



Predictors of tobacco abstinence in outpatient smokers with schizophrenia or bipolar disorder treated with varenicline and cognitive behavioral smoking cessation therapy



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HIGHLIGHTS

- Smoking remains an epidemic among those with SMI, responsible for large disparities in mortality.
- Less withdrawal, smoking less, and attentional performance were associated with abstinence.
- Past alcohol dependence and anticipating less support were associated with abstinence.

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ABSTRACT

Background: The estimated mortality gap between those with and without serious mental illness (SMI) is increasing, now estimated at 28 years, which is largely due to smoking-related diseases.

Aims: We sought to identify predictors of 14-day continuous abstinence in stable outpatient smokers with SMI.

Method: Adult smokers with schizophrenia spectrum ($n = 130$) or bipolar disorder ($n = 23$) were enrolled in a 12-week course of varenicline and cognitive-behavioral therapy for smoking cessation.

Results: Independent predictors of abstinence included reduction in withdrawal symptoms prior to the quit day, fewer cigarettes smoked per day at baseline, better baseline attention, remitted alcohol dependence, and lower expectation of peer support to aid quitting.

Conclusions: Interventions that consider these targets may improve smoking cessation outcomes in those with SMI.

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1. Introduction

Recent estimates indicate that 64–79% of those with schizophrenia spectrum disorders smoke tobacco regularly (Dickerson et al., 2013; Hartz et al., 2014), as do 44–71% of those with bipolar disorder (Dickerson et al., 2013; Hartz et al., 2014; Kreinin, Novitski, Rabinowitz, Weizman, & Grinshpoon, 2012), compared to 18% of the general U.S. population (Agaku, King, & Dube, 2014; Le Cook et al., 2014; USDHHS, 2004). Moreover, the estimated mortality gap

between those with and without schizophrenia spectrum disorders is now estimated to be 28 years, is increasing, and is largely due to diseases that are causally related to tobacco smoking (Olfson, Gerhard, Huang, Crystal, & Stroup, 2015). Although pharmacologic smoking cessation aids are effective and well tolerated in this population (Chengappa et al., 2014; Evins et al., 2014; Goff et al., 2005; Heffner, Lee, Arteaga, & Anthenelli, 2010; Pachas et al., 2012; Roberts, Evins, McNeill, & Robson, 2016; Tsoi, Porwal, & Webster, 2013; Weiner et al., 2011; Williams et al., 2012; Ziedonis et al., 2008), smokers with serious mental illness (SMI) are less likely to receive smoking cessation interventions (Druss, Bradford, Rosenheck, Radford, & Krumholz, 2001; Goff et al., 2005; Heffner & Anthenelli, 2011; Himelhoch & Daumit, 2003; Kupfer, 2005; Prochaska, 2010, 2011; Schroeder & Morris, 2010; Ziedonis et al., 2008) despite often being highly motivated to quit

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smoking (Addington, el-Guebaly, Addington, & Hodgins, 1997; Evins et al., 2004).

Among those with psychiatric illness receiving brief behavioral treatment for smoking cessation, varenicline treatment results in superior abstinence rates than placebo, nicotine patch and bupropion (Anthenelli et al., 2016). However, predictors of abstinence with varenicline among smokers with psychiatric illness have not yet been extensively studied, with the exception of a preliminary investigation that identified affective flattening as a negative predictor of abstinence in a modest sample (Dutra, Stoeckel, Carlini, Pizzagalli, & Evins, 2012). Predictors of abstinence with other smoking cessation pharmacotherapies in this population include cigarettes per day (Culhane et al., 2008), readiness to quit (Chou et al., 2015; Ferron et al., 2012), later age of smoking initiation (Culhane et al., 2008), male gender (Gonzalez-Pinto et al., 2012), and better attention and executive functioning (Culhane et al., 2008; Dolan et al., 2004; Moss et al., 2009; Steinberg et al., 2012). In the general population, predictors of abstinence with varenicline include less severe nicotine dependence (Boudrez, Hoengenaert, Nackaerts, Messig, & Metcalfe, 2013), no recent quit attempts (Heffner et al., 2010), and early initiation of abstinence during treatment (Heffner et al., 2010). Identifying characteristics of smokers most likely to quit with varenicline could inform providers who may be hesitant to prescribe to smokers with SMI (Mitchell, Vancampfort, De Hert, & Stubbs, 2015; Ratschen, Britton, Doody, Leonardi-Bee, & McNeill, 2009), thereby increasing access to guideline-concordant smoking cessation treatment.

We sought to identify independent predictors of abstinence in a sample of outpatient smokers with schizophrenia or bipolar disorder treated with 12 weeks of open label varenicline and cognitive-behavioral therapy (CBT). Candidate predictors included factors associated with abstinence in smokers treated with varenicline in the general population (e.g., smoking characteristics, prior quit attempts, and early response to treatment) and in smokers with SMI across different cessation treatments (e.g., gender, cognition), as well as potential novel predictors including smoking environment and physical health.

