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Project IMPACT: A pharmacotherapy pilot trial investigating the abstinence and treatment adherence of Latino light smokers

Marcel A. de Dios, Ph.D.[1,2], **Bradley J. Anderson, Ph.D.**[2], **Cassandra Stanton, Ph.D.**[1,2], **Daniel A. Audet, B.A.**[2], and **Michael Stein, M.D.**[2,3]

[1]Department of Psychiatry & Human Behavior, Warren Alpert Medical School of Brown University, Providence, RI 02912

[2]Butler Hospital, Providence, RI 02906

[3]Departments of Medicine and Community Health, Warren Alpert Medical School of Brown University, Providence, RI 02912

Abstract

Light smoking is particularly prevalent among Latino smokers. Nicotine replacement (NRT) and varenicline are effective medications for smoking cessation for moderate-heavy smokers, but have not been tested in light smokers and thus there are no treatment guidelines for use with light smokers. This pilot trial tested the efficacy of NRT and varenicline in increasing smoking abstinence among Latino light smokers. A 3-group (NRT, varenicline, varenicline-placebo) randomized design was used and Latino light smokers (≤10 cpd) received 12 weeks of treatment which included a culturally-informed behavioral health session and ongoing medication management visits. At follow-up, there were no abstinent participants in the placebo and NRT groups. However, 30% of participants in the varenicline group were abstinent at the 3, 4, and 6 month follow-up. This study represents the only investigation that specifically targets Latino light smokers using these treatments and characterizing their treatment adherence.

Keywords

Latinos; Hispanics; light smokers; varenicline; adherence; NRT

Introduction

The prevalence of smoking among Latinos in the United States is 15.8%, yet considerable differences exist between Latino ethnic groups and Latinos in specific geographic regions. For example, Cubans and Puerto Ricans are known to have higher rates of smoking (20.1% and 18.6%, respectively) as compared to their Mexican (11.6%) and Dominican (10.7%) counterparts. Moreover, Latinos living in the Northeast tend to have higher rates of smoking than those residing in the Southwest (Perez-Stable et al., 2001; CDC, 2008). Nevertheless,

Corresponding Author: Marcel A. de Dios, PhD, Butler Hospital, 345 Blackstone Boulevard, Weld Building, Room 211, Providence, RI 02906; USA. Telephone 401-455-6645; Fax: 401-455-6618; mdedios@butler.org.

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lung cancer, which is most often associated with smoking, is the nationally leading or second leading cause of cancer death among Latinos (Howe et al., 2006).

The majority of Latino smokers (up to 70% in some studies) are light smokers (Zhu, Pulvers, Zhuang, & Baezconde-Garbanati, 2007) which is typically defined as smoking 10 or fewer cigarettes per day (CPD) (Ahluwalia et al., 2006). Light smokers believe their lower level of smoking reduces or eliminates their health risk despite evidence to the contrary (Etter, 2004). The Copenhagen City Heart study showed an increased mortality among women smoking 3–9 CPD (Prescott, Scharling, Osler, & Schnohr, 2002). Light smoking has also been associated with increased risk of coronary heart disease and lung cancer (Luoto, Uutela, & Puska, 2000).

Smoking Cessation with Light Smokers

Several pharmacological treatments for smoking cessation have been shown to be effective in improving tobacco abstinence rates. Nicotine replacement therapy (NRT) significantly reduces withdrawal symptoms and increases the likelihood of successful smoking cessation (Silagy, Lancaster, Stead, Mant, & Fowler, 2004). Studies performed in health care settings have demonstrated that NRT is effective even when provided with limited adjunctive therapy (M. Fiore, 2000 & 2008). To date, only two NRT treatment studies have focused on light smokers. Comparing 2mg nicotine gum vs. placebo, Ahluwalia and colleagues showed no difference in 7-day quit rates in African American light smokers at 8 weeks (Ahluwalia, et al., 2006). Choice of low dose gum, poor adherence, and higher than expected baseline cotinine levels may have contributed to these results. A study by Shiffman (2005) that compared nicotine lozenges (2 mg) versus placebo found active treatment to significantly increase smoking abstinence at 12 months. However, in this study light smoking was defined as <15 CPD and this was a secondary analysis using a primarily Caucasian sample.

