

SMOKERS' RESPONSE TO COMBINATION BUPROPION, NICOTINE PATCH, AND COUNSELING TREATMENT BY RACE/ETHNICITY

Background: Evidence on how to tailor nicotine dependence treatment to specific race/ethnic groups is limited. The present study investigated responses to established smoking cessation treatments among African American, Hispanic, and White adults.

Methods: Participants were 559 smokers (126 African American, 73 Hispanic, and 360 White). All received treatment for eight weeks with open-label bupropion, the nicotine patch, and individual counseling. The dependent variable was tobacco abstinence during the last four weeks of treatment. The independent variables were race/ethnicity and other known predictors of abstinence, including sex, age, smoking history (nicotine dependence level, number of cigarettes smoked daily, serum cotinine level and expired carbon monoxide, number of past quit attempts, and age when daily smoking began), confidence in ability to stop smoking, body mass index, psychological status, and psychiatric history (past major depression and alcohol dependence).

Results: The total proportion of abstainers in the sample was 53%, with proportional differences by race/ethnicity (Whites 60%, African Americans 38%, Hispanics 41%). Compared to Whites, the odds ratios (OR) for quitting, adjusted for moderators of race/ethnicity and other predictors of abstinence, were significantly lower among African Americans (OR .44, 95% confidence interval [95% CI] .27–.72) and Hispanics (OR .46, 95% CI .26–.81).

Conclusion: Disparity in smoking cessation treatment outcome among African American and Hispanic smokers compared to Whites implies that the burden of tobacco-related illness will continue to fall disproportionately among minority racial/ethnic groups. Gaining knowledge on the effectiveness of nicotine dependence treatments and on the factors that facilitate or impede a successful response by minority smokers is a public health priority. (*Ethn Dis.* 2008;18:59–64)

Key Words: Tobacco Dependence, Smoking Cessation, Race/Ethnicity, Bupropion, Nicotine Patch, Nicotine Replacement Therapy

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INTRODUCTION

Tobacco use accounts for most morbidity and mortality due to cancer, cardiovascular disease, respiratory illness, and other chronic illnesses in the United States.¹ These health consequences are unevenly distributed by race/ethnic status, as individuals from minority (ie, non-White) racial/ethnic groups have higher rates of tobacco-related diseases.² Smoking cessation can reduce tobacco-related morbidity and mortality.¹ Efficacious cessation aids for smokers have been developed, and the current guideline for tobacco dependence treatment recommends that such treatments (eg, behavioral counseling, nicotine replacement agents, bupropion)³ can be applied to all smokers regardless of race/ethnicity.³ However, empiric evidence supporting the effectiveness of cessation aids for minorities is lacking, since most of the research has sampled White smokers. When trials examined smoking cessation response among non-White smokers,^{4–7} comparable samples of White smokers were not obtained.

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The primary objective of the present research was to compare the proportions of abstainers among African American, Hispanic, and White study participants in response to same treatment combination of bupropion, nicotine patch, and individual counseling.

The present study addressed the gap in our knowledge through an effort to recruit a substantially larger proportion of non-White smokers, enabling a statistically valid comparison of response to established nicotine dependence treatments by specific race/ethnic group. In earlier large-scale trials of smokers by our group, the proportions of non-White smokers did not exceed 14%.^{8,9} For the present study, non-White smokers made up 39% of the sample, doubling the usual proportions in our earlier trials. The primary objective of the present research was to compare the proportions of abstainers among African American, Hispanic, and White study participants in response to same treatment combination of bupropion, nicotine patch, and individual counseling.

METHODS

Study Design

The study used information from the initial segment of a three-phase maintenance treatment study for preventing smoking relapse. Participants were first treated for eight weeks with open-label bupropion, nicotine patch, and individual counseling; participants who achieved four-week sustained tobacco abstinence during the initial phase were randomized to a 16-week placebo-controlled maintenance treatment trial and followed through a 24-week non-treatment period. This study reports smoking cessation outcome at the end of the open-label treatment. Detailed information on study procedures and the results of the maintenance treatment trial, to which initial abstainers were randomized, has been previously reported.⁸ The institutional review board of the New York State Psychiatric Institute approved and monitored the study.

