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Smoking cessation treatment in community-based substance abuse rehabilitation programs

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Abstract

Nicotine dependence is highly prevalent among drug- and alcohol-dependent patients. A multisite clinical trial of smoking cessation (SC) treatment was performed at outpatient community-based substance abuse rehabilitation programs affiliated with the National Drug Abuse Treatment, Clinical Trials Network. Cigarette smokers (N = 225) from five methadone maintenance programs and two drug and alcohol dependence treatment programs were randomly assigned in a 2:1 ratio to receive either (1) SC treatment as an adjunct to substance abuse treatment-as-usual (TAU) or (2) substance abuse TAU. Smoking cessation treatment consisted of 1 week of group counseling before the target quit date and 8 weeks of group counseling plus transdermal nicotine patch treatment (21 mg/day for Weeks 1–6 and 14 mg/day for Weeks 7 and 8) after the target quit date. Smoking abstinence rates in SC, 10%-11% during treatment and 5%-6% at the 13- and 26-week follow-up visits, were significantly better than those in TAU during treatment (p < .01). In addition, SC was associated with significantly greater reductions as compared with TAU in cigarettes smoked per day (75% reduction, p < .001), exhaled carbon monoxide levels (p < .001), cigarette craving (p < .001), and nicotine withdrawal (p < .001). Smoking cessation did not differ from TAU on rates of retention in substance abuse treatment, abstinence from primary substance of abuse, and craving for primary substance of abuse. Compliance with SC treatment, moderate at best, was positively associated with smoking abstinence rates. Smoking cessation treatment resulted in significant reductions in daily smoking and modest smoking abstinence rates without having an adverse impact on substance abuse rehabilitation when given concurrently with outpatient substance abuse treatment. Substance abuse treatment programs should not hesitate to implement SC for established patients. © 2008 Published by Elsevier Inc.

Keywords: Smoking cessation; Substance abuse; Nicotine; Craving

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1. Introduction

A high proportion (70%-90%) of patients in treatment for drug or alcohol dependence smoke cigarettes (Budney, Higgins, Hughes, & Bickel, 1993; Kalman, Morissete, & George, 2005; Schnoll, Daghestani, Karrigan, Kitchen, & Hansen, 1985; Stark & Campbell, 1993). Such concurrent smoking is responsible for substantial medical problems (Hughes, 1993; Kreek, 1987) and is arguably the largest contributor to mortality among substance-dependent patients (Hurt et al., 1996). Moreover, it is associated with greater levels of substance abuse (Budney et al., 1993; Stark & Campbell, 1993; Tonneatto, Sobell, Sobell, & Kozlowski, 1995). Survey studies demonstrated that patients in substance abuse treatment are interested and willing to enroll in smoking cessation (SC) treatment (Bobo, Lando, Walker, & McIlvain, 1996; Clarke, Stein, McGarry, & Gogineni, 2001; Irving, Seidner, Burling, Thomas, & Brenner, 1994; Joseph, Lexau, Willenbring, Nugent, & Nelson, 2004; Zullino, Besson, & Schnyder, 2000), and a number of clinical trials demonstrated that SC treatment is effective among substance-dependent patients, resulting in modest abstinence rates (Bobo, McIlvain, Lando, Walker, & Leed-Kelly, 1998; Burling, Burling, & Latini, 2001; Burling, Marshall, & Seidner, 1991; Campbell, Wander, Stark, & Holbert, 1995; Hurt et al., 1994; Hurt, Eberman, Slade, & Karan, 1993; Joseph, 1993; Joseph, Willenbring, Nugent, & Nelson, 2004; Pletcher, 1993; Saxon, McGuffin, & Walker, 1997; Shoptaw et al., 2002).

However, SC treatment is not part of routine clinical practice in most substance abuse treatment programs, and the field is dominated by the unsubstantiated notion that treatment of concurrent nicotine dependence is a low priority and may even interfere with treatment of the primary substance abuse problem (Capretto, 1993; Gill & Bennett, 2000; Joseph, Lexau, et al., 2004; Knapp, Rosheim, Meister, & Kottke, 1993; Rustin, 1998; Sharp, Schwartz, Nightingale, & Novak, 2003; Sterling, Gottheil, Weinstein, Kurtz, & Menduke, 1994). The existing clinical trials of treatment for co-occurring nicotine dependence are limited in several respects, being confined to one or a few sites, often university affiliated, and many were based on inpatient or residential treatment programs in which the impact on substance abuse outcomes could not be fully evaluated (Bobo et al., 1998; Burling et al., 1991, 2001; Gariti et al., 2002; Hurt et al., 1994; Joseph, 1993; Joseph, Willenbring, et al., 2004; Kalman et al., 2001; Saxon et al., 1997). These suggest the need for a clinical trial to test the effectiveness of SC treatment across multiple community-based outpatient substance abuse treatment programs and to examine its impact on the outcome of concurrent drug and alcohol problems.

We therefore conducted a randomized trial of nicotine replacement therapy (NRT; NicoDerm CQ) plus group cognitive—behavioral counseling as compared with treatment-as-usual (TAU) across multiple community-based outpatient substance abuse treatment programs within the

National Drug Abuse Treatment, Clinical Trials Network. Nicotine replacement therapy was chosen based on its widespread use as well as over-the-counter availability and because of its potential generalizability among treatment programs with little or no medical coverage. A mood management and cognitive-behavioral SC counseling program (Hall, Munoz, & Reus, 1994; Munoz, Organista, & Hall, 1988) with which NRT was coupled was chosen based on past use in patients with substance abuse history and because such approach has been shown to enhance the effectiveness of NRT among substance-dependent patients (Bobo et al., 1998; Burling et al., 1991, 2001; Campbell et al., 1995; Hurt et al., 1994; Joseph, 1993; Patten, Martin, Myers, Calfas, & Williams, 1998; Pletcher, 1993; Saxon et al., 1997; Shoptaw et al., 2002). It was hypothesized that this treatment package would be well accepted by patients and effective in promoting smoking abstinence and that concurrent drug and alcohol problems would not worsen as a result of SC treatment.