Varenicline, a partial nicotine receptor agonist, increases smoking abstinence rates and may be the most efficacious pharmacotherapy currently available. The efficacy of varenicline, a $\alpha 4\beta 2$ nAChR partial agonist, has been assessed in multiple clinical trials involving chronic cigarette smokers (>10 CPD) (Niaura, Jones, & Kirkpatrick, 2006). Varenicline's effects on craving and smoking satisfaction suggest it may be effective for light smokers. Yet, there are no studies that have evaluated the efficacy of varenicline among light smokers.

Latinos and Smoking Cessation

Despite the availability of efficacious smoking cessation treatments, Latinos experience smoking cessation treatment disparities including decreased access to health care (Guendelman & Wagner, 2000; Kang-Kim et al., 2008; Mayberry, Mili, & Ofili, 2000; Vargas Bustamante, Chen, Rodriguez, Rizzo, & Ortega, 2010) and physician delivered advice to quit (Denny, Serdula, Holtzman, & Nelson, 2003; Houston, Scarinci, Person, & Greene, 2005; Lopez-Quintero, Crum, & Neumark, 2006; Reed & Burns, 2008), and poor smoking cessation treatment outcomes (Covey et al., 2008; Gandhi, Foulds, Steinberg, Lu, & Williams, 2009). Adherence to treatment is a significant barrier for Latinos (Fu et al., 2008) who are also known to have high rates of non-adherence to medication regimens for chronic medical conditions (Frankenfield et al., 2010) such as diabetes (Huang et al., 2009), hypertension (Natarajan, Santa Ana, Liao, Lipsitz, & McGee, 2009; Perez-Stable & Salazar, 2004), HIV/AIDS (Oh et al., 2009), and psychiatric conditions (Nicole M. Lanouette, 2009). These findings have led investigators to explore the unique characteristics of Latino smokers that may influence success of smoking cessation treatment (Levinson, Borrayo, Espinoza, Flores, & Perez-Stable, 2006; Levinson, Perez-Stable, Espinoza, Flores, & Byers, 2004). Levinson and colleagues (2004) demonstrated that Latinos are less likely to use pharmacotherapy treatments for smoking cessation than other ethnic/racial groups, even

after controlling for factors such as health care access, income, physician advice to quit, health status and smoking level. In a follow-up study Levinson and colleagues (2006) identified a number of potential barriers and concerns of Latinos with regard to pharmacotherapies including: concerns about side effects, fears of becoming dependent on medications, cultural inclinations towards quitting without chemical aid, a lack of knowledge about the effectiveness and use of medications, and misconceptions about the perceived risks of smoking (Levinson, et al., 2006).

Despite public health recommendations issued over a decade ago (Fiore, 2000) which called for the development of culturally targeted (or tailored) smoking cessation interventions for ethnic and racial minorities, a limited number of interventions have been developed and tested for Latino smokers. To date, only three identified studies have attempted to culturally target interventions to Latinos smokers (Borrelli, McQuaid, Novak, Hammond, & Becker, 2010; Nevid & Javier, 1997; Woodruff, Talavera, & Elder, 2002). Nevid and colleagues' (1997) pilot trial with 93 Latino smokers in New York City found a modestly higher rate of post-treatment abstinence (13% versus 9%) among the culturally-tailored intervention group. However, this difference diminished at the 12 month follow-up. In a larger trial of 313 Latino smokers in San Diego County California, Woodruff and colleagues' (2002) culturally tailored intervention was associated with a 20.5% abstinence rate as compared to an 8.7% rate among controls. However, this finding was limited to a 1-week post-treatment follow-up assessment and a more extended follow-up assessment was not conducted. In Borrelli and colleagues' (2010) study of 133 Latina mothers of asthmatic children, a culturally enhanced intervention was shown to have a 20.5% abstinence rate at a 2 month follow-up, 19.1% at 3 months as compared to 9.1% and 12.3% in the non-culturally tailored intervention.