Recruitment and Entry Criteria

Recruitment efforts included advertising on radio, television, movie theatres, buses and bus stations, print media, and other community outlets in the New York metropolitan area. Substantial resources were devoted to placing advertisements in media outlets oriented to African American and Hispanic audiences. Inclusion criteria were age ≥ 21 years, a previous quit attempt, and smoking ≥ 10 cigarettes daily. Exclusion criteria were a medical history contraindicating use of bupropion or nicotine patch; unstable medical condition; major depressive disorder or alcohol/drug dependence within the past six months; lifetime history of bipolar disorder or any psychotic illness; current treatment for tobacco dependence; current use of psychoactive medication; and among women, lactation, pregnancy, or intent to become pregnant during the period covered by the study.

Clinical Procedures

Intervention and research materials were in English; bilingual staff assisted Hispanic participants of limited English fluency. Participants provided signed consent at the screening visit and were then examined by a physician. The physician also gathered an extensive medical history of the participant. Eligible subjects used bupropion (150 mg for the first three days, then 150 mg twice a day for the remainder of the eight weeks) and began using nicotine patches daily (21 mg for four weeks, 14 mg for two weeks, 7 mg for one week) on quit day, that is, the day selected by the participant as his or her first day of abstinence. Participants returned to the clinic at the end of weeks 1, 2, 4, 6, and 8 after quit day; they were monitored for vital signs and adverse reactions to the medications. In the six clinic visits during the open-label phase, trained counselors covered topics on the addictive nature of smoking, selection and preparation for quit day, and cognitive behavioral techniques for coping with withdrawal symptoms and urges to smoke.

Research Measures

The dependent variable was sustained (no slip or lapse) abstinence during the last four weeks of the eight-week treatment period, confirmed by expired carbon monoxide level ≤ 8 ppm¹⁰ at the week 6 and week 8 visits. The main predictor variable was race/ethnicity as determined by subjects' self-report on a personal history form. Other baseline variables examined because of their putative associations with smoking abstinence were demographic and socioeconomic characteristics (age, sex, marital status, education, occupational status),¹⁰⁻¹² smoking history (age began smoking daily, nicotine dependence level, number of cigarettes smoked daily, serum cotinine level and expired carbon monoxide, number of past quit attempts),^{13,14} confidence in ability to stop smoking,⁵ body mass

index¹⁶ (BMI, weight in pounds/height in inches² $\times 703$), psychological status,¹⁷ and history of major depression¹⁸ or alcohol dependence.¹⁹ The influence of early quitting (abstinence within seven days after the quit day), a process variable previously found to predict end-of-treatment abstinence,²⁰ was also examined.

The Fagerstrom Test for Nicotine Dependence (FTND), a six-item instrument with acceptable reliability and validity^{21,22} and widely used in smoking cessation research, measured nicotine dependence level. The Profile of Moods States (POMS), an internally consistent 65-item adjective rating scale that yields a total mood disturbance score (the sum of scores on the Anger, Fatigue, Tension, Depression, and Confusion subscales minus the score on Vigor) assessed psychological status.²³ The presence of lifetime major depressive disorder and alcohol dependence were ascertained by trained interviewers using the Schedule for Clinical Interviews (SCID),²⁴ a semi-structured interview based on the American Psychiatric Association's Diagnostic and Statistical Manual.²⁵ Confidence in ability to quit smoking was measured by a single-item 10-point scale (10 equals highest confidence) completed by participants at the screening visit. The Analytic Pharmacology Laboratory of the Nathan Kline Institute in Rockland, New York, assayed serum cotinine level at baseline. The Bedfont Scientific Smokerlyzer (Medford, NJ) indicated expired carbon monoxide level.

Analysis of Data

Comparisons of subject characteristics by race/ethnicity or quit vs non-quit status used the χ^2 test for categorical variables and the *F* test for continuous variables. The independence of variables identified in unadjusted analysis as potential predictors of treatment outcome ($P < .10$), was assessed through multiple logistic regression.²⁶ Design variables, with Whites as the referent

Table 1. Racial/ethnic differences among participants in open-label, eight-week treatment with bupropion, nicotine patch, and individual counseling (n=559)

