Electronic Cigarette Use and Cigarette Abstinence Over Two Years among U.S. Smokers in the Population Assessment of Tobacco and Health Study

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ABSTRACT

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<u>Introduction</u>: Electronic cigarettes (e-cigarettes) could benefit public health if they help current smokers to stop smoking long-term, but evidence that they do so is limited. We aimed to determine the association between e-cigarette use and subsequent smoking cessation in a nationally representative cohort of U.S. smokers followed for two years.

Methods: We analyzed data from adult cigarette smokers in Waves 1 to 3 of the Population Assessment of Tobacco and Health (PATH) Study. The primary exposure was e-cigarette use at Wave 1. The primary outcome was prolonged cigarette abstinence, defined as past 30-day cigarette abstinence at Waves 2 and 3 (1 and 2-year follow-up).

Results: Among Wave 1 cigarette smokers, 3.6% were current daily e-cigarette users, 18% were current non-daily e-cigarette users, and 78% reported no current e-cigarette use. In multivariable adjusted analyses, daily e-cigarette use at Wave 1 was associated with higher odds of prolonged cigarette smoking abstinence at Waves 2 and 3 compared to non-use of e-cigarettes (11% vs 6%, AOR 1.77, 95% CI 1.08-2.89). Non-daily e-cigarette use was not associated with prolonged cigarette smoking abstinence. Among Wave 1 daily e-cigarette users who were abstinent from cigarette smoking at Wave 3, 63% were using e-cigarettes at Wave

<u>Conclusions</u>: In this longitudinal cohort study of U.S. adult cigarette smokers, daily but not non-daily e-cigarette use was associated with higher odds of prolonged cigarette smoking abstinence over two years, compared to no e-cigarette use. Daily use of e-cigarettes may help some smokers to stop smoking combustible cigarettes.

IMPLICATIONS

Electronic cigarettes (e-cigarettes) could benefit public health if they help current smokers to stop smoking long term, but evidence that they do so, particularly from observational "real world" studies, is limited. In this nationally-representative longitudinal cohort study of U.S. adult cigarette smokers, daily e-cigarette use, compared to no e-cigarette use, was associated with a 77% increased odds of prolonged cigarette smoking abstinence over the subsequent two years. Regular use of e-cigarettes may help some smokers to stop smoking combustible cigarettes.

INTRODUCTION

Electronic cigarettes (e-cigarettes) are novel nicotine-delivery devices that heat a nicotine-containing liquid, producing an aerosol that users inhale. While e-cigarettes expose users to nicotine, they do not burn tobacco. Consequently, they expose users to fewer and lower levels of the many other chemicals found in tobacco smoke.¹ It is these combustion products, rather than nicotine, that are the primary source of smoking-related morbidity and mortality.² National evidence reviews from England and the U.S have concluded that while e-cigarette use is not harmless, cigarette smokers who switch to e-cigarettes will likely reduce their smoking-attributable health risks.^{1,3}

E-cigarettes therefore have the potential for substantial public health benefit if cigarette smokers, especially those who are unwilling or unable to quit using current treatment, switch to e-cigarettes and stop smoking combustible cigarettes. This potential benefit must be balanced against two potential harms. First, the long-term health effects of e-cigarette use are not known. Second, nonsmoking youths and young adults who would not otherwise have become cigarette smokers might try e-cigarettes, develop nicotine dependence, and transition to smoking combustible cigarettes. Modelling studies indicate that, under likely scenarios, e-cigarette use in the U.S. population is likely to produce a net public health benefit. However, definitive information about the magnitude of the effect of e-cigarettes on cessation, initiation, and human

health is not yet available. Recently two national surveys reported a dramatic increase in e-cigarette use among U.S. high school students in 2018.^{5,6} Whether this will lead to an increase in adolescent cigarette smoking is not yet known, but this concern makes even more urgent the need to better define both the potential public health benefits and risks of e-cigarette use.