The above summarized studies of culturally tailored interventions for Latinos are promising, yet, much remains to be investigated. Namely, little is known about adherence to smoking cessation treatment by Latinos smokers. As noted previously, Latinos are known to have poor adherence to smoking cessation treatment (Fu et al., 2008) however, patterns of non-adherence and reasons for non-adherence have not been well documented or investigated.

The current study initiates a line of research in two understudied areas. First, we seek to test varenicline and NRT among light smokers through a 3-group (nicotine patch, varenicline, & varenicline placebo) randomized pilot trial. This investigation will provide preliminary findings for the feasibility and treatment efficacy of varenicline and NRT with light smokers. Considering the paucity of studies testing pharmacotherapy interventions for light smokers, this pilot study will offer critical data for advancing the treatment of light smokers. Secondly, the current study will focus exclusively on Latino light smokers in an attempt to further elucidate the adherence related factors that may be related to poor response to treatment. We will specifically examine the relationship between adherence and smoking cessation, as well as reasons and patterns for treatment non-adherence.

Methods

We utilized a 3-group (nicotine patch, varenicline, & varenicline placebo) randomized pilot trial of Latino smokers. Latinos in this study received a brief one-session culturally-informed behavioral intervention session during their first visit. Ongoing medication management visits occurred at 2 weeks, 1 and 2 months. Follow-up assessments with biochemically verified tests of tobacco abstinence occurred at 1 and 2 months, the conclusion of treatment (3 months), 4 months, and 6 months. All participants set a quit date during their first session.

Participants

Participants were Latino light smokers recruited in Rhode Island and Southern Massachusetts through radio advertising, referrals from community health agencies, and flyers posted in the community. Inclusion criteria included: 18+ years of age, current light smoker (≤10 CPD for the past 3 months), speak English or Spanish, agree to participate in the study and be available for 24 weeks, willing to set a quit date, and identify as being of Latino (or Hispanic) heritage, ethnicity, or ancestry.

Participants were excluded if they: suffered from an unstable medical condition precluding the use of varenicline or the NRT patch (e.g., severe or chronic heart disease, kidney disease requiring dialysis, severe skin disorders, etc); currently taking insulin, blood thinners, Cimetidine, Metformin, Phenformin, Pindolol, Procainamide; currently using smokeless tobacco, NRT or other smoking cessation treatment; a history of a suicide attempt/s; pregnant or nursing; employed as a pilot, driver or operator of heavy machinery; suffering from a chronic or acute severe psychiatric disorder that would interfere with participation; substance dependence other than nicotine dependence.

During the 4 months of active enrollment (April 2010 – July 2010) a total of 83 participants were screened over the phone. Of those, 32 were eligible to participate and provided informed consent. The most common reasons for ineligibility were: unwilling or unable to attend the baseline appointment (n=14); smoke more than 10 cigarettes per day (n=11); psychiatric conditions (n=9); employment that involves operating heavy machinery (n=7); medical conditions that would interfere with the study medication (n=6); taking medications that are contraindicated with the study medication (n=4).

Participants were compensated with gift cards and received $20 to complete the baseline assessment, $30 for the 3-month visit, $30 for the 4-month visit, and $40 for the 6-month visit. Research personnel contacted and reminded participants about follow-up appointments through phone calls and mailed appointment reminder letters. Transportation vouchers were provided if necessary. Participants were also offered the option of having follow-up visits in their home or at a private location in the community. However, study visits were primarily conducted at Butler Hospital with only 5 assessment visits (3 participants) conducted outside of our clinic. The study was approved by the Butler Hospital Institutional Review Board.

Pharmocotherapy Protocol—Participants in the varenicline group received 12-weeks of varenicline (Pfizer) dispensed in 0.5 mg or 1.0 mg tablets. Participants followed the typical dosing schedule for varenicline starting with 0.5 mg (orally) once daily for days 1 through 3; 0.5 mg twice daily for days 4 through 7, then 1 mg twice daily thereafter. Medication was dispensed at visit 1 (baseline), visit 2 (2 weeks), visit 3 (1 month) and visit 4 (2 months) for a total of 12-weeks of therapy. Interviews and pill counts at these visits assessed adherence and side effects. At each visit, participants received encouragement regarding adherence and brief smoking cessation counseling (described further below). The varenicline-placebo control condition consisted of 12 weeks of identical placebo tablets (prepared by contracted research pharmacy). The participants followed the identical dosing and visit schedule to the active varenicline group. Study personnel and participants in the 2 pill groups (varenicline, varenicline-placebo) were blinded to treatment condition. The research pharmacy maintained the study blind.

