Brief Report

A Pilot Clinical Trial of Varenicline for Smoking Cessation in Black Smokers

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Abstract

Introduction: Varenicline, a first-line non-nicotine medication, has not been evaluated in Black smokers, and limited attention has been paid to pharmacotherapy adherence in smoking cessation trials. This pilot study estimated quit rates for Black smokers treated with varenicline and tested a behavioral intervention to aid varenicline adherence.

Methods: Seventy-two Black smokers (>10 cigarettes per day; cpd) were randomly assigned to adherence support (AS; $n = 36$) or standard care ($n = 36$). All participants received 3 months of varenicline and a single counseling session focused on making a quit plan. AS participants received 5 additional counseling sessions to encourage medication use. Outcome measures included salivary cotinine, and carbon monoxide confirmed smoking abstinence, reductions in self-reported cpd, and pill counts of varenicline adherence at Months 1, 2, and 3.

Results: Sixty-one participants (84.7%) completed follow-up at Month 3. Participants were female (62.5%), 46.8 years of age, and smoked 16.3 cpd. No treatment group differences were found on the smoking or adherence outcome measures ($p > .05$). Collapsing across treatment, varenicline adherence was adequate (86.1%), yet despite a reduction of 12.2 (6.5) cpd from baseline to Month 3 ($p < 0.001$), only 23.6% were confirmed quit at Month 3. Participants who were quit at Month 3 had higher varenicline adherence rates (95.8%) than those who continued to smoke (80.8%, $p \leq .05$).

Conclusions: Studies are needed to examine the efficacy of varenicline among Black smokers. Interventions to facilitate adherence to pharmacotherapy warrant further attention as adherence is linked to improved tobacco abstinence.

Introduction

Black smokers use fewer cigarettes per day (cpd) than White smokers but bear a disproportionate share of tobacco-related disease (Fu et al., 2008; Trinidad et al., 2009). Blacks have the highest incidence rates for all cancers combined and a 43%–55% higher relative risk of smoking-attributable lung cancer compared with Whites (Haiman et al., 2006). Although Blacks are more likely to attempt to stop smoking within a given year, they are less likely to quit, making the identification of effective tobacco use treatments for this high-risk group a national health priority (Fiore et al., 2008).

Varenicline, a first-line non-nicotine medication approved for tobacco use treatment in 2006, has been found to be more effective than other available pharmacotherapies (Fiore et al., 2008; Garrison & Dugan, 2009). While existing studies are promising, they have been conducted among predominately White smokers (Garrison & Dugan, 2009). In clinical trials of other available therapies—that is, nicotine gum, nicotine patch, and bupropion—Blacks have achieved lower quit rates than those achieved by Whites (Croghan et al., 2010; Cropsey et al., 2009; Gariti et al., 2009; Murray, Connett, Buist, Gerald, & Eichenhorn, 2001). These differences in treatment outcomes support the need to examine the effectiveness of pharmacotherapy, including varenicline, for Black smokers.

Blacks are at increased risk for nonadherence to smoking cessation medications compared with Whites (Cokkinides, Halpern, Barbeau, Ward, & Thun, 2008; Fu et al., 2008). For example, two recent population-based studies found that Blacks were 23%–40% less likely to use nicotine replacement therapy than Whites even after controlling for medication access (Cokkinides et al., 2008; Fu et al., 2008). In addition, two pharmacotherapy trials with Black smokers found no measurable benefit of nicotine patch or nicotine gum (Ahluwalia et al., 2006; Nollen et al., 2007). Secondary analyses revealed less than optimal adherence to pharmacotherapy, which may in turn explain the lack of drug effect for Black smokers in these trials.