	African American n=126	Hispanic n=73	White n=360	All n=559	African American vs Hispanic	African American vs White	Hispanic vs White
	%	%	%	P	P	P	P
Sex				.001	.001	.003	NS
Male	39	63	54				
Female	61	37	46				
Marital Status				.03	NS	.04	.09
Never married	44	30	38				
Formerly married	26	30	19				
Married	30	40	43				
Education				.07	NS	.001	.002
High school	24	30	19				
College	56	44	41				
Graduate/Professional	21	25	40				
Occupation				.001	NS	.001	.02
Blue collar	22	31	20				
Technical/Sales	56	44	40				
Profession/Executive	21	25	40				
	Mean (sd)	Mean (sd)	Mean (sd)				
Age (years)	41.9 (8.6)	39.4 (9.2)	42.4 (11.4)	.10	.05	NS	.04
Number of past quit attempts	2.9 (2.3)	3.8 (3.5)	3.7 (3.1)	.03	.04	.008	NS
Serum cotinine (ng/mL)	314 (150)	254 (106)	239 (106)	.001	.004	.001	NS
Fagerstrom Test for Nicotine Dependence	5.0 (2.2)	5.8 (2.1)	5.3 (2.1)	.02	.005	NS	.04
Age began to smoke regularly	18.1 (3.7)	17 (3.5)	17.4 (4.1)	.04	NS	NS	NS
Confidence in ability to quit	8.2 (1.7)	8.4 (1.8)	7.8 (1.9)	.007	NS	.03	.008
Body mass index	28.4 (6.0)	27.1 (5.1)	26.0 (6.0)	.01	.10	.001	.007

NS = not significant.

group, were created for the assessment of White vs African American and White vs Hispanic race/ethnicity.²⁶ Odds ratios (OR) and 95% confidence intervals (CI) were calculated. Statistical significance was set at $P < .05$ for two-tailed tests. Analyses were conducted by using SPSS 14.0 for Windows.

RESULTS

Participant Characteristics

Of 1859 smokers screened by telephone, 588 met eligibility criteria and entered the study. One American Indian and 28 Asians were not included in the data analysis because of small numbers. In the remaining 559 individuals, the racial/ethnic distribution was 23% African American, 13% Hispanic, and 64% White. The mean (\pm standard deviation) age was 41.8 (\pm 10.6) years;

40% of the group was married; most had attended college (51%) or graduate school (28%); 34% held a position at the professional/executive level; the average number of cigarettes smoked daily was 21.2 (\pm 8.6); all had made a previous quit attempt.

Participant Characteristics by Race/Ethnicity

Differences by race/ethnicity were observed on several baseline characteristics: sex, occupational status, BMI, confidence in ability to stop smoking, serum cotinine level ($P < .01$), marital status, the number of past quit attempts, nicotine dependence level (FTND score), and age at which daily smoking began ($P < .05$) (Table 1). Additionally, pairwise comparisons indicated significantly ($P < .05$) more women and higher cotinine levels at baseline among African American than White or Hispanic

participants and higher confidence in ability to quit smoking, fewer professionals and executives, and greater BMI among African Americans and Hispanics than Whites. Marital status was most frequent among Whites, African Americans had made the fewest quit attempts, and nicotine dependence level was highest among Hispanics. Statistical trends ($P < .10$) indicated somewhat higher educational level among Whites than African American or Hispanic smokers and younger mean age among Hispanics than among Whites or African Americans. No differences by race/ethnicity ($P > .10$, not shown in Table 1) were observed on the number of cigarettes smoked daily, expired carbon monoxide level at the screening visit, living with a smoker, psychological status as measured by the POMS, or history of major depression or alcohol dependence.