A critical unanswered question about e-cigarettes' potential public health benefit is whether the devices help smokers to stop smoking combustible cigarettes. Cigarette smokers commonly report using e-cigarettes in their attempts to quit smoking. In 2016, 52.5% of current smokers in the U.S. reported ever using e-cigarettes and 10.8% were current e-cigarette users. In Clinical trial evidence that e-cigarettes promote smoking cessation is limited to three randomized trials, III-III all of which were conducted outside of the United States. A Cochrane meta-analysis of two of these trials IIII concluded that nicotine-containing e-cigarettes produced more smoking cessation than e-cigarettes without nicotine. In comparing the effectiveness of e-cigarettes to evidence-based cessation treatment, one trial found no difference in quitting between the two groups, While the other found significantly more cessation in the group receiving e-cigarettes compared to the group receiving nicotine replacement therapy.

In the absence of clinical trials, non-experimental observational studies provide the strongest available epidemiologic evidence and have the advantage of demonstrating the effect

of e-cigarettes under real world conditions of use as widely-available consumer products. Observational studies have had mixed results, in part due to variability in how current ecigarette use was defined, in what devices were used, and in smokers' motivation to quit.1 Among observational trials, those analyzing large population-based surveys provide the most generalizable evidence. Two nationally-representative U.S. surveys have found e-cigarette use to be associated with quit attempts and smoking cessation. 8,15 These studies analyzed data from repeated cross-sectional samples of U.S. adults rather than analyzing data from a cohort of individuals followed over time. In contrast, a prospective cohort study using a U.S. populationbased web-panel found that smokers who used e-cigarettes had a lower odds of having quit smoking at one-year follow-up. 16 These discrepant findings highlight the need for further research to explore the association of e-cigarettes and smoking cessation, ideally in larger samples and with longer follow-up.

The Population Assessment of Tobacco and Health (PATH) Study provides a unique opportunity to assess whether e-cigarette use is associated with subsequent smoking cessation in a large nationally-representative cohort of smokers being followed over time. Data from the third year of data collection, allowing for two-years of follow-up, were recently released. We analyzed PATH data to assess the association between e-cigarette use at baseline and

cigarette smoking abstinence after two years of follow-up. Specifically, we evaluated whether different frequencies of e-cigarette use at Wave 1 were associated with prolonged cigarette abstinence at Waves 2 and 3. In secondary analyses, we evaluated whether e-cigarette use at Wave 1 was associated with abstinence from Waves 1 to 2 and Waves 1 to 3. We hypothesized that more frequent e-cigarette use would be associated with prolonged cigarette abstinence.

METHODS

Study Population

Data from Waves 1 through 3 of the PATH study, which has followed a longitudinal cohort of US adults and youth since 2013, was used for this study. 17,18 Wave 1 data were collected from September 2013 to September 2014, Wave 2 data were collected from October 2014 to October 2015, and Wave 3 data were collected from October 2015 to October 2016. Participants identified through address-based sampling were surveyed about tobacco use using audio computer-assisted self-interviews. While the PATH study collects data on both adults and youth, this analysis included only data from adults age 18 and older who were current cigarette smokers at Wave 1. We defined Wave 1 current cigarette smokers as adults who reported (1) smoking 100 or more cigarettes in their lifetime and (2) now using cigarettes

every day or some days. The Institutional Review Board of Westat approved the parent study.

Only de-identified publicly available data were used for the present study, and this study was deemed exempt by the Institutional Review Board at Partners Healthcare.

Measures

Baseline demographics (measured at Wave 1) included age, sex, race/ethnicity, education, and income as a percentage of the federal poverty level.

To assess e-cigarette use, participants at Wave 1 were asked "Have you ever heard of an electronic cigarette or e-cigarette before this study?" and those who reported "yes" were asked "Have you ever used an e-cigarette, such as NJOY, Blu, or Smoking Everywhere, even one or two times?" Respondents who said yes were asked "Do you now use e-cigarettes..." with potential response options of "every day", "some days" or "not at all". Current e-cigarette use was defined as reporting now using e-cigarettes every day or some days. Some-day e-cigarette users were further asked, "On how many of the past 30 days did you use an e-cigarette?" For analysis, we first dichotomized current e-cigarette users into non-daily (use on 0-29 days of the past 30 days) and daily users. In subsequent exploratory analyses, we re-categorized frequency of past-month e-cigarette use into three groups based on the distribution of e-cigarette use frequency found at Wave 1: <9 days, 10-19 days, and 20-30 days.