Pharmacotherapy adherence has been consistently linked to improved treatment outcomes, but adherence to the prescribed dose and treatment length is necessary to achieve maximum

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drug effect (Hays, Leischow, Lawrence, & Lee, 2010; Shiffman, Sweeney, Ferguson, Sembower, & Gitchell, 2008). Adherence to varenicline may be particularly challenging because of the high frequency of side effects (Garrison & Dugan, 2009). In varenicline trials, more than one third of participants reported side effects, such as nausea, trouble sleeping, and gastrointestinal upset (Garrison & Dugan, 2009). Counseling can help patients manage medication side effects (Mooney, Sayre, Hokanson, Stotts, & Schmitz, 2007), yet only a few studies have looked at the use of counseling to facilitate adherence in smoking cessation clinical trials. Two studies of bupropion utilized brief adherence support (AS) counseling in combination with objectively measured adherence feedback and found that participants receiving counseling and feedback demonstrated greater adherence than those receiving no counseling and feedback (Mooney et al., 2007). Moreover, greater bupropion adherence was associated with higher cessation rates (Mooney et al., 2007). These studies demonstrate the importance of AS counseling in improving pharmacotherapy adherence and smoking abstinence.

Given the lack of data on the efficacy of varenicline in Blacks and lack of attention to behavioral interventions supporting pharmacotherapy adherence, this study estimated quit rates for Black smokers treated with varenicline and tested the ability of an AS program to improve varenicline use. We hypothesized that participants randomized to receive AS counseling would have higher smoking abstinence rates and greater adherence to varenicline than those randomized to standard care (SC).

Methods

Study Design

This was a pilot trial of 72 Black moderate-to-heavy smokers (>10 cigarettes per day; cpd) conducted at a community-based clinic serving a predominately Black population. Medically eligible smokers were randomly assigned to AS (n = 36) or SC (n = 36; described below). Participants provided written informed consent. Study procedures were approved and monitored by the University of Kansas Medical Center's Institutional Review Board.

Participants, Screening, and Randomization

Inclusion criteria included being Black and ≥18 years of age, smoking >10 cpd, wanting to quit, and willing to take varenicline. Participants were excluded if they were planning to move from the area within three months or had contraindications to the use of varenicline, including a cardiovascular event in the month prior to enrollment, renal impairment, taking insulin for diabetes but unwilling to closely monitor blood sugar, or history of clinically significant allergic reactions to varenicline; a major depressive disorder in the past year requiring treatment, history of alcohol or drug dependency in the past year, history of psychosis, panic disorder, bipolar disorder, or any eating disorders; or current breast feeding, pregnancy, or plans to get pregnant in the next three months (Jorenby et al., 2006). Participants were randomized between March and August 2009, with Month 3 follow-up completed by January 2010. A sealed envelope with preassigned randomization numbers was drawn at the randomization visit to determine which form of counseling the participant would receive.

Intervention Components

Culturally Targeted Quit Smoking Guide (SC and AS)

At the randomization visit, all participants received a culturally sensitive guide addressing the health consequences of smoking, benefits of quitting, and strategies to promote abstinence. The guide was developed by members of the investigative team for use in a prior trial and was revised for use in this study to include specific discussion of varenicline for smoking cessation (Ahluwalia et al., 2006).

Varenicline (SC and AS)

At the randomization visit, all participants received a one-month supply of varenicline in a monthly pill box. Participants were verbally instructed on how to take the medication, with titration to full strength in the first week following standard dosing guidelines. Participants were encouraged to initiate varenicline on Day 1, set a quit date on Day 8, and to not smoke cigarettes during the 3-month treatment phase. Participants returned to the clinic at the end of Months 1 and 2 for medication refills.

Standard Counseling (SC and AS)

All participants met with a study counselor during the randomization visit to develop a plan for quitting on Day 8. Counselors followed semi-structured scripts to provide information about the risks of continued smoking, benefits of quitting, discuss strategies for coping with withdrawal and craving, and assist participants in developing a quit plan. This approach is consistent with the current *Treating Tobacco Use and Dependence Clinical Practice Guidelines* and has been found to be effective with Black smokers (Ahluwalia et al., 2006; Fiore et al., 2008; Gariti et al., 2009).

Adherence Counseling (AS Only)

Participants randomized to AS received five additional counseling sessions on Days 8, 12, 20, 30, and 60. Adherence counseling was based on the Information–Motivation–Behavioral Skills model of adherence behavior change (Fisher, Fisher, Amico, & Harman, 2006). Using this model, counselors provided information to enhance participant's motivation in their ability to take the medication as prescribed (e.g., consequences of adherence/nonadherence) and behavioral skills for managing side effects (e.g., nausea) and remembering to take their medication (e.g., timing doses with daily activities). All counseling sessions were audiotaped. Counselors participated in weekly supervision of audiotaped sessions to ensure the integrity of the counseling protocols.