Participants assigned to the NRT condition received 12 weeks of NRT patches along with information describing its proper use, i.e., placement, use of one patch a day, importance of not smoking while using the patch, and tapering of patches. The patch, Nicoderm® (GlaxoSmithKline) was given at visit 1 (baseline), visit 2 (2 weeks), visit 3 (1 month) and visit 4 (2 months) for a total of 12-weeks of therapy: 4 weeks at moderate strength (14 mg),

followed by tapering to the 7 mg patch for 8 weeks. At each visit, participants received encouragement regarding adherence (e.g., "*it's important to remember to take your medicine*") and brief smoking cessation counseling (5A's) for up to 10 minutes (M. C. Fiore, 2000; Fiore et al., 2008).

Culturally-Informed Behavioral Session—At the first treatment visit, participants in all three groups received a culturally-informed smoking cessation behavioral intervention. The content of this 30 minute face-to-face session was based on that of a concurrent trial of a culturally tailored intervention with Latino smokers - Project Aurora, (Stanton, P.I. -R01-DA12344) which was developed through community focus groups of multi-ethnic Latinos in Southern New England. The intervention was also developed in consultation with experts in behavioral interventions for Latino smokers. All study personnel (interventionists and research assistants [RA]) had previous experience working with the Latino community, 3 of the 4 were bilingual in Spanish, and all had received training and ongoing supervision on maintaining cultural sensitivity.

The session was initiated with informal conversations about family and cultural background in order to enhance rapport and emphasize the Latino values of *respeto*, *personalismo*, and *familismo* (Marin & Marin, 1991). The content of the formalized intervention consisted of brief didactic information and discussions about the effectiveness of NRT/varenicline, the increased probabilities of quitting using pharmacotherapy as directed, barriers to adherence, the importance of social support, myths associated with NRT/varenicline use, and pan-Latino values (identified by Marin & Marin, 1991) that the investigative team hypothesized to impact treatment adherence. For example, *machismo* (association between masculine ideals and the use of pharmocotherapy), *familismo* (responsibility to family, including setting examples for children), the de-emphasis of *fuerza de voluntad* (willpower) as the primary means for achieving cessation, as well as a de-emphasis of *fatalismo*, (fatalistic outlook) of health and wellness. Participants were also provided with a smoking cessation self-help brochure which provided information on how to use the study medication. This self help brochure was taken from a concurrent trial of NRT and varenicline and did not include any culturally tailored components. All the study materials, including the consent form, the self help brochure, and the assessment measures were available in both English and Spanish. For measures and materials not previously translated, a two-step back-translation method with two independent translators was employed. Any discrepancies between translators were resolved by an independent translator.

Measures

Tobacco Use and Dependence—Tobacco dependence was assessed using the Fagerström Test of Nicotine Dependence (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991). Self-reported tobacco use was assessed using the timeline followback (TLFB; Sobell & Sobell, 1992). The TLFB is a calendar-based interview that asks participants to recall the frequency of substance use. The TLFB has been used extensively in assessing the use of a variety of substances as well as health behaviors (Sobell & Sobell, 1992). In the current study, we also collected medication adherence data using the TLFB interview. Participants were asked about both tobacco use and the use of the study medication. A *day of adherence* was defined in the patch group as using 1 patch. For the medication groups (varenicline & placebo), a *day of adherence* was defined as taking both prescribed doses (unless it was during the first 3 days of treatment when only one dose is taken).Treatment offered in all three groups consisted of 12 weeks (84 days) of medications or patch use. As a summary measure we calculated the percentage of days adherent during active treatment.

