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Smoking cessation treatment among patients in community-based substance abuse rehabilitation programs: Exploring predictors of outcome as clues toward treatment improvement

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INTRODUCTION

Treatment of nicotine dependence with combined pharmacotherapy and counseling yields modest abstinence rates (1,2,3,4,5,6), which tend to deteriorate over long-term follow-up (1,2,3,4,5,6). The need for more effective interventions for smoking is especially pronounced among drug- and alcohol-dependent patients, the majority of whom smoke (70–90%) (7,8,9,10), and among whom smoking is associated with greater levels of substance abuse (7,10,11), nicotine dependence (12,13,14), medical problems (15,16), and mortality (17), and low abstinence rates (10% to 20%) in response to smoking cessation interventions (18,19,20,21,22,23,24,25,26,27,28).

Analysis of characteristics of patients and of interventions that predict outcome in clinical trials may offer clues on how to improve the interventions. The widely recognized stage model of treatment development for substance use disorders (29) emphasizes an iterative process, beginning with small Stage 1 pilot trials and progressing to fully powered efficacy

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(Stage 2) and community-based effectiveness trials (Stage 3). The process of treatment optimization has received more emphasis during Stages 1 and 2, although Stage 3 trials, because of their large, representative samples, may offer a particularly fruitful platform for analyzing predictors of outcome as clues toward further treatment improvement.

We therefore conducted an exploratory analysis of baseline demographic and clinical predictors of smoking cessation during a recently completed, multi-site randomized trial of nicotine replacement therapy plus group cognitive behavioral counseling, compared to treatment-as-usual, conducted at drug treatment programs within the National Drug Abuse Treatment Clinical Trials Network (NIDA-CTN)(26). As previously reported, interest in smoking cessation treatment was high among these substance-dependent patients (9), and the intervention was superior to treatment as usual in smoking outcomes (26). However, the overall quit rates were low, highlighting the need for efforts to improve smoking cessation interventions, identify subgroups for which specific interventions might be most effective, and develop subgroup-focused tailored interventions.

METHODS

Study Design and Treatment Settings

This was a randomized, open-label, multi-site study investigating smoking cessation treatment as an adjunct to standard substance abuse rehabilitation. Treatment consisted of mood management and cognitive behavioral group counseling (Weeks -1 thru 8) plus transdermal nicotine patch (NicoDerm CQ®) treatment (21 mg/day Weeks 1 thru 6, 14 mg/day Weeks 7 thru 8). Individuals, 18 years of age or older, were eligible if they smoked at least 10 cigarettes/day, had an interest in quitting smoking, were in substance abuse treatment for at least 30 days prior to enrollment, and had no medical conditions contraindicated for nicotine patches. Eligible participants were randomized on a 2:1 ratio to either: *Group 1*) substance abuse treatment-as-usual plus smoking cessation treatment (SC, N=153) or *Group 2*) substance abuse treatment-as-usual (TAU, N=72). The study was conducted at 7 community-based treatment programs (CTP) within the CTN, 5 methadone maintenance treatment programs and 2 outpatient (non-methadone) programs. As previously reported, the distribution of baseline demographic and clinician characteristics was similar between the SC and TAU groups (26).

Assessments

Baseline and screening evaluations included demographics, self-reported cigarettes/day, exhaled carbon monoxide (CO) test, Fagerström Test for Nicotine Dependence (FTND) (30), smoking history survey, Smokers Beliefs Questionnaire (31), the Reasons for Quitting Questionnaire (RNQ) (32), an abbreviated version of the Addiction Severity Index (ASI-Lite) (33), urine drug screen, and alcohol breathalyzer (the impact of prior or current depression on smoking abstinence rates is presented elsewhere (34)). Treatment assessments, once a week through week 8 with follow-up assessments at weeks 13 and 26, included self-reported cigarettes/day, exhaled CO levels, treatment compliance, cigarette withdrawal (35) and primary substance of abuse craving (36) assessments, self-reported substance abuse, and urine drug screen or alcohol breathalyzer tests.