Retention

Participants were called, and postcard reminders were mailed before every counseling visit. Participants were given a $20 gift card at randomization and at Month 3 as compensation for their time/travel.

Measures

Baseline assessment of demographic information included age, gender, and income. Standard smoking questions included cpd, use of menthol or nonmenthol cigarettes, and number of years smoked. Side effects were monitored at Months 1, 2, and 3 by

asking participants about 10 common symptoms associated with quitting smoking and/or smoking cessation pharmacotherapy (e.g., nausea, trouble sleeping, gas). A similar medication symptoms checklist has been used in varenicline clinical trials (Jorenby et al., 2006).

Smoking Cessation Outcomes

Smoking cessation outcomes included salivary cotinine (COT)–verified 7-day point prevalence smoking abstinence at Month 3 with COT of <20 ng/ml indicating abstinence (Benowitz et al., 2002), carbon monoxide–verified abstinence at Months 1 and 2 using the recommended cutoff of <10 parts per million (Benowitz et al., 2002), and reduction in self-reported cpd from baseline to Month 3.

Adherence Outcome

Varenicline adherence was calculated as the total doses taken over the total number of doses prescribed at Months 1, 2, and 3. Adherence was measured by pill counts, a reliable and well-validated approach for assessing medication adherence (Kalichman et al., 2007), completed by research staff during monthly medication refill visits.

Statistical Analyses

Differences between AS and SC on the outcomes of interest were assessed by independent *t* tests for continuous variables and chi-square tests for discrete variables. All data analyses were conducted using SAS v. 9.2 (SAS Institute Inc.). A significance level of $p < .05$ was used for all analyses.

Results

A total of 302 individuals were screened; 116 were eligible and invited to participate, 44 did not keep their randomization appointment, and 72 were randomized. Among the 72 randomized participants, 60 (80.3%), 57 (79.2%), and 61 (84.7%) were followed-up at Months 1, 2, and 3, respectively. There was no difference in attrition by treatment group. No significant baseline differences were seen between treatment groups. Participants smoked an average of 16.3 (5.4) cpd, were 46.8 (11.3) years of age, predominately female (62.5%), and low income (58.2% had a family income <$1,800month). The majority (81.7%) smoked menthol cigarettes.

Smoking Abstinence Rates and Smoking Reduction

Biochemically confirmed abstinence rates for AS and SC are shown in Table 1. No statistically significant differences were found in smoking abstinence rates or smoking reduction by treatment group. Collapsing across treatment, cotinine-verified abstinence at Month 3 was 23.6%. Among participants who continued to smoke, there was a significant reduction in cigarettes smoked per day, with nonquitters reporting smoking 16.1 cpd ($SD = 5.6$) at baseline and 4.5 cpd ($SD = 5.3$) at Month 3, for a mean reduction of 12.2 cpd ($SD = 6.5$; $p < .0001$).

Medication Adherence Rates

Medication adherence rates for AS and SC are shown in Table 1. No statistically significant differences were found in medication adherence by treatment. Collapsing across treatment, participants had 90.4%, 89.4%, and 85.7% adherence at Months 1, 2, and 3, respectively, with an average of 86.1% adherence across all timepoints.

Relationship Between Medication Adherence and Smoking Abstinence

Because no significant differences were found between AS and SC on the outcomes of interest, we collapsed across treatment to examine associations between medication adherence and smoking abstinence. Mean adherence among participants who were quit at Months 1 and 3 was 95.5% and 95.8%, respectively, compared with adherence rates of 85.6% and 80.8% among

Table 1. Smoking Cessation and Adherence Outcomes by Treatment Group

	Smoking cessation outcomes			
	Overall	Adherence Support	Standard Care	p[b]
	Cotinine-verified (<20 ng/ml), n (%)[a]			
Quit at Month 3	17 (23.6)	8 (22.2)	9 (25.0)	0.78
	Carbon monoxide-verified (<10 ppm), n (%)[a]			
Quit at Month 1	13 (18.1)	6 (18.8)	7 (25.0)	0.55
Quit at Month 2	11 (15.3)	5 (18.5)	6 (20.7)	0.84
	Reduction in cigarettes per day, Mean (SD)			
Baseline to Month 3	12.2 (6.5)	11.3 (5.7)	13.4 (7.4)	0.31
	Medication adherence outcomes			
	Overall	Adherence Support	Standard Care	p[b]
	Adherence %, mean (SD)			
% adherence at Month 1	90.4 (18.1)	85.8 (23.0)	90.7 (9.5)	0.27
% adherence at Month 2	89.4 (18.1)	91.7 (17.4)	87.1 (18.9)	0.37
% adherence at Month 3	85.7 (30.8)	82.1 (36.4)	89.2 (24.4)	0.48