TLFB reports of tobacco abstinence were confirmed using expired carbon monoxide testing with a *Bedfont MicroSmokerlyzer™* machine with > 5 parts per million (ppm) as the cutoff indicating a positive smoking result (Benowitz, Bernert, Caraballo, Holiday, & Wang, 2009). In addition, salivary cotinine testing was employed as a secondary confirmation of abstinence in the varenicline and placebo groups. Since NRT impacts cotinine levels, the NRT group's cotinine levels were not used to confirm abstinence. Salivary cotinine was collected and testing with the *Accutest NicAlert™ Saliva* testing kit which displays seven categories representing cotinine levels from 0 (0–10 ng/ml) to 6 (> 1000 ng/ml). Values ≥1 indicated tobacco use (Marrone, Paulpillai, Evans, Singleton, & Heishman, 2010).

For participants reporting any medication non-adherence during the TLFB interview, the RA queried the participant about reasons for non-adherence using an open-ended interview question (i.e., *what was the reason/s that you did not take your medications/patch as intended?*). Lastly, standard self-report interview questions assessed demographic characteristics and smoking history (e.g., past quit attempts, smoking initiation, etc.).

Data Analysis—We present simple descriptive statistics to summarize sample characteristics and describe between group differences. In this pilot study with small sample size, we focus on the substantive magnitude of observed between group differences. We do, however report Fischer's exact p-values and the nonparametric Kruskal-Wallis test for equality of rank-ordered population distributions when comparing treatment groups on categorical and continuous outcomes, respectively. Graphical methods were used to explore and describe the association between adherence to treatment and smoking in each of the intervention groups.

Results

Sample Characteristics

Participants averaged 42.9 (± 9.7) years of age, 15 (46.9%) were male, 12 (37.5%) were Puerto Rican, 11 (34.4%) were Dominican, 4 (12.5%) were Columbian, 2 (6%) were Mexican, 2 (6%) were Guatemalan, and 1 (3%) was Peruvian. On average, participants smoked 7.6 (± 2.4) cigarettes per day during the 30-days prior to baseline and on average they initiated regular cigarette smoking at 19.3 (± 5.4; Median=17) years of age (Table 1). On average, participants reported 4.5 (± 4.6, Median=3) lifetime quit attempts and 17 (54.8%) said they had tried to quit at least once in the year prior to baseline. Twelve (38.7%) participants reported ever trying some form of NRT and 1 (3.2%) reported previously trying varenicline. There were no reports of previously using Zyban or Wellbutrin for smoking quit attempts. The rate of follow-up was 75% at 2-weeks; 56.3% at 1 month, 59.4% at 2 months (1 and 2 month visits included both medication management and research assessments), 65.6% at 3 months, 65.6% at 4 months, and 71.9% at 6 months. Ninety-seven percent of participants completed at least 1 follow-up beyond 2 weeks. The Kruskal-Wallis analysis of variance on rank-ordered data and Fisher's exact test were used to compare intervention arms with respect to baseline characteristics and rate of follow up. There were no significant differences and all associated p-values exceeded 0.1.

Tobacco Abstinence

Observed rates of CO/cotinine confirmed 7-day smoking abstinence at follow-up favored the group receiving varenicline at months 1 through 6 (Table 2). Differences were statistically significant (Fischer's exact p=.011) only at the 2-month follow-up when 5 (62.5%) of 8 participants receiving varenicline were abstinent. In the varenicline group, rates of confirmed 7-day smoking abstinence were 33.3% at the 1 month visit, 62.5% at the 2 month visit, 37.5% at the 3 month visit, 37.5% at the 4 month visit, and 42.9% at the 6 month visit.

One participant randomized to placebo was abstinent at the week 2 week (11.1%) visit and 1 month (14.3%) visit. There were no abstinent participants in the NRT group.

To assess sensitivity, we replicated these analyses under the assumption that all observations missing at follow-up were smoking (Table 3). Under this assumption, observed rates of CO/cotinine confirmed 7-day smoking abstinence again favored those randomized to varenicline at all follow-ups from month 1 through month 6. Differences were statistically significant at month 2 (Fisher's exact p=.001), month 3 (Fisher's exact p=.024), and month 4 (Fisher's exact p=.024). The product-moment and rank-order correlations between treatment adherence and % days smoking were −.84 (p=.002) and −.91 (p < .001), respectively.