Data Analysis

Because rates of abstinence in TAU were negligible, these predictor analyses were limited to patients in the SC group (N = 153). The primary outcome measure was 7-day point prevalence smoking abstinence, defined as a self-report of no smoking confirmed by exhaled breath CO level ≤ 10 ppm during each study week (criterion based on SRNT Subcommittee on Biochemical Verification (37)). For each baseline predictor variable, a generalized linear mixed model (GLMM) was fit, using PROC GLIMMIX in SAS (SAS Institute Inc. Cary, North Carolina), modeling weekly point prevalence smoking abstinence as a function of treatment week (weeks 1 through 8), with the predictor as covariate, sites as random effects, and depression (baseline Beck Depression Inventory score) as a control variable, given the previously demonstrated adverse prognostic effect of depression in this sample (34). The possible interactions between time and covariates were tested and explored in further detail if significant. Secondary analyses evaluated smoking abstinence at each of the follow-up time points, week 13 and week 26 with the same panel of predictor variables. We also examined the associations between two primary substance abuse outcome measures (abstinence status and craving ratings) with smoking abstinence status, by including the substance outcome measure as a time-varying covariate in the GLMM models. As exploratory analyses, all tests were conducted at a significant level of $\alpha = 0.05$ without adjustment for multiple testing.

RESULTS

Study Sample

The demographics and baseline characteristics of participants assigned to SC treatment are presented in Table 1. Of note, there were more study participants enrolled in methadone programs (n=122) than in non-methadone programs (n=31).

Primary Outcome Measure

Smoking abstinence rates across the 8 weeks of treatment averaged 7.5±2.4% (mean±SD) (range: 4/133 (3%) in week 1, to 13/136 in week 2 (10%)). Assessment completion rates were on average 84+4% (mean±SD) across baseline through week 8.

Demographic and Baseline Predictors of Smoking Abstinence

The associations of baseline characteristics with smoking abstinence are displayed in Table 2. Among demographic variables, greater likelihood of smoking abstinence was associated with younger age, Hispanic or Caucasian ethnicity/race, and current employment or student status. Among the smoking variables, smoking abstinence was associated with lower nicotine dependence severity (FTND) and lower RNQ motivation to quit. Exploration of interactions suggested those with higher FTND scores at baseline improved more in abstinence over time. Among substance abuse variables smoking abstinence was associated with fewer prior days in substance abuse treatment and higher methadone dose (among those in methadone treatment). The size of these effects was not changed by control for depression, with the exception of days in substance abuse treatment, which was reduced by control for depression but still significant. Associations of abstinence with lower smoking

rate (cigarettes/day) and lower addiction severity (ASI drug or alcohol composite score) were significant only in the absence of control for depression.

Smoking abstinence at the week 13 (5.5%) and week 26 (5.7%) follow-up time points were predicted by similar, though fewer, baseline variables. Week 13 abstinence was associated with shorter duration of substance abuse treatment ($t=3.87$, $p<0.01$), fewer prior attempts at quitting smoking ($t=2.45$, $p<0.05$), and higher methadone maintenance dose at a trend level ($t=3.08$, $p=0.051$). Week 26 abstinence was associated fewer cigarettes per day ($t=3.11$, $p<0.01$), fewer prior attempts at quitting smoking ($t=2.57$, $p<0.05$), and higher methadone dose ($t=2.31$, $p<0.05$).

Substance Abuse Treatment Outcome and Smoking Abstinence

During treatment, smoking abstinence was associated with abstinence from the primary substance of abuse ($F=3.75$, $p=0.05$) and at a trend level with craving for the primary substance of abuse ($F=3.23$, $p=0.07$).

DISCUSSION

We conducted an exploratory analysis of predictors of abstinence from smoking in a trial of nicotine patch plus group cognitive behavioral therapy among drug-dependent patients in community-based treatment programs in order to generate hypotheses for future efforts to improve interventions for smoking in this population. In the main outcome analyses, previously reported, we showed that abstinence in response to the intervention, although superior to treatment as usual, was low, while the likelihood of abstinence was associated with better adherence to nicotine patch and to counseling (26) and absence of depression (34). Gender was not associated with abstinence (26). The present analysis explored a broad range of other demographic and clinical predictors, controlling for depression. The pattern that emerged is that that younger, more functional patients with less chronicity and severity of the primary substance of abuse and of nicotine dependence were more able to quit smoking. Specific variables associated with greater likelihood of smoking abstinence during treatment included younger age, Hispanic or Caucasian ethnicity (as opposed to African American), current employment or student status, lower nicotine dependence ratings (by the Fagerstrom), shorter duration of current substance abuse treatment, greater abstinence from the primary drug during treatment, and higher methadone dose.