2. Methods

2.1. Participants

Participants were patients in treatment for drug or alcohol dependence at one of seven community-based treatment programs affiliated with the Clinical Trials Network, including five methadone maintenance treatment programs and two outpatient drug and alcohol rehabilitation clinics. Participating community-based treatment programs did not have existing SC treatment programs onsite. Participants were eligible if they smoked at least 10 cigarettes per day, were interested in quitting smoking, met eligibility for current drug or alcohol dependence (methadone-maintained patients in remission were also eligible), had been enrolled in their respective substance abuse treatment programs for at least 30 days, and were medically and psychiatrically stable. Participants were recruited at each site by word of mouth, use of study-specific recruitment materials (study brochures and fliers), clinic announcements, and referral from nonresearch clinic staff. The study was approved by the institutional review board of the New York University School of Medicine as well as the institutional review boards of the participating sites, and all participants gave their written informed consent.

2.2. Procedures

Eligible participants were randomly assigned on a 2:1 ratio to either (1) substance abuse TAU plus SC treatment or (2) substance abuse TAU. Randomization was computer generated, using permuted blocks of six, stratified by site and sex. A study statistician, who had no other contact with site study staff, performed the randomization, and staff were blind as to stratification and block size strategies. Assignment to treatment occurred when at least seven participants

were eligible for randomization to ensure an adequate number of participants in the SC counseling groups.

For the SC condition, SC counseling was done in a closed group format and was based on the mood management and cognitive—behavioral therapy for smoking cessation manual from the Habit Abatement Clinic of the University of California-San Francisco (San Francisco, CA, USA; Hall et al., 1994; Munoz et al., 1988), which had been tailored for substance abuse treatment patients with the assistance of the original authors. Participants were scheduled for nine group SC counseling sessions beginning 1 week before and continuing for 6 weeks after the target quit date (Day 1 in the protocol schedule). For the first 2 weeks (Weeks -1 and 1), counseling sessions were held twice weekly; for Weeks 2-6, they were held once a week. Smoking cessation pharmacotherapy consisted of open-label transdermal nicotine patches (NicoDerm CQ) provided in two strengths: 21 and 14 mg/day. Participants began medication on the target quit date and continued through the end of Week 8 (Day 56), starting with 21-mg/day patches for Weeks 1–6 and then with 14-mg/day patches for Weeks 7 and 8. Participants unable to tolerate the 21-mg/day patch were allowed to have a dose reduction to the 14-mg/day patch. In the TAU condition, participants were offered deferred SC treatment after the completion of their last follow-up visit. Treatment was free of charge, and all participants were compensated with \$10 in scrip or cash for each study week, with a bonus payment of \$20 in scrip or cash upon completing study participation through Week 8.

Counselors and counselor supervisors received standardized training in the SC counseling program. In addition, all study counselors completed practice sessions for each of the nine counseling sessions, rated by counselor supervisors using a standardized counselor fidelity monitoring checklist, and demonstrated a 75% adherence to the checklist to be certified and begin treating study participants. In the conduct of the study, each counselor supervisor reviewed and rated counseling sessions on a monthly basis using the counselor fidelity monitoring checklist. Counselors were given refresher training when 75% adherence levels were not met.

2.3. Assessments

Baseline and screening evaluations included demographics, smoking status, exhaled carbon monoxide (CO) test results, urine cotinine levels, the Fagerstrom Nicotine Tolerance Questionnaire (Heatherton, Kozlowski, Freckler, & Fagerstrom, 1991), a smoking history survey, the Smokers' Beliefs Questionnaire (Frosch, Shoptaw, Jarvik, Rawson, & Ling, 1998), the Reasons for Quitting Questionnaire (Curry, Grothaus, & McBride, 1997), an abbreviated version of the Addiction Severity Index (Lite version; McLellan et al., 1985), urine drug screen results, alcohol breathalyzer results, vital signs, urine pregnancy results, and medical and psychiatric history. After randomization, study visits were scheduled once a week through Week 9, with follow-up assessments at Weeks 13 and 26, and included

self-reported average cigarettes per day, exhaled CO levels, SC and drug rehabilitation treatment compliance, a modified Minnesota withdrawal scale (Hughes, Gust, Skoog, Keenan, & Fenwick, 1991; Hughes & Hatsukami, 1986), a timeline followback for self-reported substance abuse, a urine drug screen, an alcohol breathalyzer test, vital signs and weight, adverse events, and concomitant medication information.

2.4. Data analysis

The demographic and diagnostic characteristics at baseline were compared across two treatment groups with chi-square test for categorical variables and t test for continuous variables.

For evaluation of the treatment effect on SC and substance abuse, the primary analytical strategy used mixed effect models for continuous repeated measures and generalized linear mixed models (GLMMs) for categorical repeated measures. The mixed effect models and GLMMs are ideally suited for analysis of longitudinal data in that they allow for estimations both within-subject and within-site correlation structures. PROC MIXED (for mixed effect models) and PROC GLIMMIX (for GLMMs) in SAS (SAS Institute, Cary, NC, USA; SAS Institute, 1990a, 1990b) were used to estimate and test the models.

The primary outcome measure was 7-day point prevalence of smoking abstinence, assessed at each study visit and defined as a self-report of no smoking confirmed by an exhaled breath CO level of 10 ppm or lower. Missing data were imputed as nonabstinent. A GLMM was used to fit the weekly smoking abstinence status during active treatment (Week -1 through Week 9) as a function of treatment, time (weeks), and the interaction between treatment and time with subject and site as random variables. If the interaction between treatment and time was not significant, a model with no interaction term was fit. Analysis of the sex effect on smoking abstinence, performed in SC only because of negligible abstinence rates in TAU, was done using the same approach. The effect of treatment on secondary smoking outcome measures, including weekly measures of cigarettes smoked per day, exhaled CO levels, self-reported nicotine withdrawal, and craving, was estimated and tested using PROC MIXED for mixed effect models with baseline values of the outcome variables included in the model when applicable.