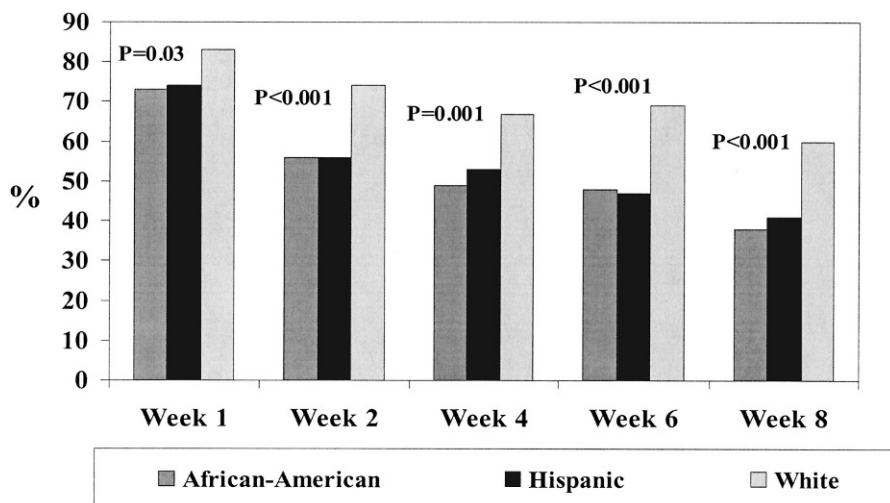


Fig 1. Abstinence rates by race/ethnicity during eight weeks of open label treatment with bupropion, nicotine patch, and individual counseling

Predictors of Abstinence

At the end of the eight-week treatment, 53% of the sample had achieved four-week sustained abstinence. The proportions of abstainers varied by race/ethnicity (38% African-American, 41% Hispanic, 60% White; $\chi^2=23.02$, $df=2$, $P<.001$). As shown in Figure 1, these differences were apparent early and throughout the eight-week treatment. In further unadjusted analyses, abstinence was significantly associated with early quitting, older age, higher educational attainment, higher occupational status, absence of a smoker at home, lower carbon monoxide level, and higher

confidence in ability to quit smoking ($P<.05$); borderline significant effects of male sex, lower serum cotinine level, lower FTND score, and higher BMI ($P<.10$) were observed. No variability according to abstinence status was observed on marital status, a history of major depression or alcohol dependence, age at which smoking daily began, number of cigarettes smoked daily, number of past quit attempts, or psychological status as measured by the POMS.

Race/ethnicity and other predictors of abstinence, as well as moderators of race/ethnicity, were entered in a backward multiple logistic regression model, with

Table 2. Predictors of four-week sustained abstinence in response to eight-week combination treatment with bupropion, nicotine patch, and individual counseling, backward multiple logistic regression* ($n=559$)

	Adjusted Odds Ratio	95% Confidence Interval	P
Race/ethnicity			
White	1.00		
African American	.44	.27-.72	.001
Hispanic	.46	.26-.81	.007
Lives with smoker	.57	.37-.87	.010
Early quitting (end of week 1 after quit day)	3.44	2.15-5.62	.001
Confidence in ability to quit	1.20	1.08-1.33	.001
Body mass index	1.04	1.01-1.08	.021
Age (years)	1.03	1.01-1.05	.001

* Other variables ($P>.05$) included in the model: sex, education, marital status, age began smoking daily, Fagerstrom Test for Nicotine Dependence score, carbon monoxide level, number of past quit attempts.

four-week sustained abstinence as the dependent variable. As shown in Table 2, the adjusted ORs for quitting were significantly lower among African Americans and Hispanics than among Whites. Other significant predictors of abstinence in the final logistic regression model (Table 2) were age, BMI, confidence in ability to quit smoking, early quitting, and living with a smoker. Tests of interactions showed that only the age \times Hispanic term was significant ($P<.01$); that is, among smokers aged ≤ 40 years, there were significantly fewer abstainers among Hispanic smokers (26%) than among Whites (55%) ($P<.001$), but no difference was observed among smokers aged ≥ 41 years (63% vs. 65%, respectively, $P=.89$). Proportionately more African-American and Hispanic than White smokers had dropped out (18%, 22%, 10%, $\chi^2=10.70$, $df=2$, $P<.005$) by the second week after the initial study visit. Analysis restricted to the subsample ($n=484$) that completed at least two weeks of treatment produced results similar to those obtained from the entire sample.

Predictors of Abstinence by Race/Ethnicity

Table 3 shows that early quitting predicted abstinence for each of the racial/ethnic groups, whereas other predictors did so in a race-specific manner. Within African Americans only, higher BMI was significant ($P<.05$), and the absence of a smoker at home was marginally significant ($P<.10$) in predicting abstinence. For Whites, older age ($P<.04$) and higher confidence in ability to quit smoking ($p<.05$) were significant predictors; lower BMI ($P<.10$) was marginally significant. For Hispanics, the only significant predictor of abstinence was older age ($P<.001$).