Abstinence from cigarette smoking, the outcome measure, was defined by a "no" response to this question asked at both Waves 2 and 3, "In the past 30 days, have you smoked a cigarette, even one or two puffs?" The primary outcome measure was prolonged cigarette abstinence, assessed at both Waves 2 and 3. Secondary outcomes measures were cigarette abstinence at Wave 2 and cigarette abstinence at Wave 3. Relapse was defined as cigarette abstinence at Wave 2, but no abstinence at Wave 3.

Other covariates used in analyses included mean number of cigarettes per day, which we censored at the 99th percentile to reduce the impact of extreme outliers, and nicotine dependence, which was measured as smoking the first cigarette of the day within 30 minutes of waking.¹⁹ To examine the pattern of e-cigarette use over time, current e-cigarette use at Waves 2 and 3 was defined as now using any electronic nicotine delivery product (specifically e-cigarette, e-cigar, e-hookah, e-pipe, or other electronic nicotine product) every day or some days.

Statistical Analysis

We used complex survey procedures and replicate weights in Stata version 14 for all analyses (StataCorp LLC, College Station, Texas). The weighting accounted for selection probabilities and nonresponse rates. For the primary outcome, the study population was limited

to adult respondents available at all three waves (unweighted n=8218). For the secondary outcomes of abstinence at one wave, the study population of adult smokers was limited to respondents available at both Waves 1 and 2 (unweighted n=9264) or at Waves 1 and 3 (unweighted n=8575).

Multivariable logistic regression was used to evaluate the association between Wave 1 e-cigarette use and follow-up smoking abstinence. These analyses controlled for age (18-34 years, 35-54 years, and \geq 55 years), sex, race/ethnicity (non-Hispanic white, Hispanic, non-Hispanic black, and non-Hispanic other), education (less than high school, high school diploma/GED, or some college, or 4 year college degree or more), income as a percentage of the federal poverty level (<100%, 100%-199%, or \geq 200%), mean cigarettes per day, and nicotine dependence (first cigarette of the day <= or >30 minutes after waking). Only

RESULTS

Among all adult current cigarette smokers at Wave 1, the weighted percentage of current e-cigarette use was 22% (95% CI 20-23%) Current daily e-cigarette use was reported by 3.6% (95% CI 3.1-4.2%) and current non-daily e-cigarette use was reported by 18% (95% CI 17-19%). The percentage reporting no current e-cigarette use was 78% (95% CI 77-79%).

Characteristics of the sample by e-cigarette use at Wave 1 are shown in Table 1.

Smokers who reported current daily or non-daily e-cigarette use were younger than smokers who reported not currently using e-cigarettes (Table 1). A higher percentage of current daily e-cigarette users had non-Hispanic white race/ethnicity. Current daily and non-daily e-cigarette users had higher education than smokers not currently using e-cigarettes. Groups also differed in cigarettes smoked per day, with current daily e-cigarette users reporting the lowest number of cigarettes per day.

Among smokers, current daily e-cigarette use at Wave 1 was associated with higher odds of prolonged cigarette smoking abstinence at both Waves 2 and 3 (11% vs 6%, AOR 1.77, 95% CI 1.08-2.89, p=0.02, Tables 2 and 3). There was no statistically significant association between non-daily e-cigarette use and prolonged cigarette smoking abstinence.

Income below the federal poverty level, a higher number of cigarettes per day, and high nicotine dependence were all negatively associated with prolonged cigarette smoking abstinence (Table 3).

The association of e-cigarette use at Wave 1 with secondary outcomes was similar.

Current daily e-cigarette use at Wave 1, compared to non-use of e-cigarettes, was associated with higher odds of abstinence from cigarette smoking at both Wave 2 (p=0.03) and Wave 3

(p=0.01) (Table 3). Non-daily e-cigarette use did not significantly increase odds of cigarette smoking abstinence compared to non-use of e-cigarettes. Males had higher odds of abstinence from cigarettes at Wave 3 (Table 3). Income below the federal poverty level, high nicotine dependence, and a higher number of cigarettes smoked per day at Wave 1 were negatively associated with cigarette abstinence at Waves 2 and 3.

Smoking relapse between Waves 2 and 3 was seen in 4.4% of current daily e-cigarette users at Wave 1, 3.2% of non-daily e-cigarette users at Wave 1, and 3.3% of non-users of e-cigarettes Wave 1 (p=0.62, data not shown in Tables). Neither daily nor non-daily e-cigarette use associated with cigarette smoking relapse between Waves 2 and 3 in multivariable logistic regression models (AOR 1.41, 95% CI 0.76-2.61 for daily use; AOR 1.07, 95% CI 0.73-1.58 for non-daily use).