Patterns of Treatment Adherence

On average participants were adherent on 55.5% (SD 37.6) of active treatment days. Rates of adherence to study medications did not differ significantly between intervention groups (Kruskal-Wallis $\chi^2 = 2.02$, df = 2, p = .366); mean rates of adherence were 67.7% (SD=36.5), 53.2% (SD=36.6), and 46.7% (SD=37.9) in the varenicline, placebo, and NRT conditions, respectively. The most commonly endorsed reasons for non-adherence were: forgetting (n=9), running out of medications due to session non-attendance (n=4), experiencing side effects (n=3), significant life events (e.g., hospitalization or vacation) interfering with treatment regimen (n=3), believing there was no longer a need for taking the medications (n=3), smoking relapse (n=3), and concerns over potential side effects or interactions (n=2).

Our limited sample size did not allow for empirically deriving adherence patterns through latent class analyses. Nevertheless, four basic patterns of treatment adherence were apparent by examining data on the number of days of adherence/non-adherence, the number of non-adherence episodes (episode is defined as 2 or more days of non-adherence), and the timing of non-adherence (i.e., beginning of treatment). There were a total of 12 participants (41.3%) who can be characterized as *Mostly Adherent.* On average, participants in this group were adherent 95.4% of treatment days and had an average of .58 (SD=.90) episodes of non-adherence. This group was comprised of 5 varenicline participants, 3 placebo, and 4 NRT participants.

Eight participants (27.6%) showed an *Erratic* treatment adherence pattern with adherence on 55.8% days of treatment and had an average of 4.37 (SD=4.77) episodes of non-adherence. The *Erratic* group was comprised of 3 varenicline participants, 3 placebo, and 2 NRT participants. A third group of 6 participants (20.6%) can be characterized as *Initially Adherent* (followed by complete non-adherence). In this group, participants averaged 21% adherence, which included a single, prolonged episode of non-adherence occurring after the initial week/s of treatment. The *Initially Adherent* group was comprised of 1 varenicline participant, 3 placebo, and 2 NRT participants. Lastly, 3 participants (10.3%) can be characterized as *Completely Non-Adherent*. Participants in this group were non-adherent on all 84 days of treatment (SD=0; 0% adherence). The *Completely Non-Adherent* group was comprised of 1 varenicline participant, 1 placebo, and 1 NRT participant.

Discussion

This pilot study represents the first investigation that specifically targets light smokers using a three group randomized design of varenicline, varenicline placebo, and NRT. Furthermore, this is the only study that has tested these treatments with Latino light smokers. Latino smokers are known to have high rates of light smoking as well as health disparities associated with smoking, smoking cessation treatment, and smoking related diseases.

Findings from the current study showed varenicline to be associated with greater levels of abstinence at follow-up as compared to NRT and placebo.

However, our overall abstinence rates were lower than reported in studies using varenicline with heavier smokers (Cahill, Stead, & Lancaster, 2008) and the abstinence rates at follow-up in the NRT group were unusually low and inconsistent with the numerous studies that have established NRT to be associated with a two-fold increase in cessation (See Cochrane Database review, Silagy et al., 2004). Several factors may have contributed to this atypical finding. Although the clinical practice guidelines for tobacco treatment (M. C. Fiore, 2000; Fiore et al., 2008) recommend a lowered initial dose of NRT (14mg) for light smokers, our finding may suggest that participants may have not received a clinically effective dose. Similarly, Ahluwalia and colleagues (2006) used a lower initial dose of nicotine gum in their trial of light smokers which also resulted in sub-optimal levels of abstinence. Our lack of an NRT placebo control arm and a higher NRT dose arm severly limits our ability to fully investigate this dosing issue. Our findings offer future studies a rationale for testing a standard initial dose of NRT for light smokers.

Another possible reason for our relatively lower abstinence rates may be the poor levels of medication adherence that occurred across all three treatment conditions, including the varenicline arm. Adherence to smoking cessation treatment is known to be a significant predictor of smoking abstinence (Catz et al., 2011). Adherence to smoking cessation interventions among Latinos has also been shown to be a barrier to treatment success (Fu, et al., 2008). Studies have revealed possible mediating factors including general mistrust of pharmacological treatments, language barriers, concerns over side-effects, misconceptions about the risks of smoking, and cultural values associated with quitting (Levinson, et al., 2006; Levinson, et al., 2004), some of which were addressed by our protocol.