Note. [a]Lost to follow-up treated as smokers
[b]Adherence Support versus Standard Care

participants who continued to smoke ($p < .05$). In addition, participants who were quit at Month 3 had significantly higher Month 1 adherence (95.3%) compared with those who continued to smoke (85.6%, $p = .006$). No significant associations were found between medication adherence and smoking abstinence at Month 2.

Side Effects

Side effects attributed to varenicline are displayed in Figure 1. Participants experienced, on average, 2.9 ($SD = 1.8$) side effects during the 3–month treatment phase. The most common side effects were abnormal dreams (86.0%), nausea (77.0%), and gas (63.2%). No significant relationships were found between side effects, medication adherence, or smoking abstinence ($p > .05$).

Discussion

Contrary to the hypothesis, this pilot study found that adherence counseling was not associated with higher smoking abstinence or medication adherence relative to SC. While there was a reduction of 12.2 cpd ($SD = 6.5$) from baseline to Month 3, quit rates were lower than expected. Specifically, despite good overall adherence (86.1% of doses taken), cotinine-verified abstinence at Month 3 was 23.6%. Among White smokers in varenicline clinical trials, continuous abstinence rates at Month 3 (end of varenicline treatment) are 43%–69%, while continuous abstinence rates range from 30% to 47% at Month 6 and 22% to 35% at Month 12 (Garrison & Dugan, 2009). Therefore, despite the same length of varenicline treatment, the short-term (Month 3) abstinence rates achieved for Black smokers in this trial approximate those achieved by White smokers at long-term follow-up (Month 12) in published varenicline trials. This study contribute to a growing body of literature documenting differential quit rates in Blacks relative to Whites (Cropsey et al., 2009; Gariti et al., 2009; Murray et al., 2001) and leads to questions about the reasons for this disparity. Several mechanisms, including poorer adherence to treatment (Cokkinides et al., 2008; Fu et al., 2008), higher use of menthol cigarettes (Gandhi, Foulds, Steinberg, Lu, & Williams, 2009; Gundersen, Delnevo, & Wackowski, 2009), differences in nicotine dependence and smoking patterns (Ahijevych & Garrett, 2004; Garten & Falkner, 2004), and variations in the rate of nicotine metabolism in Blacks relative to Whites (Ho, Mwenifumbo, Zhao, Gillam, & Tyndale, 2008; Ho et al., 2009) have been examined, but, to date, no adequately powered study has been conducted to prospectively examine these questions. A trial of this design could appropriately examine Black–White differences in response to pharmacotherapy, begin to elucidate the mechanisms accounting for any differences, and most importantly, could have significant implications for improving tobacco treatment outcomes among Black smokers.

The lack of effect of adherence counseling on medication adherence differs from two other smoking treatment studies, which found a positive effect of medication management counseling on bupropion adherence (Mooney et al., 2007; Schmitz, Sayre, Stotts, Rothfleisch, & Mooney, 2005); however, the high rate of adherence achieved in this study is encouraging. Pill boxes have been found to be an effective intervention for increasing adherence (Petersen et al., 2007). Findings from this study suggest that dispensing medications in a pill box along with regular monitoring may be adequate for achieving sufficient levels of adherence without the addition of adherence counseling, but findings should be confirmed in a larger sample. This area warrants further study as methods to increase pharmacotherapy adherence have implications for improving tobacco treatment outcomes (Hays et al., 2010).