2. Material and methods

The study was approved by the institutional review boards at all study sites and by an independent data and safety monitoring board. Participants provided written informed consent and demonstrated understanding of study procedures via a written test of competency to consent.

2.1. Participants

Two hundred and four participants were enrolled in the parent trial (Evins et al., 2014) involving a 12-week, open-label trial of varenicline and weekly group CBT for smoking cessation (NCT00621777). Participants were stable adult outpatient daily smokers with a DSM-IV-TR diagnosis of schizophrenia, schizoaffective disorder, or bipolar disorder, enrolled from 10 community mental health centers in six states. Participants were eligible to enroll who smoked ≥ 10 cigarettes per day, had expired carbon monoxide (CO) >9 parts per million (ppm), were on a stable, clinically determined antipsychotic or mood stabilizing medication for at least one month before enrollment, and willing to take varenicline and set a quit date within four weeks of enrollment. Current or recent suicidality or homicidality, hospitalization for suicidality in the prior 12 months, a major depressive episode in the prior six months, an active substance use disorder, or unstable medical illness were exclusionary. Analyses only included the 153 participants (75% of participants in parent project) who had withdrawal scores within two weeks of the quit date, as change in withdrawal was evaluated as a predictor of abstinence.

2.2. Intervention

The 12-week intervention (Pachas et al., 2012) was open label varenicline 0.5 mg once daily for three days, 0.5 mg twice daily for four days, then 1 mg twice daily for 11 weeks, along with weekly one-hour manualized group CBT for smokers with SMI (Cather et al., 2013). Participants began study medication at baseline and set a quit date between study weeks four and five.

Fourteen-day point prevalence abstinence at study week 12 was the outcome of interest and was defined as self-reported 7-day continuous abstinence at study week 12, biochemically verified by semi-quantitative urine cotinine (Accutest NicAlert Urine Screen, Jant Pharmaceuticals) and self-reported 7-day continuous abstinence at study week 11, biochemically verified by expired CO <9 ppm. Expired CO was assessed at all study visits and CO <9 ppm was the a priori CO concentration cut-off for biochemical confirmation of self-reported abstinence at week 12 if cotinine data were missing (Hughes et al., 2003; Evins et al., 2014). Participants who discontinued the study before week 12 ($n = 39$) were considered to be non-abstinent for the analyses (Hajek et al., 2013).

2.3. Candidate predictors (Table 2)

2.3.1. Cognitive performance

Participants were administered three measures of neurocognition at baseline, which yielded over 25 variables. A principal component analysis (PCA) was conducted for variable reduction, as in prior studies with this population (Kern et al., 2006). Orthogonal rotation produced five factors with eigenvalues >1 : vigilance, memory, speed of processing, accuracy, and reaction time variability (Table 1). Resultant factors were included as candidate abstinence predictors.

2.3.2. Patient characteristics

Age, gender, race, marital status, history self-reported lifetime alcohol dependence, education, and estimated full-scale IQ (Wechsler Test of Adult Reading, WTAR (Wechsler, 2001)) were assessed at baseline. Prior analyses from this sample indicated no difference in abstinence rates by primary diagnosis, and therefore diagnosis was not considered as a candidate predictor (Evins et al., 2014).

2.3.3. Treatment characteristics

Participants' antipsychotic treatment regimen was assessed at baseline by a clinician. Clozapine versus non-clozapine antipsychotic treatment was examined as a potential predictor of abstinence, as other studies have found clozapine treatment to improve substance use outcomes in general and smoking cessation outcomes in particular compared to other antipsychotic agents (George, Sernyak, Ziedonis, & Woods, 1995; McEvoy et al., 1995).

2.3.4. Smoking characteristics

Expired CO concentration at baseline (Bedfont Smokerlyzer, Kent, England), age of smoking initiation, years smoked, number of cigarettes smoked per day, percent change in number of cigarettes smoked per day from baseline to quit day, severity of nicotine dependence (total score on the Fagerstrom Test for Nicotine Dependence, FTND (Fagerstrom, 2012)), percent change in nicotine withdrawal symptom rating scale total score from baseline to quit day (Wisconsin Smoking Withdrawal Scale, WSWS (Welsch et al., 1999)), smoking expectancies (total score on the Tiffany Questionnaire of Smoking Urges, TQSU (Tiffany & Drobes, 1991)), self-reported motivation to quit smoking, and number of lifetime quit attempts were assessed for each participant.

2.3.5. Smoking environment

At baseline, participants reported the number of people who smoked in their households (other than self), percent of closest friends

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