The finding that younger patients were more likely to quit smoking is at odds with previous findings in substance abuse patients that older smokers (38) and patients that started smoking at an older age (28) were more likely to quit smoking, as well as similar findings among smokers without other addictions (39,40). The discrepancy with these findings may be due to population differences (one of the prior studies involved inpatient substance abusers (28)) or differences in the interventions tested, which included contingency management (38), nicotine patch without counseling (28), and bupropion (39,40). Older age in the present sample might reflect greater chronicity, severity and treatment resistance.

Poorer smoking cessation outcome among African Americans has been previously observed in a large general sample of smokers from two clinical trials of nicotine replacement

products and bupropion (41). The similar finding in the present sample suggests the need for further research to better understand the influence of race/ethnicity on treatment response and whether the basis of this is cultural or in part biological. Future research is also suggested on tailored approaches in an effort to improve quit rates among African Americans.

The association of lower baseline smoking rates and nicotine dependence severity (FTND) with abstinence is consistent with previous studies (28,38,42), suggesting the influence of severity. The greater improvement in abstinence over time among those with higher FTND scores at baseline suggests inconsistency in this association and comports with our finding that baseline exhaled CO did not predict smoking cessation treatment outcome. Others have also reported inconsistent associations of nicotine dependence severity with smoking cessation outcomes in substance abuse patients (28,38,43,44), and it has been suggested that this association is weaker in studies of treatment with nicotine patch (38,45).

Surprisingly, motivation to quit smoking (RNQ) was inversely related to smoking abstinence rates, while patient attitudes with regards to perceived severity of nicotine addiction and difficulty of quitting were not associated with smoking abstinence rates. These results may indicate weakness in the methods of assessing patient attitudes towards cigarette smoking among substance-dependent patients and are consistent with the findings from our prior feasibility study (9).

The associations of smoking abstinence with lower ASI drug and alcohol composite scores at baseline (before control for depression), drug/alcohol abstinence and lower drug craving during treatment, and higher methadone doses suggest an important role for the severity of the primary substance problem. It is well known that successful treatment of opioid dependence depends on adequate dosage of methadone, and our present findings suggest that the success of treatment of nicotine dependence may depend in part on adequate treatment of the other substance problems. These findings are consistent with previous studies in which measures of severity of concurrent alcohol (46,47,44), or drug problems (38,43,46) predicted lower smoking abstinence rates. Several laboratory-based studies (48,49) and one small clinical trial (50) have suggested that acute methadone dosing or dose increases may increase smoking or nicotine craving, although the laboratory studies did not involve patients seeking to quit smoking, and the clinical trial did not examine methadone dose increases to optimize treatment for opioid use.

The sizes of the effects of several of the variables related to severity or chronicity of nicotine or drug addiction (cigarettes/day, ASI drug or alcohol severity, and duration of current substance abuse treatment) were diminished by control for baseline depression. Thus, depression, already a known predictor of poor smoking cessation outcome in this study (34) and others in the literature may explain some of the observed adverse prognostic effect of addiction severity.

Weaknesses of this study include that the rate of abstinence was low, and since we examined a large number of predictors in an exploratory analysis without a priori hypotheses, the opportunity for Type I error is elevated. These analyses should be considered as hypothesis-

generating for future research. We did not attempt multivariate analyses, other than controlling for depression; hence we cannot estimate the extent to which the predictors identified may be independent of one another. Although type of treatment program did not predict abstinence, the preponderance of methadone clinics in the sample, with only two non-methadone outpatient programs accounting for 20 percent of the patient sample, restricts generalizability and confidence in the findings among the non-methadone patients. It is also not possible to examine whether predictors differed by type of treatment program. No inpatient or residential treatment programs were included in the study. The present design intentionally did not separate the contributions of the pharmacological and counseling interventions to smoking abstinence rates.

The previously reported findings from this trial showed that the abstinence rate in response to nicotine patch plus cognitive behavioral counseling was low, while abstinence was associated with better adherence to nicotine patch and to counseling (26) and absence of depression (34). This already suggested the need to test more powerful treatments (e.g. bupropion or varenicline) and to add features to maximize adherence (e.g. voucher incentives) and to address co-occurring depression. The present analysis, exploring an expanded panel of predictors of outcome, suggests the importance of adequate treatment of the concurrent substance problems to minimize their severity. That depression may explain some of the adverse prognostic effect of several of the addiction severity variables should further focus future attention on identification and intervention for depression. The findings also suggest that consideration be given to tailoring interventions for patients with more chronic or severe smoking and with more severe concurrent drug or alcohol problems, as well as interventions tailored for different racial/ethnic groups. From a methodological standpoint, the present analysis suggests the potential utility of exploring predictors of outcome in large stage 2/3 multi-site trials to generate hypotheses for future treatment development efforts.