For the purpose of monitoring substance abuse, each individual's primary substance of abuse (determined based on *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria and confirmed by clinical interview) was evaluated. Abstinence from primary substance of abuse was defined as self-report of no use over the last week confirmed by urine drug screen or breath alcohol test results negative for that substance. Estimating and testing the effect of SC versus TAU treatment on patients' weekly substance abuse abstinence were based on the same approach as described for smoking abstinence. Separate analyses were

carried out on primary substance of abuse craving levels and adherence rates to substance abuse counseling.

We conducted supplementary post hoc analyses to examine the associations between primary substance of abuse abstinence and cigarette use during active treatment. Separate GLMMs were used to conduct these analyses with two smoking outcome measures (weekly smoking abstinence status and cigarettes smoked per day) treated as a time-varying predictor and the substance abstinence status treated as the dependent variable. A similar approach was used to test the association between weekly substance abuse craving (dependent variable) and cigarettes smoked per day (time-varying predictor).

Retention in the study and that in substance abuse treatment were tested using the log-rank test on time to dropout. The distribution and severity of adverse events were compared between two treatment groups using a two-sided Kruskal—Wallis test. Within the SC group, weekly compliance rates with SC counseling attendance and use of nicotine patches were compared between methadone and nonmethadone study sites using a mixed effect model. Comparisons of SC compliance with smoking abstinence rates were analyzed using Pearson's correlation coefficients.

3. Results

3.1. Study sample

Four hundred fifteen potential participants were screened, and 225 were randomized—153 to SC and 72 to TAU (Fig. 1). Common criteria for ineligibility included not

meeting substance dependence criteria (21%), smoking less than 10 cigarettes per day (12%), receiving other forms of SC treatment (current or within the last 30 days; 9%), and being hypertensive (8%). No significant difference (p > .05) was noted for any of the comparisons in the baseline demographic characteristics between the two treatment groups (Table 1). Participants were on average middle aged and high school educated; most were unemployed, and approximately half were female. Participants smoked slightly more than a pack a day and had been smoking for approximately 25 years; the Fagerstrom score was approximately 6, indicating moderate to high levels of nicotine dependence. Prior attempts to quit smoking had been made by 78% of those in the SC group and 75% of those in the TAU group, on average five times in each group. Based on psychiatric history, half of the participants reported prior treatment for depression and a third reported prior treatment for anxiety disorder. The distributions of primary substance of abuse, severity of addiction (Addiction Severity Index coefficients and Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition symptoms), and history of or prior substance abuse treatment interventions were similar in the SC and TAU groups. However, there were more study participants enrolled in methadone programs (n = 179) than in nonmethadone programs (n = 46); as such, the average number of days that patients had been enrolled in their current substance abuse treatment program was fairly long (>1 year).

3.2. Study retention and compliance

Study retention through the end of the treatment period was high overall (94%) and did not differ in time to dropout

Disposition of Study Patients

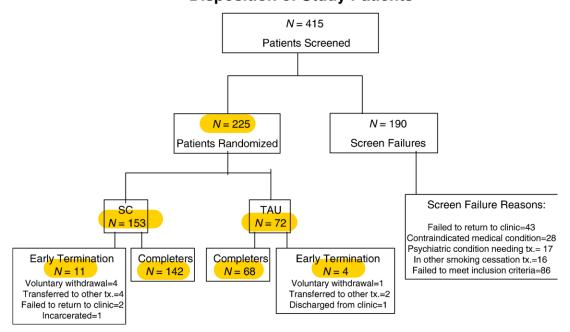


Fig. 1. Participants' disposition during the screening and enrollment phases of the study.

Table 1 Characteristics of the study participants

| SC | TAU |
|-------------------|---|
| | |
| 41.6 ± 10.2 | 41.0 ± 8.6 |
| 49 | 47 |
| | |
| 37 | 42 |
| 28 | 22 |
| _ | 2 |
| _ | 3 |
| 35 | 30 |
| 11.4 ± 2.3 | 11.9 ± 2.1 |
| 40 | 33 |
| | |
| 7 | 14 |
| 23 | 18 |
| 28 | 26 |
| | |
| 50 | 47 |
| 37 | 28 |
| 7 | 7 |
| 10 | 4 |
| | |
| 22.3 ± 11.6 | 21.6 ± 10.2 |
| 1.217 ± 686 | $1,198 \pm 658$ |
| 25.2 ± 11.4 | 24.3 ± 10.0 |
| 5.9 ± 2.1 | 6.0 ± 1.8 |
| 12.9 ± 4.2 | 12.0 ± 4.5 |
| | |
| 4.1 ± 0.7 | 4.0 ± 0.9 |
| 3.4 ± 1.1 | 3.4 ± 1.0 |
| 5.2 ± 11.9 | 4.9 ± 12.3 |
| | |
| 790 ± 1.215 | $799 \pm 1,384$ |
| , , | , |
| 5.1 ± 6.9 | 5.0 ± 7.1 |
| | 0.6 ± 2.1 |
| | 0.210 ± 0.064 |
| | |
| 0.184 ± 0.102 | 0.186 ± 0.122 |
| | |
| Disorders, Fou | rth Edition |
| | |
| 84 (55) | 43 (60) |
| | 10 (14) |
| | 2 (2) |
| ` ′ | 9 (12) |
| | 4 (6) |
| | 4 (6) |
| 5.7 ± 1.3 | 5.5 ± 1.6 |
| | |
| | 41.6 ± 10.2 49 37 28 $-$ $-$ 35 11.4 ± 2.3 40 7 23 28 50 37 7 10 22.3 ± 11.6 $1,217 \pm 686$ 25.2 ± 11.4 5.9 ± 2.1 12.9 ± 4.2 4.1 ± 0.7 3.4 ± 1.1 5.2 ± 11.9 $790 \pm 1,215$ 5.1 ± 6.9 1.0 ± 3.9 0.262 ± 0.158 0.184 ± 0.102 Disorders, Four 84 (55) $34 (22)$ $15 (10)$ $10 (7)$ $6 (4)$ $4 (3)$ |