Another encouraging finding of this study is the positive association found between adherence and smoking abstinence. Our findings are consistent with studies that have found a relationship between early adherence and later abstinence (Fish et al., 2009; Leischow, Ranger-Moore, Muramoto, & Matthews, 2004) and a relationship between pharmacotherapy adherence and smoking cessation (Fish et al., 2009; Hays et al., 2010;

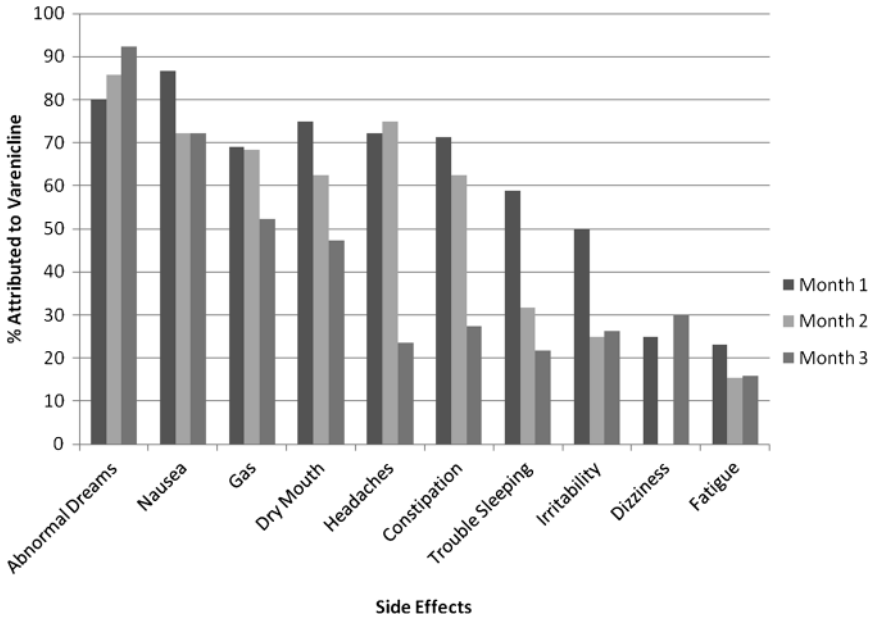

Figure 1. Side effects attributed to varenicline by month of treatment.

Mooney et al., 2007; Shiffman et al., 2008). These findings point to the importance of focusing on medication adherence, especially adherence early in treatment, as a means to improving tobacco treatment outcomes.

One final finding is worth noting. Side effects were common, but participants experiencing more side effects were as likely to adhere to varenicline and to quit smoking as those experiencing fewer side effects. These findings are consistent with other pharmacotherapy studies (Hays et al., 2010; Shiffman et al., 2008) and suggest that participants are willing to tolerate a reasonable amount of discomfort in their effort to quit smoking. Notably, the experience of medication-related side effects in this study is higher than that found in published varenicline clinical trials (Garrison & Dugan, 2009) and is likely elevated because participants were prompted about each side effect. In addition, there was no placebo comparison group in this study. It is possible that participants receiving placebo may have also reported high side effects.

The study has limitations. This is a pilot study with a small sample size, which limits the ability to demonstrate statistically significant differences between groups. However, the results provide data for sample size and power estimates for larger fully powered studies. The use of pill boxes and pill counts may have enhanced adherence in the control group and created a "ceiling effect." Studies using more objective measures of adherence, such as medication event monitoring systems, computerized pill bottle caps that unobtrusively record the exact dates and times medication containers are opened, may reduce this potential risk of a cointervention effect. This study included participants from the Midwest who were largely female; therefore, the results may not generalize to the larger population of Black smokers. Finally, participants were moderate-to-heavy smokers. Given the prevalence of light smoking among Blacks (Trinidad et al., 2009), examination of the efficacy of varenicline for light smoking warrants further attention.

Conclusions

While there was significant reduction in cigarettes smoked per day, the quit rates in this sample of Black smokers were lower than those found for Whites in published varenicline clinical trials. In addition, adherence-based counseling did not increase adherence to smoking cessation medication. However, participants who were more adherent to medication did have higher quit rates compared with those who were less adherent. Studies are needed to examine the efficacy of varenicline among Black smokers. Finally, interventions to facilitate adherence to pharmacotherapy warrant further attention as adherence is linked to improved tobacco abstinence.

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Declaration of Interests

Dr. JSA serves as a paid consultant to Pfizer Global Pharmaceuticals.

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