Findings from the current study provide a descriptive account of treatment non-adherence among Latino light smokers who have enrolled in pharmacotherapy trial. Our findings suggest that Latino light smokers are non-adherent for a variety of reasons including forgetting, running out of medications, side effects, and life events. There was no pattern that suggested a higher side-effect profile for those in the varenicline group. These findings may have implications for treatment interventions that seek to increase adherence to smoking cessation pharmacotherapy. Treatments that target these factors directly by providing medication reminders, home visits to deliver medications, informational didactics about side effects to expect, and developing plans for continued adherence during unplanned life events may result in greater adherence. Our findings also shed light on patterns of non-adherence and future interventions may be enhanced through proactive adherence enhancing strategies that preempt such patterns of non-adherence.

The limitations of the current study must be considered when interpreting our findings. Foremost, this was a pilot study and thus we are limited in a number of ways by our small sample size. While varenicline outperformed NRT in terms of abstinence outcomes here, larger trials are needed before determining the relative efficacy of these medications. Furthermore, if a future study tests higher doses of NRT, the addition of an NRT placebo patch group might be of interest as well. Second, our sample was limited to Latino light smokers and results may not generalize to non-Latino light smokers. Another limitation of the current study was the method of measuring adherence which was self-reported using the TLFB. This approach may have under or over-represented participant's adherence. Utilizing a more rigorous approach to capturing adherence data, e.g., electronic pill bottles (Medication Event Monitoring System, MEMS (Shi et al., 2010) could have validated self-report. The follow-up rate was a final limitation of our study. Despite our efforts to enhance retention through multiple forms of communication and reminders, participants missed 25–

40% of follow-up assessments across the six study visits. Notably, our follow-up rates for assessment visits that included monetary incentives (3, 4 & 6 month visits) were higher than at other visits. Future studies seeking to enhance retention rates should consider participant incentives for all study visits.

Despite our limitations, this is the first study of varenicline and NRT patch with Latino light smokers, an understudied and vulnerable subpopulation of smokers. As noted in the review of the literature, a limited number of studies have sought to develop and test interventions for Latino smokers. In the three identified studies involving culturally tailored interventions (Nevid et al., 1997; Woodruff et al., 2002 & Borrelli et al., 2010) abstinence rates ranged between 9 and 20%. Considering our varenicline group findings, future trials involving culturally tailored interventions for Latinos may benefit from adjunctive varenicline or other pharmocotherapy treatment. Our findings also support the development of novel medication adherence interventions that can be incorporated into standard smoking cessation treatment in order to address the specific needs of Latino smokers.

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Table 1

Baseline Demographic and Smoking Characteristics by Intervention Group

		INTERVENTION GROUP			
	Total (n = 32)	**Patch (n = 11)**	**Varenicline (n = 10)**	**Placebo (n = 11)**	**p =**
Age	42.9 (± 9.7)	39.1 (± 9.1)	45.7 (± 12.7)	44.2 (± 6.1)	.382[a]
n (%) Male	15 (46.9%)	6 (54.5%)	4 (40.0%)	5 (45.5%)	.905[b]
Cigs / Day	7.6 (± 2.4)	8.6 (± 1.2)	7.4 (± 3.1)	6.9 (± 2.4)	.268[a]
Age Regular Smoking	19.3 (± 5.4)	20.3 (± 8.1)	18.8 (± 3.8)	18.6 (± 2.6)	.855[a]
FTND	2.9 (± 1.8)	3.6 (± 1.7)	2.7 (± 1.8)	2.3 (± 1.7)	.151[a]
Lifetime Quit Attempts	4.5 (± 4.6)	3.7 (± 3.4)	5.3 (± 5.1)	4.5 (± 5.4)	.855[a]
n (%) Prior NRT Use	12 (38.7%) [c]	5 (45.5%)	1 (11.1%) [c]	6 (54.5%)	.130[b]
n (%) Prior Zyban Use	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1.00[b]
n (%) Prior Chantix Use	1 (3.2%) [c]	0 (0.0%)	1 (11.1%) [c]	0 (0.0%)	.290[b]
# Valid Follow-Ups	3.9 (± 1.9)	3.7 (± 1.7)	4.4 (± 2.0)	3.7 (± 2.2)	.520[a]
Completed Week 2 F/U	24 (75.0%)	8 (72.7%)	7 (70.0%)	9 (81.8%)	.884[b]
Completed Month 1 F/U	18 (56.3%)	5 (45.5%)	6 (60.0%)	7 (63.6%)	.742[b]
Completed Month 2 F/U	19 (59.4%)	5 (45.5%)	8 (80.0%)	6 (54.6%)	.289[b]
Completed Month 3 F/U	21 (65.6%)	7 (63.6%)	8 (80.0%)	6 (54.6%)	.580[b]
Completed Month 4 F/U	21 (65.6%)	7 (63.6%)	8 (80.0%)	6 (54.6%)	.580[b]
Completed Month 6 F/U	23 (71.9%)	9 (81.8%)	7 (70.0%)	7 (63.6%)	.709[b]