between treatment groups (log-rank test, p=.28). In subgroup analyses, there was no difference in retention between treatment groups at either the methadone (p=.15) or the nonmethadone (p=.60) study sites. Smoking cessation counseling attendance rates across all sites were moderate, with the highest levels of attendance (40%-60%) seen during Weeks 1-3 after the target quit date. Overall, 86% of participants assigned to SC treatment attended at

least one counseling session, 47% attended at least five counseling sessions, and 1% attended all nine counseling sessions. There was no difference in counseling attendance between participants in methadone programs and those in nonmethadone programs. Adherence with daily patch use across all sites was highest (50%–80%) during Weeks 1–3 after the target quit date. Overall, 83% of participants assigned to SC used nicotine patches for at least 1 week, 58% used nicotine patches for at least 4 weeks, and 34% used the patches through the end of treatment. Adherence to nicotine patch was greater among participants in methadone programs versus those in nonmethadone programs, F(1,141) = 6.75, p < .05. None of the participants assigned to the TAU condition reported any SC treatment during the study.

3.3. Smoking abstinence

The rates of smoking abstinence across weeks in the trial are shown in Fig. 2. As can be seen, smoking abstinence rates in the SC condition were 10%-11% during Weeks 2-7, whereas abstinence rates in TAU were negligible. There was a significant main effect of treatment, F(1,1724) = 2.81, p < .01. Smoking abstinence rates in SC at follow-up were 5.5% at Week 13 and 5.7% at Week 26, as compared with 0% at Week 13 and 5.2% at Week 26 in TAU, $\chi^2(1) = 3.395$, p = .065, for Week 13 and $\chi^2(1) = 0.002$, p = .963, for Week 26. Total number of weeks abstinent during treatment was positively associated with counseling adherence (r = 0.306, p < .001) and, at a weaker level, with nicotine patch adherence (r = 0.152, p < .05). Smoking abstinence rates in the SC group were similar between male and female participants, F(1,1018) = 1.93, p = .16.

3.4. Other smoking outcomes

The average number of cigarettes smoked per day is plotted by treatment week in Fig. 3. There was roughly a 75% reduction in the number of cigarettes smoked per day, F(8,1084) = 10.84, p < .001, and there was a more modest



Fig. 2. Percentage of study participants meeting criteria for smoking abstinence across the study weeks (-1 through 9) by treatment group. Smoking abstinence criteria included self-report of no smoking over the last week confirmed by an exhaled breath CO level of 10 ppm or lower.



Fig. 3. Average number of cigarettes smoked per day reported by study participants across the study weeks (-1 through 9) by treatment group.

decrease in exhaled CO levels, F(1,751) = 22.64, p < .001, in SC compared with TAU. Average number of cigarettes smoked per day in SC at follow-up on Week 13 (8.8 ± 9.1) and that on Week 26 (10.2 ± 8.5) were slightly higher than those during treatment but still significantly less than the numbers in TAU on Week 13 (14.9 ± 8.9) and Week 26 (15.1 ± 9.0), t = 5.90, p < .001, for Week 13 and t = 4.25, p < .001, for Week 26. Nicotine withdrawal symptoms also decreased during treatment, F(1,346) = 4.03, p < .05, as did craving for cigarettes, F(1,175) = 5.02, p < .05, in SC compared with TAU.

3.5. Substance abuse treatment outcomes

Retention in substance abuse rehabilitation through the end of study treatment was excellent, approximately 93% for all participants, and was not different between treatment groups (log-rank test, p=.28). In subgroup analyses, there was no difference in substance abuse rehabilitation retention between SC and TAU participants in methadone programs (SC = 93%, TAU = 98%, p=.17) and those in nonmethadone programs (SC = 84%, TAU = 93%, p=.38). However, a significant interaction between treatment and program type, $\chi^2(1) = 14.63$, p < .001, on substance abuse rehabilitation counseling attendance rates was observed. This difference in attendance between SC and TAU was greater in the nonmethadone programs (SC = 64%, TAU = 80%) as compared with the methadone programs (SC = 89%, TAU = 91%).

Abstinence rates for primary substance of abuse were approximately 50%–60% through the end of treatment (Fig. 4). There was no difference in abstinence rates between SC and TAU over the course of treatment, F(1,1632) = 0.00, p = .955, and there was no main effect of treatment, F(1,1633) = 0.82, p = .444. Similar results were obtained when using a model adjusted for patients' baseline abstinence status. Primary substance of abuse abstinence rates at follow-up on Week 13 (SC = 52%, TAU = 60%) and Week 26 (SC = 48%, TAU = 48%) were similar to those seen during study treatment and were not significantly different by treatment group, $\chi^2(1) = 1.074$, p = .300, for Week 13 and $\chi^2(1) = 0.084$, p = .771, for Week 26. Self-reported craving (Brief

Substance Craving Scale total score) for primary substance of abuse underwent a significant decrease across time in both treatment groups, F(1,1629) = 47.07, p < .001, with no effect of treatment condition, F(1,1629) = 0.01, p = .920.

3.6. Smoking cessation and substance abuse

On average, 85% of smoking-abstinent participants and 55% of smoking-nonabstinent participants were abstinent from their primary substance of abuse. However, a GLMM fit to substance abuse abstinence status did not find smoking abstinence to be a statistically significant predictor, F(1,874) = 2.00, p = .157, probably because of the small number of nonsmoking participants in the data set. Similar results were found for daily smoking rates during treatment, F(1,1260) = 0.75, p = .385. However, comparison of substance abuse craving levels with daily smoking rates revealed a significant effect in which fewer cigarettes smoked per day predicted lower craving for primary substance of abuse during the same period, F(1,1091) = 20.03, p < .001.

