in past 30 days)	5.61	0.021	64.8	5.31	0.909-0.992
UDS	43.67	<0.001	68.9	26.07	0.020-0.175