In exploratory analyses that categorized current e-cigarette use into 3 groups, current e-cigarette use on 20 or more days per month at Wave 1 was associated with a higher odds of prolonged cigarette smoking abstinence at both Waves 2 and 3 (AOR 1.60, 95% CI 1.05-2.43, data not shown in tables). Less frequent e-cigarette use at Wave 1 was not significantly associated with prolonged abstinence (AOR 1.07, 95% CI 0.74-1.55 for <9 days of e-cigarette

use; AOR 1.84, 95% CI 0.88-3.83 for 10-19 days of e-cigarette use; data not shown in tables).

Among Wave 1 current daily e-cigarette users who were abstinent from cigarette smoking at Wave 3, 63% were using e-cigarettes at Wave 3. Among Wave 1 current non-daily e-cigarette users who were abstinent from cigarette smoking at Wave 3, 31% were using e-cigarettes at Wave 3. Among Wave 1 current non-users of e-cigarettes who were abstinent from cigarette smoking at Wave 3, 13% were using e-cigarettes at Wave 3.

DISCUSSION

In this nationally-representative longitudinal cohort study of U.S. adult cigarette smokers, daily e-cigarette use, compared to no e-cigarette use, was associated with a 77% increased odds of prolonged cigarette smoking abstinence over the subsequent two years. Non-daily e-cigarette use was not associated with subsequent abstinence. These are the first nationally representative cohort study data to show an association between e-cigarette use and sustained combustible cigarette abstinence rates over two years. These results are consistent with the hypothesis that when used daily, e-cigarettes may help smokers to stop smoking combustible cigarettes, but that less frequent e-cigarette use may not do so.

The study results are consistent with findings of previous cross-sectional studies that also found an association between more frequent e-cigarette use and smoking cessation. For example, a population-based study using cross-sectional data from the 2014-2015 Tobacco Use Supplement-Current Population Survey found that a higher number of days of e-cigarette use in the last 30 days was associated with higher odds of both making a cigarette quit attempt and successfully quitting among attempters.²⁰ In another study using data from two U.S. cities, daily e-cigarette use for at least one month was associated with a higher odds of quitting smoking 2-3 years later.²¹ Two longitudinal studies using cohort data from only Waves 1 and 2 of the PATH Study found results similar to ours. 22,23 One study found daily e-cigarette use at Wave 1 to be associated with smoking cessation after one year.²³ Another found that initiation of ecigarette use by Wave 2 among non-users at Wave 1 was associated with smoking cessation at Wave 2.22 The present study expands on these findings by including data from Wave 3 of the PATH study and showing an association between daily e-cigarette use and prolonged cigarette abstinence over 2 years. This is a key observation because of concerns that former smokers using e-cigarettes may be more likely to relapse. 23,24

One explanation for the difference in cigarette smoking abstinence among daily and non-daily e-cigarette users may be that these groups differ in their reasons for e-cigarette

users. They may be aiming to reduce harm from cigarettes without committing to total abstinence. Another explanation may be that non-daily e-cigarette use is unlikely to completely control symptoms of nicotine withdrawal in daily cigarette users with high levels of nicotine dependence, and therefore these smokers will continue cigarette use to manage cravings and withdrawal.

In contrast to our findings, several prior observational studies examining the relationship between e-cigarette use and cigarette abstinence found that e-cigarette use was associated with a lower likelihood of successful cessation. This is likely due to heterogeneity in the way that these prior studies defined current e-cigarette use. Our findings suggest that combining daily and non-daily e-cigarette users is likely to underestimate the association between e-cigarette use, and subsequent cigarette abstinence and may miss differences in smoking abstinence among subgroups of e-cigarette users. Observational studies should account for the frequency of e-cigarette use when evaluating the association between e-cigarette use and cigarette smoking abstinence. A recent longitudinal cohort study conducted during the same years as Wave 3 of the PATH study reported different findings from ours. In that study, smokers who used e-cigarettes at baseline had a lower adjusted odds of cigarette abstinence one year later

than baseline e-cigarette non-users.. The smaller sample size of this study compared to PATH may have limited the statistical power to find an effect. It also differed from PATH in obtaining data from a web-based panel. 16