4. Discussion

This study was undertaken to examine the effectiveness of SC treatment among patients enrolled in outpatient community-based substance abuse rehabilitation programs and to examine its impact on the treatment for their primary drug or alcohol problem. A combination of NRT and cognitive—behavioral/mood management counseling was found to be safe and modestly effective, producing small increases in abstinence from smoking but significant reductions in number of cigarettes smoked, breath CO levels, and craving for cigarettes. Smoking cessation treatment was well accepted by patients in terms of compliance measures and program retention, and there was no adverse impact on the substance abuse treatment outcomes.

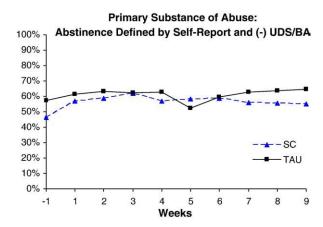


Fig. 4. Percentage of study participants meeting criteria for abstinence from their primary substance of abuse across the study weeks (-1 through 9) by treatment group. Primary substance of abuse abstinence criteria included self-report of no use over the last week confirmed by urine drug screen or breath alcohol test results negative for that substance.

Weekly point prevalence smoking abstinence rates in the treatment group increased to 10% by Week 2 and remained near this level through the end of treatment and then decreased to between 5% and 6% at the 3- and 6-month follow-up points. These are considerably lower than the abstinence rates of 30%-50% at the end of treatment and 10%-20% at the long-term follow-up typically observed with SC interventions in the general population (Fiore, Smith, Jorenby, & Baker, 1994; Gonzalez et al., 2006; Hughes, Goldstein, Hurt Richard, & Schiffman, 1999; Jorenby et al., 1999, 2006; Rose, Levin, Behm, Adivi, & Schur, 1990), but they are consistent with the lower end-oftreatment and follow-up smoking abstinence rates, averaging 12% and 7%, respectively, reported in a review of studies on SC treatment with patients in substance abuse rehabilitation programs (Prochaska, Delucchi, & Hall, 2004). Observational studies in general population samples suggested that repeated quit attempts are associated with greater smoking abstinence rates (Etter & Sutton, 2002; Knoke, Andersen, & Burns, 2006; Richards et al., 2003). Furthermore, other medications, bupropion and varenicline, are equally if not more powerful than NRT in promoting abstinence (Fiore et al., 1994; Gonzalez et al., 2006; Hughes, Goldstein, et al., 1999; Jamerson et al., 2001; Jorenby et al., 1999, 2006; Nides et al., 2006). Future studies among drug- and alcoholdependent patients should test the effectiveness of treatment algorithms that move sequentially from NRT to bupropion and varenicline as well as emphasize repeated quit attempts.

Although the modest abstinence rates observed might be viewed as discouraging, it is not surprising that nicotine dependence would be more difficult to treat among drug- and alcohol-dependent patients, who likely carry a greater vulnerability to addictions in general. The 75% reduction in self-reported cigarette consumption during treatment is more impressive, resembles observations from other studies (Burling et al., 1991; Gariti et al., 2002; Kalman et al., 2001; Saxon et al., 1997; Shoptaw et al., 2002), and was corroborated by findings of reduced breath CO levels. Moreover, reduced smoking in the treated group was partially maintained at the 6-month follow-up. The clinical significance of such reductions in smoking short of abstinence is controversial, however (Carpenter, Hughes, Solomon, & Callas, 2004; Hughes, Cummings, & Hyland, 1999; Hughes, Lindgren, Connett, & Nides, 2004). Despite some patients quitting smoking and many reducing their daily smoking, cigarette craving and withdrawal did not increase. Rather, both measures decreased in the SC group. This may be attributed to the effectiveness of the psychosocial and pharmacological treatments in managing these symptoms or, alternatively, the ability of participants to manage symptoms with only a small number of cigarettes.

An important goal of this study was to address the belief, still common in the treatment community, that SC treatment will interfere with treatment of patients' primary drug or alcohol problem. This is important because it is a likely barrier to the widespread adoption of SC interventions for

drug- and alcohol-dependent patients. Data addressing this concern are limited and variable, with most studies showing either no change (Burling et al., 2001; Gariti et al., 2002) or improvement (Bobo et al., 1998; Kalman et al., 2001) in drug and alcohol abstinence rates as a function of SC treatment, although a few have reported worsening (Joseph, 1993; Joseph, Willenbring, et al., 2004). There was no support for this concern in the present data as no difference in treatment retention, craving, and substance abuse abstinence rates was observed between the treatment and control groups. The only impact on substance abuse treatment detected was a drop in substance abuse counseling attendance among patients in nonmethadone treatment programs. Interestingly, attendance returned to pretreatment levels as soon as the SC counseling program ended. However, caution is in order when interpreting the present data on substance abuse treatment outcomes. Many of the patients who enrolled in this trial were established patients of long tenure, particularly in the methadone programs, so the issue of aggressive treatment of smoking at the outset of a course of substance abuse treatment is less clearly addressed. It can be argued that a treatment regimen with a more powerful impact on smoking might unmask a greater tendency for other forms of substance abuse to worsen, perhaps through the mechanism of substituting one drug for another. However, observational (Lemon, Friedmann, & Stein, 2003) and treatment intervention (Shoptaw et al., 2002) studies, as well as correlations in the present data, suggest that smoking abstinence and reduced smoking are associated with lower drug craving and higher rates of substance abuse abstinence. These are also consistent with prior studies of nicotine agonist and antagonist effects on cue-induced cocaine craving (Reid, Mickalian, Delucchi, & Berger, 1999; Reid, Mickalian, Delucchi, Hall, & Berger, 1998).