DISCUSSION

The treatment goal of four-week sustained abstinence was met by 60% of

Table 3. Comparison of quitters (four-week sustained abstinence) and non-quitters in response to combination bupropion, nicotine patch, and individual counseling on selected predictors by race/ethnicity (n=559)

	African American			Hispanic			White		
	Quitters (n=48)	Non-quitters (n=78)	P	Quitters (n=30)	Non-quitters (n=43)	P	Quitters (n=217)	Non-quitters (n=143)	P
	%	%		%	%		%	%	
Early quitting (week 1)	85.4	65.4	.01	86.7	65.1	.04	88.9	73.4	.001
Lives with a smoker	25.0	39.7	.09	23.3	30.2	NS	23.5	29.4	NS
Age (years)	42.6 (8.2)	45.8 (8.8)	NS	43.7 (7.5)	36.4 (7.6)	.001	43.3 (10.9)	40.8 (12.0)	.04
Body mass index	29.8 (6.6)	27.6 (5.4)	.05	27.9 (4.5)	26.5 (5.4)	NS	26.4 (5.7)	25.0 (5.1)	.09
Confidence in ability to quit	8.5 (1.7)	8.0 (1.8)	NS	8.7 (1.5)	8.2 (1.9)	NS	8.0 (1.7)	7.4 (2.1)	.001

NS = not significant.

White smokers but less than half of African American and Hispanic smokers. Comparison of smoking cessation outcome across racial/ethnic groups within the same study has been rarely reported. In one recent study, drawn from a free nicotine patch program and also conducted in New York City, the prevalence of seven-day abstinence six months after quit day was also lower among Hispanic and non-Hispanic Black smokers than among non-Hispanic White smokers (26%, 27%, and 32%, respectively).²⁷

Race-specific Predictors: Some Implications

Exploratory analyses of abstinence predictors within racial/ethnic groups produced a few significant associations. Among African Americans, quitting occurred less frequently among participants with lower BMI and a household member who smoked; attitudes regarding weight and weight gain²⁸ and

household restrictions against smoking²⁹⁻³⁰ could be salient intervention targets for this subgroup. For Hispanics, age was a significant predictor, possibly reflecting the importance of generational status, being foreign- or US-born, and acculturation.³¹ Among Whites, higher confidence in ability to quit smoking was a highly significant predictor of success; psychological interventions that enhance self-efficacy could increase who will stop smoking.³² Early quitting was a strong predictor regardless of race/ethnicity, which suggests that efficacious treatment should occur as early as possible for all smokers during a smoking cessation attempt.

Limitations

The selected nature of our sample restricts the external validity of our findings—our observations may not apply to smokers who have never made a quit attempt, suffer from medical or psychiatric conditions that disqualified some smokers from this study, do not have the high motivation to stop smoking implied by enrollment in a long-term clinical trial, or are unable to access intensive and frequent treatments of the kind received by the participants in our study. An additional limitation is the brevity of the eight-week period observed in the present analysis. At least six months of abstinence is recommended for evaluating effectiveness of smoking cessation treatment.³³ As reported elsewhere,³⁴ abstinence at 6 and 12 months

in the present sample was unrelated to race/ethnicity, but inadequate statistical power for analyzing long-term results limited the reliability of that observation.

With respect to African American smokers, their greater use of mentholated cigarettes has been proposed as an explanation for their lower quit rates relative to White smokers;³⁵ however, our study did not ask about mentholation of the cigarettes smoked. With regard to Hispanic participants, that our intervention materials were not in Spanish might have contributed to the lower treatment response.³¹

Conclusion

Effectiveness for all smokers who wish to stop is the goal of nicotine dependence treatment research. In earlier trials of bupropion⁵ and nicotine patch⁶ with African American smokers, the proportions of abstainers who received the active treatments were 36% and 22%, respectively. Because those proportions were approximately twice as high as in placebo-treated groups in those studies, those treatments were concluded to be efficacious and worthwhile.^{5,6} The present data, however, showed that the benefit experienced by White smokers in our study was experienced by proportionately fewer than their African American and Hispanic counterparts. Multiple factors could account for this variability; what they are should be further explored. Disparity in smoking cessation affects the prevalence of tobacco-related diseases

The treatment goal of four-week sustained abstinence was met by 60% of White smokers but less than half of African American and Hispanic smokers.

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among minority racial/ethnic groups. Gaining knowledge on the effectiveness of nicotine dependence treatments by race/ethnicity and on the factors determining that association are matters of public health priority.

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