Nearly 40% of the current smokers at Wave 1 who used e-cigarettes (and 63% of the smokers who used e-cigarettes daily) and were abstinent from combustible cigarettes at Wave 3 were still using e-cigarettes at Wave 3. This may explain why other nationally-representative surveys have found that daily e-cigarette use is most prevalent among former smokers who quit smoking within the past year.²⁷ A cross-sectional study in the United Kingdom found that former smokers who used e-cigarettes for at least 6 months significantly reduced their exposure to many of the toxins and carcinogens in combustible cigarettes.²⁸ Smokers who transition completely from combustible cigarettes and maintain e-cigarette use likely reduce their tobaccorelated health risks. 1,3 Because the long-term health effects of using e-cigarettes remain unknown, to minimize potential harms from e-cigarette use, smokers who use e-cigarettes to successfully quit smoking might be encouraged to aim to quit e-cigarette use as well, but only when they are confident that they can do so without returning to smoking.²⁹

This study has several limitations. First, bias from unmeasured confounders is a limitation in any observational study. Self-selection bias is a potential limitation of this study if

the smokers who chose to use e-cigarettes daily were more likely to quit for another reason. Our analyses controlled for multiple demographic factors and for nicotine dependence but could not adjust for factors such as motivation to quit or confidence in ability to quit due to the PATH survey question structure. Second, all data, including those on cigarette abstinence, were obtained by participant self-report and were not biochemically verified, introducing the possibility of social desirability bias. However, guidelines do not consider biochemical validation needed for large population or observational studies that do not include smoking cessation interventions.³⁰ Third. Wave 1 of the PATH study only asked about use of e-cigarettes, and may have underestimated the total prevalence of other electronic nicotine delivery system use if respondents did not know that a product they were using was an e-cigarette. This has been shown in studies of youth.31 Whether the same is true in adults is not known, but misclassification should bias results toward accepting the null hypothesis. Fourth, the exact timing of e-cigarette use in relation to stopping smoking is not known. Participants who were both smoking and using e-cigarettes at Wave 1 may have stopped using e-cigarettes before quitting cigarette smoking. Finally, smokers who used e-cigarettes at baseline might also have used smoking cessation pharmacotherapies approved by the U.S. Food and Drug Administration (FDA), such as nicotine replacement therapy, varenicline, or bupropion. In our analyses, we

were not able to adjust for use of these products due to limitations in the way in which these questions were asked on the PATH survey.

In conclusion, smokers in this large nationally-representative longitudinal study who used e-cigarettes daily were more likely to be abstinent from combustible cigarettes after two years compared to smokers who did not use e-cigarettes. Further defining the potential public health benefit that e-cigarettes could offer in terms of smoking cessation will require randomized controlled trials, but these observational data suggest that frequent e-cigarette use is associated with subsequent abstinence from combustible tobacco products.

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Table 1. Study Sample Characteristics by E-cigarette Use at Wave 1					
	Daily e-cig use	Non-daily e-cig use	No current e-cig use		
	(N=299)	(N=1523)	(N=6379)	p value	
	% (95% CI)	% (95% CI)	% (95% CI)		
<u>Age</u>					
18-34	43 (37-50)	46 (44-49)	37 (36-38)	<0.001	
45-54	36 (29-43)	39 (36-42)	39 (38-41)	~ 0.001	
<u>≥</u> 55	21 (16-27)	14 (12-17)	24 (22-25)		
Male sex	59 (52-66)	52 (50-55)	55 (54-56)	0.07	
Race/ethnicity					
Hispanic	7 (4-10)	11 (10-13)	11 (10-12)		
Non-Hispanic white	82 (77-86)	74 (71-77)	68 (67-70)	<0.001	
Non-Hispanic black	6 (4-10)	8 (6-10)	15 (14-16)		
Non-Hispanic other	5 (3-8)	7 (5-9)	6 (5-6)		
Education					
Less than HS	14 (11-19)	12 (10-14)	17 (16-18)		
HS/GED	38 (31-45)	35 (32-38)	39 (38-41)	<0.001	
Some college	36 (29-43)	39 (37-42)	33 (32-34)		
4-year college degree or higher	12 (9-17)	14 (12-15)	11 (10-12)		
Income as percentage of federal poverty level					
<100%	36 (30-42)	35 (33-38)	38 (36-40)	0.32	
100-199%	26 (21-33)	27 (25-30)	28 (26-29)	0.32	
<u>≥</u> 200%	38 (30-45)	37 (34-40)	34 (33-36)		
Cigarettes per day, mean (SE)	11.2 (0.7)	14.2 (0.3)	13.6 (0.2)	<0.001 (daily vs	
Olygarettes per day, mean (SE)	11.2 (0.7)	14.2 (0.3)	13.0 (0.2)	non-daily and daily	