The strengths of this study include the generalizability of the findings, with treatment conducted by community-based programs across multiple sites and an intervention with a low dropout rate. Average treatment adherence rates, 41% of counseling sessions attended and 61% of the patches used according to protocol, although leaving room for improvement, were comparable with those observed in other SC studies done in outpatient substance abuse treatment settings (Gariti et al., 2002; Joseph, Willenbring, et al., 2004; Saxon et al., 2003; Shoptaw et al., 2002) and with studies on the treatment of chronic medical conditions such as hypertension and diabetes (McLellan, Lewis, O'Brien, & Kleber, 2000). The importance of treatment adherence was noted by the positive correlation of both counseling and medication adherence with smoking abstinence rates.

The weaknesses of this study include the preponderance of methadone clinics in the sample, which included only two nonmethadone outpatient programs, accounting for only 20% of the patient sample. More outpatient programs originally signed up for the study but dropped out when recruitment proved infeasible (see Reid et al., 2007). The group treatment format, although favored by providers for its

low cost of delivery, appeared to be one of the key barriers to enrollment because it did not suit patients' needs for flexibility of scheduling and may also have figured in the limited counseling adherence rates (Reid et al., 2007). The present design did not separate the contributions of the cognitive—behavioral/mood management counseling versus the nicotine replacement to smoking abstinence rates and reductions in smoking. Varying levels of intensity of behavioral treatment might be examined in future studies, but consideration should be given to brief interventions that can be integrated with other individual or group substance abuse counseling sessions.

Cigarette smoking among drug- and alcohol-dependent patients is of high public health significance because of its prevalence, chronicity, and serious adverse health consequences. The present study showed that a combination of nicotine patch and cognitive-behavioral/mood management counseling was feasible to implement in outpatient community-based substance abuse treatment settings, was effective in producing modest abstinence rates and strong reductions in smoking behavior, and did not worsen the outcomes of the primary drug or alcohol problem. Future research should examine more powerful medications for SC as well as behavioral interventions that can be integrated in a flexible fashion into existing substance abuse treatments minimizing barriers to participation and should consider algorithms with a stepped approach to SC with an emphasis on a chronic disease model and repeated quit attempts. Bupropion and varenicline are prescription SC medications also worth considering.

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References

- Bobo, J. K., Lando, H. A., Walker, R. D., & McIlvain, H. E. (1996). Predictors of tobacco quit attempts among recovering alcoholics. *Journal of Substance Abuse*, 8, 431–433.
- Bobo, J. K., McIlvain, H. E., Lando, H. A., Walker, R. D., & Leed-Kelly, A. (1998). Effect of smoking cessation counseling on recovery from alcoholism: Findings from a randomized community intervention trial. *Addiction*, 93, 877–887.
- Budney, A. J., Higgins, S. T., Hughes, J. R., & Bickel, W. K. (1993). Nicotine and caffeine use in cocaine-dependent individuals. *Journal of Substance Abuse*, 5, 117–130.
- Burling, T. A., Burling, A. S., & Latini, D. (2001). A controlled smoking cessation trial for substance-dependent patients. *Journal of Consulting* and Clinical Psychology, 69, 295–304.
- Burling, T. A., Marshall, G. D., & Seidner, A. L. (1991). Smoking cessation for substance abuse inpatients. *Journal of Substance Abuse*, *3*, 269–276.
- Campbell, B. K., Wander, N., Stark, M. J., & Holbert, T. (1995). Treating cigarette smoking in drug-abusing clients. *Journal of Substance Abuse Treatment*, 12, 89–94.
- Capretto, N. A. (1993). Confronting nicotine dependency at the Gateway Rehabilitation Center. *Journal of Substance Abuse Treatment*, 10, 113–116
- Carpenter, M. J., Hughes, J. R., Solomon, L. J., & Callas, P. W. (2004). Both smoking reduction with nicotine replacement therapy and motivational advice increase future cessation among smokers unmotivated to quit. *Journal of Consulting and Clinical Psychology*, 72, 371–381.
- Clarke, J. G., Stein, M. D., McGarry, K. A., & Gogineni, A. (2001). Interest in smoking cessation among injection drug users. *American Journal on Addictions*, 10, 159–166.
- Curry, S. J., Grothaus, L., & McBride, C. (1997). Reasons for quitting: Intrinsic and extrinsic motivation for smoking cessation in a population-based sample of smokers. *Addictive Behaviors*, 22, 727–739.
- Etter, J. F., & Sutton, S. (2002). Assessing 'stage of change' in current and former smokers. *Addiction*, 97, 1171–1182.
- Fiore, M. C., Smith, S. S., Jorenby, D., & Baker, T. (1994). The effectiveness of the nicotine patch for smoking cessation: A meta-analysis. *Journal of* the American Medical Association, 271, 1940–1947.
- Frosch, D. L., Shoptaw, S., Jarvik, M. E., Rawson, R. A., & Ling, W. (1998). Interest in smoking cessation among methadone maintained outpatients. *Journal of Addictive Diseases*, 17, 9–19.
- Gariti, P., Alterman, A., Mulvaney, F., Mechanic, K., Dhopesh, V., Yu, E., et al. (2002). Nicotine intervention during detoxification and treatment for other substance use. *American Journal of Drug and Alcohol Abuse*, 28, 671–679.
- Gill, B. S., & Bennett, D. L. (2000). Addiction professionals' attitudes regarding treatment of nicotine dependence. *Journal of Substance Abuse Treatment*, 317–318 (Letter to the editor).
- Gonzalez, D., Rennard, S. I., Nides, M., Oncken, C., Azoulay, S., Billing, C. B., et al. (2006). Varenicline, an α4β2 nicotinic acetylcholine receptor partial agonist, vs sustained-release bupropion and placebo for smoking cessation. *Journal of the American Medical Association*, 296, 47–55.
- Hall, S. H., Munoz, R. F., & Reus, V. (1994). Cognitive-behavioral intervention increases abstinence rates for depressive-history smokers. *Journal of Consulting and Clinical Psychology*, 62, 141–146.