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Table 1

Smoking Cessation Treatment Study Participants

Demographics	**Percent or Mean ± STD**
Age (yr)	41.6 ± 10.2
Female	49%
Race	
White (not Hispanic)	37%
Black (not Hispanic)	28%
American Indian/Alaskan Native	0%
Asian Pacific	0%
Hispanic - Puerto Rican	35%
Education (yr)	11.4 ± 2.3
Employed or Student	40%
Medical Treatment History	
Heart Condition	7%
High Blood Pressure	23%
Asthma	28%
Psychiatric Treatment History	
Major Depression	50%
Anxiety Disorder	37%
ADHD	7%
Schizophrenia	10%
Cigarette Smoking	
Cigarettes/day	22.3 ± 11.6
Exhaled CO (ppm)	20±10
Fagerström (FTND) (range: 0–10)	5.9 ± 2.1
Smokers Motivation (RNQ) (range: 0–80)	12.9 ± 4.2
Smokers Belief: Nicotine Addiction Severity (range: 1–5)	4.1 ± 0.7
Smokers Belief: Difficulty in Quitting Smoking (range: 1–5)	3.4 ± 1.1
Number of Prior Quit Attempts	5.2 ± 11.9
Substance Abuse Treatment	
Duration Current Substance Abuse Treatment (days)	790 ± 1215
ASI Alcohol Coefficient (alcoholic, n=17) (range: 0.00–1.00)	0.262 ± 0.158
ASI Drug Coefficient (drug-dependent, n=208) (range: 0.00–1.00)	0.184 ± 0.102
DSM-IV Primary Substance of Abuse	
Opiates	84 (55%)
Cocaine	34 (22%)
Alcohol	15 (10%)
Cannabis	10 (7%)
Amphetamines	6 (4%)

Demographics	**Percent or Mean ± STD**
Benzodiazepines/Sedatives	4 (3%)
DSM-IV Symptom Severity Score (range: 3–7)	5.7 ± 1.3

Table 2

Baseline Demographic and Clinical Variables as Predictors of Smoking Cessation (SC) among Drug-Dependent Patients, Controlling for Baseline Severity of Depression [a]

Participant Variables	F	DF	p-value	Direction of Association
Demographic, Medical and Psychiatric History				
Gender	2.14	1, 979	0.1437	
Age	14.21	1, 979	<0.001	better SC with younger age
Race/Ethnicity	28.23	2, 979	<0.0001	better SC in hispanic and white
Education	0.87	1, 979	0.351	
Employment/Student Status	7.43	1, 979	0.007	better SC with employed/student
Cigarette Smoking				
Cigarettes/Day	3.14	1, 979	0.078	better SC with lower cigarettes/day [b]
Fagerstrom Nicotine Severity	4.90	1, 979	0.027	better SC with lower severity
Exhaled CO	0.07	1, 979	0.788	
Curry Smokers Motivation	25.13	1, 979	<0.001	better SC with lower motivation
Nicotine Addiction Severity Belief	0.32	1, 979	0.575	
Difficulty in Quitting Smoking Belief	1.74	1, 979	0.188	
Number Prior Quit Attempts	1.04	1, 979	0.308	
Duration Longest Quit Attempt	0.92	1, 979	0.339	
Substance Abuse				
ASI drug or alcohol severity	1.95	1, 979	0.1631	better SC with lower ASI [b]
DSM-IV severity score	0.63	1, 979	0.428	
Duration current substance abuse treatment	7.97	1, 979	0.005	better SC with fewer days treatment [b]
Treatment Setting (methadone vs non methadone)	0.01	1, 979	0.924	
Methadone Maintenance Dose	11.6	1, 979	<0.001	better SC with higher methadone dose
Opiate Dependence	0.35	1, 979	0.554	
Cocaine Dependence	0.53	1, 979	0.548	
Alcohol Dependence	0	1, 979	0.959	

[a] Values in the Table are F statistics, degrees of freedom, and significance levels, for the main effect of the predictor variable in a generalized linear mixed model (GLMM) predicting smoking cessation, controlling for the Beck Depression Inventory score at baseline.

[b] For these baseline predictor variables, the association was larger when the analysis was conducted without control for depression (cigarettes per day: F = 5.16, p = .028; ASI drug or alcohol addiction severity: F= 4.82, p = .028; duration current substance abuse treatment: F = 14.36, p = .001), suggesting those associations may be at least partly explained by level of depression.