				vs no current use)
First cigarette within 30 mins of waking	67 (60-72)	62 (59-65)	60 (58-61)	0.06

Missing data were 2% or fewer for all variables except income, for which 7% of data were missing

	Prolonged Cigarette Abstinence at Waves 2 and 3		Cigarette Abstinence at Wave 2		Cigarette Abstinence at Wave 3	
Wave 1 e-cigarette use status	N	Weighted %	N	Weighted %	N	Weighted %
No current e-cigarette use	366	6 (5-7)	672	10 (9-11)	852	13 (12-14)
Current non-daily e-cigarette use	81	6 (5-7)	150	10 (8-11)	192	12 (10-14)
Current daily e-cigarette use	31	11 (7-16)	51	14 (11-20)	61	21 (17-27)
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Table 3. Factors Associated with Cigarette Abstinence at Follow-up					
	Prolonged Cigarette Abstinence	Cigarette Abstinence at	Cigarette Abstinence at		
	at Waves 2 and 3	Wave 2	Wave 3		
	AOR	AOR	AOR		
	(95% CI)	(95% CI)	(95% CI)		
Current e-cigarette use at Wave 1					
None	Ref	Ref	Ref		
Non-daily	1.16 (0.84-1.61)	1.07 (0.84-1.37)	1.02 (0.80-1.28)		
Daily	1.77 (1.08-2.89)*	1.53 (1.04-2.23)*	1.57 (1.12-2.21)*		
Age					
18-34	0.69 (0.50-0.95)*	0.86 (0.68-1.09)	0.97 (0.78-1.21)		
45-54	0.74 (0.53-1.04)	0.80 (0.60-1.06)	0.90 (0.72-1.12)		
<u>≥</u> 55	Ref	Ref	Ref		
Male sex	1.19 (0.96-1.47)	1.05 (0.90-1.23)	1.33 (1.14-1.54)***		
Race/ethnicity	0				
Non-Hispanic white	Ref	Ref	Ref		
Hispanic	1.24 (0.87-1.78)	1.23 (0.95-1.59)	1.05 (0.81-1.35)		
Non-Hispanic black	0.87 (0.57-1.31)	0.83 (0.63-1.11)	0.86 (0.65-1.14)		
Non-Hispanic other	1.51 (0.92-2.49)	1.12 (0.74-1.68)	1.19 (0.87-1.65)		
Education					
Less than HS	1.05 (0.61-1.81)	1.03 (0.72-1.47)	0.83 (0.57-1.19)		
HS/GED	1.10 (0.74-1.63)	0.91 (0.68-1.21)	0.84 (0.63-1.11)		
Some college	1.07 (0.72-1.58)	0.98 (0.77-1.23)	1.00 (0.77-1.29)		
4-year college degree or higher	Ref	Ref	Ref		
Income as percentage of federal poverty level					

<100%	0.53 (0.40-0.70)***	0.68 (0.54-0.85)**	0.71 (0.58-0.86)**
100-199%	0.72 (0.56-0.93)*	0.85 (0.70-1.04)	0.84 (0.68-1.04)
<u>></u> 200%	Ref	Ref	Ref
Cigarettes per day	0.93 (0.90-0.95)***	0.94 (0.93-0.96)***	0.95 (0.93-0.96)***
First cigarette within 30 mins of waking	0.73 (0.55-0.98)*	0.73 (0.55-0.98)***	0.72 (0.59-0.87)**

Boldface indicates statistical significance

*p<0.05, **p<0.01, ***p<0.001

Multivariable logistic regression models controlled for age, race/ethnicity, sex, education, income, cigarettes per day, and time to first morning cigarette.