- Heatherton, T., Kozlowski, L., Freckler, R., & Fagerstrom, K. (1991).
 The Fagerstrom Test for Nicotine Dependence: A revision of the Fagerstrom Tolerance Questionnaire. *Journal of Consulting and Clinical Psychology*, 86, 1119–1127.
- Hughes, J. R. (1993). Treatment of smoking cessation in smokers with past alcohol/drug problems. *Journal of Substance Abuse Treatment*, 10, 181–187.
- Hughes, J. R., Cummings, K. M., & Hyland, A. (1999). Ability of smokers to reduce their smoking and its association with future smoking cessation. *Addiction*, 94, 109–114.
- Hughes, J. R., Goldstein, M. G., Hurt Richard, R. D., & Schiffman, S. (1999). Recent advances in the pharmacotherapy of smoking. *Journal of the American Medical Association*, 281, 72–76.
- Hughes, J. R., Gust, S. W., Skoog, K., Keenan, R. M., & Fenwick, J. W. (1991). Symptoms of tobacco withdrawal: A replication and extension. *Archives of General Psychiatry*, 48, 52–59.
- Hughes, J. R., & Hatsukami, D. (1986). Signs and symptoms of tobacco withdrawal. Arch Gen Psychiatry, 43, 289–294.
- Hughes, J. R., Lindgren, P., Connett, J., & Nides, M. (2004). Smoking reduction in the Lung Health Study. Nicotine & Tobacco Research, 6, 275–280.
- Hurt, R. D., Eberman, K. M., Croghan, I. T., Offord, K. P., Davis, L. J., Morse, R. M., et al. (1994). Nicotine dependence treatment during inpatient treatment for other addictions: A prospective intervention trial. *Alcoholism, Clinical and Experimental Research*, 18, 867–872.
- Hurt, R. D., Eberman, K. M., Slade, J., & Karan, L. (1993). Treating nicotine addiction in patients with other addictive disorders. In C.T., Orleans & J., Slade (Eds.), *Nicotine addiction: Principles and management* (pp. 310–326). New York: Oxford University Press.
- Hurt, R. D., Offord, K. P., Croghan, I. T., Gomez-Dahl, L., Kottke, T. E., Morse, R. M., et al. (1996). Mortality following inpatient addictions treatment: Role of tobacco use in a community-based cohort. *Journal of the American Medical Association*, 275, 1097–1103.
- Irving, L. M., Seidner, A. L., Burling, T. A., Thomas, R. G., & Brenner, G. F. (1994). Drug and alcohol abuse inpatients' attitudes about smoking cessation. *Journal of Substance Abuse Treatment*, 6, 267–278.
- Jamerson, B. D., Nides, M., Jorenby, D. E., Donahue, R., Garrett, P., Johnston, J. A., et al. (2001). Late-term smoking cessation despite initial failure: An evaluation of bupropion, sustained release, nicotine patch, combination therapy, and placebo. *Clinical Therapeutics*, 23, 744–752
- Jorenby, D. E., Hays, J. T., Rigotti, N. A., Azoulay, S., Watsky, E. J., Williams, K. E., et al. (2006). Efficacy of varenicline, an alpha4beta2 nicotinic acetylcholine receptor partial agonist, vs placebo or sustainedrelease bupropion for smoking cessation: A randomized controlled trial. *Journal of the American Medical Association*, 296, 56–63.
- Jorenby, D. E., Leischow, S. J., Nides, M. A., Rennard, S. I., Johnston, J. A., Hughes, A. R., et al. (1999). A controlled trial of sustained release bupropion, a nicotine patch, or both for smoking cessation. *New England Journal of Medicine*, 340, 685–691.
- Joseph, A. M. (1993). Nicotine treatment at the drug dependency program of the Minneapolis VA Medical Center: A researcher's perspective. *Journal of Substance Abuse Treatment*, 10, 147–152.
- Joseph, A. M., Lexau, B., Willenbring, M., Nugent, S., & Nelson, D. (2004).
 Factors associated with readiness to stop smoking among patients in treatment for alcohol use disorder. *American Journal on Addictions*, 13, 405–417
- Joseph, A. M., Willenbring, M. L., Nugent, S. M., & Nelson, D. B. (2004). A randomized trial of concurrent versus delayed smoking intervention for patients in alcohol dependence. *Journal of Studies on Alcohol*, 65, 681–691.
- Kalman, D., Haves, K., Colby, S. M., Eaton, C. A., Rohsenow, D. J., & Monti, P. M. (2001). Concurrent versus delayed smoking cessation treatment for persons in early alcohol recovery: A pilot study. *Journal of Substance Abuse Treatment*, 20, 233–238.
- Kalman, D., Morissete, S. B., & George, T. P. (2005). Co-morbidity of smoking in patients with psychiatric and substance use disorders. *American Journal on Addictions*, 14, 106–123.