[a] Comparisons of continuous characteristics were tested with the Kruskal-Wallis equality of populations test for rank-ordered data.

[b] Fisher's exact p.

[c] In the placebo group, 1 participant did not complete the assessment which captured prior use of cessation treatments. Therefore, the noted % values correspond to a denominator of 10.

Table 2

Rates of 7-Day Abstinence at Follow-Up by Intervention Group

		INTERVENTION GROUP			
	Total	**Patch (n = 11)**	**Varenicline (n = 10)**	**Placebo (n = 11)**	**Fisher's Exact p**
Week 2 (n = 24)	1 (4.2%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1.00
Month 1 (n = 18)	3 (16.7%)	0 (0.0%)	2 (33.3%)	1 (14.3%)	.588
Month 2 (n = 19)	5 (26.3%)	0 (0.0%)	5 (62.5%)	0 (0.0%)	.011
Month 3 (n = 21)	3 (14.3%)	0 (0.0%)	3 (37.5%)	0 (0.0%)	.083
Month 4 (n = 21)	3 (14.3%)	0 (0.0%)	3 (37.5%)	0 (0.0%)	.083
Month 6 (n = 23)	3 (13.0%)	0 (0.0%)	3 (42.9%)	0 (0.0%)	.040

Table 3

Rates of 7-Day Smoking Abstinence at Follow-Up by Intervention Group with Persons Lost to Follow-Up Assumed Actively Smoking (n = 32).

		INTERVENTION GROUP			
	Total	**Patch (n = 11)**	**Varenicline (n = 10)**	**Placebo (n = 11)**	**Fisher's Exact p**
Week 2	1 (3.1%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	.765
Month 1	3 (9.4%)	0 (0.0%)	2 (20.0%)	1 (9.1%)	.290
Month 2	5 (15.6%)	0 (0.0%)	5 (50.0%)	0 (0.0%)	.001
Month 3	3 (9.4%)	0 (0.0%)	3 (30.0%)	0 (0.0%)	.024
Month 4	3 (9.4%)	0 (0.0%)	3 (30.0%)	0 (0.0%)	.024
Month 6	3 (9.4%)	0 (0.0%)	3 (30.0%)	0 (0.0%)	.094

Table 4

Adherence Patterns by Treatment Condition

Adherence Group	Total (n = 29)[a]	Intervention Group			*% Days Treatment Adherence*	*Mean # of Non-Adherence Episodes*
		NRT Patch (n = 9)	Varenicline (n = 10)	Placebo (n = 10)		
Mostly Adherent	12 (41.3%)	4 (33.3%)	5 (41.6%)	3 (25.0%)	95.4	.58 (.90)
Erratic	8 (27.6%)	2 (25.0%)	3 (37.5%)	3 (37.5%)	55.8	4.37 (4.77)
Initially Adherent	6 (20.6%)	2 (33.3%)	1 (16.6%)	3 (50.0%)	21	1 (0)
Completely Non-Adherent	3 (10.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	0	1 (0)

[a]Three participants did not complete the assessment of treatment adherence.