- Knapp, J. M., Rosheim, C. L., Meister, E. A., & Kottke, T. E. (1993).
 Managing tobacco dependence in chemical dependency treatment facilities: A survey of current attitudes and policies. *Journal of Addictive Diseases*, 12, 89–104.
- Knoke, J. D., Andersen, C. M., & Burns, D. M. (2006). Does a failed quit attempt reduce cigarette consumption following resumption of smoking? The effects of time and quit attempts on the longitudinal analysis of selfreported cigarette smoking intensity. *Nicotine & Tobacco Research*, 8, 415–423.
- Kreek, M. J. (1987). Multiple drug use patterns and their consequences. In M. Y., Meltzer (Ed.), *Psychopharmacology: The third generation of progress* (pp. 1597–1604). NY: Raven Press.
- Lemon, S. C., Friedmann, L., & Stein, M. D. (2003). The impact of smoking cessation on drug abuse treatment outcome. *Addictive Behaviors*, 28, 1323–1331.
- McLellan, A. T., Lewis, D. C., O'Brien, C. P., & Kleber, H. D. (2000). Drug dependence, a chronic medical illness. Implications for treatment, insurance, and outcomes evaluation. *Journal of the American Medical Association*, 284, 1689–1695.
- McLellan, A. T., Luborsky, L., Cacciola, J., Griffith, J., Evans, F., Barr, H. L., et al. (1985). New data from the Addiction Severity Index: Reliability and validity in three centers. *Journal of Nervous and Mental Disease*, 173, 412–423.
- Munoz, R. F., Organista, K., & Hall, S. M. (1988). Mood management training to prevent smoking relapse: A cognitive-behavioral treatment manual. San Francisco: Department of Psychiatry, University of California.
- Nides, M., Oncken, C., Gonzales, D., Rennard, S., Watsky, E. J., Anziano, R., et al. (2006). Smoking cessation with varenicline, a selective alpha4beta2 nicotinic receptor partial agonist: Results from a 7-week, randomized, placebo- and bupropion-controlled trial with 1-year follow-up. Archives of Internal Medicine, 166, 1561–1568.
- Patten, C. A., Martin, J. E., Myers, M. G., Calfas, K. J., & Williams, C. D. (1998). Effectiveness of cognitive-behavioral therapy for smokers with histories of alcohol dependence and depression. *Journal of Studies on Alcohol*, 59, 327–335.
- Pletcher, V. C. (1993). Nicotine treatment at the drug dependency program of the Minneapolis VA Medical Center. *Journal of Substance Abuse Treatment*, 10, 139–145.
- Prochaska, J. J., Delucchi, K., & Hall, S. M. (2004). A meta-analysis of smoking cessation interventions with individuals in substance abuse treatment or recovery. *Journal of Consulting and Clinical Psychology*, 72, 1144–1156.
- Reid, M. S., Mickalian, J. D., Delucchi, K., & Berger, S. P. (1999). A nicotine antagonist, mecamylamine, reduces cue-induced cocaine craving in cocaine-dependent subjects. *Neuropsychopharmacology*, 20, 297–307.
- Reid, M. S., Mickalian, J. D., Delucchi, K. L., Hall, S. M., & Berger, S. P. (1998). An acute dose of nicotine enhances cue-induced cocaine craving. *Drug and Alcohol Dependence*, 49, 95–104.
- Reid, M. S., Fallon, B., Sonne, S., Nunes, N., Lima, J., Tyson, C., et al. (2007). Implementation of smoking cessation treatment at substance abuse rehabilitation programs: Smoking behavior and treatment feasibility across varied community-based outpatient programs. *Journal of Addiction Medicine* (in press).
- Richards, D., Toop, L., Brockway, K., Graham, S., McSweeney, B., MacLean, D., et al. (2003). Improving the effectiveness of smoking cessation in primary care: Lessons learned. New Zealand Medical Journal, 116, U417.
- Rose, J. E., Levin, E. D., Behm, F. M., Adivi, C., & Schur, C. (1990). Transdermal nicotine facilitates smoking cessation. *Clinical Pharmacology And Therapeutics*, 47, 323–330.
- Rustin, T. (1998). Incorporating nicotine dependence into addiction treatment. *Journal of Addictive Diseases*, 17, 83–108.
- SAS Institute. (1990a). SAS/STAT user's guide, version 6, vol. 1. (4th ed., pp. 943). Cary, NC: SAS Institute.
- SAS Institute. (1990b). SAS/STAT user's guide, version 6, vol. 2. (4th ed., pp. 839). Cary, NC: SAS Institute.

- Saxon, A. J., Baer, J. S., Davis, T. M., Sloan, K. L., Malte, C. A., Fitzgibbons, K., et al. (2003). Smoking cessation treatment among dually diagnosed individuals: Preliminary evaluation of different pharmacotherapies. *Nicotine & Tobacco Research*, 5, 589–596.
- Saxon, A. J., McGuffin, R., & Walker, R. D. (1997). An open trial of transdermal nicotine replacement therapy for smoking cessation among alcohol- and drug-dependent inpatients. *Journal of Substance Abuse Treatment*, 14, 333–337.
- Schnoll, S. H., Daghestani, A. N., Karrigan, J., Kitchen, S. B., & Hansen, T. (1985). Characteristics of cocaine abusers presenting for treatment. *NIDA Research Monograph*, 61, 171–181.
- Sharp, J. R., Schwartz, S., Nightingale, T., & Novak, S. (2003, November). Targeting nicotine addiction in a substance abuse program. Clinical perspectives—Targeting nicotine addiction. *NeATTC Newsletter*, 33–39.

- Shoptaw, S., Rotheram-Fuller, E., Yang, X., Frosch, D., Nahom, D., Jarvik, M. E., et al. (2002). Smoking cessation in methadone maintenance. *Addiction*, 97, 1217–1228 (Discussion 1325).
- Stark, M. J., & Campbell, B. K. (1993). Drug use and cigarette smoking in applicants for drug abuse treatment. *Journal of Substance Abuse*, 5, 175–181.
- Sterling, R. C., Gottheil, E., Weinstein, S. P., Kurtz, J. W., & Menduke, H. (1994). The effect of a no-smoking policy on recruitment and retention in outpatient cocaine treatment. *Journal of Addictive Diseases*, 13, 161–168.
- Tonneatto, A., Sobell, L., Sobell, M. B., & Kozlowski, L. T. (1995). Effect of cigarette smoking on alcohol treatment outcome. *Journal of Substance Abuse Treatment*, 7, 245–252.
- Zullino, D., Besson, J., & Schnyder, C. (2000). Stage of change of cigarette smoking in alcohol-dependent patients. *European Addiction Research*, 6, 84–90.