Pilot Evaluation of a Brief Intervention to Improve Nicotine Patch Adherence Among Smokers Living with HIV/AIDS

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Abstract

Nicotine replacement therapy is an effective intervention for smoking cessation, but adherence tends to be low. This paper presents results from a pilot evaluation of a brief smoking cessation treatment to improve adherence to the nicotine patch among Latino smokers living with HIV/ AIDS. Forty smokers were randomized to receive either a standard 5 A's counseling session and 8-week treatment of nicotine patch, or a similar intervention that added a 10-minute module to the 5 A's counseling that focused on improving adherence to the nicotine patch. Smoking outcomes (CO verified 7-day point prevalence and continuous abstinence) were evaluated through a 3-month follow-up. Patch usage during the follow-up period was also assessed. Intention to treat analyses indicated that abstinence rates were 2–3 times higher in the adherence condition compared to the standard condition (7-day point prevalence abstinence: 35.0% vs. 15.0%; continuous abstinence: 30.0% vs. 10.0%). Nicotine patch compliance over an 8-week period was also higher in the adherence condition than the standard condition (44% vs. 25%). Although this small pilot was conducted to estimate effect sizes, and was not powered to detect group differences, results are promising and suggest that adding a 10-minute module focused on nicotine patch adherence to a standard 5 A's protocol can increase abstinence rates. Given that this smoking cessation treatment was not specifically tailored to either HIV-positive smokers or Latino smokers, future research should examine whether it may be a promising approach for improving nicotine patch adherence in the general population of smokers.

Keywords

Smokers; adherence; nicotine patch; Latino; HIV-positive

Introduction

Smoking is a highly prevalent and significant risk factor among people living with HIV/ AIDS (PLWHA). Smoking rates among PLWHA are estimated to be two to three times higher than in the general U.S. population (Kariuki et al., 2016; Pacek, Harrell, & Martins, 2014). PLWHA smokers have significantly higher mortality compared to PLWHA non-smokers (Crothers et al., 2005; Lifson et al., 2010), and are now more likely to die from a smoking-related disease than from an AIDS-defining illness (Helleberg et al., 2013). Quitting smoking could substantially improve the health risk profiles of PLWHA (Marshall, McCormack, & Kirk, 2009; Valiathan, Miguez, Patel, Arheart, & Asthana, 2014). High smoking prevalence rates, combined with the serious health risks from smoking, motivate a search for effective interventions to help PLWHA smokers quit.

A number of smoking cessation trials have been conducted with PLWHA, evaluating a range of counseling or motivational approaches combined with provision of the nicotine patch (e.g., Gritz et al., 2013; Humfleet, Hall, Delucchi, & Dilley, 2013; Ingersoll, Cropsey, & Heckman, 2009; Lloyd-Richardson et al., 2009; Stanton et al., 2015; Vidrine, Arduino, Lazev, & Gritz, 2006; Vidrine, Marks, Arduino, & Gritz, 2012; Wewers, Neidig, & Kihm, 2000; see Ledgerwood & Yskes, 2016 for recent review). Although these trials have demonstrated the feasibility of implementing cessation interventions with PLWHA, no particular treatment or approach has demonstrated long-term efficacy compared to standard control treatments (Moscou-Jackson, Commodore-Mensah, Farley, & DiGiacomo, 2014). The modest results to date may be largely due to the important, yet understudied, issue of nicotine patch non-adherence. Across different populations, adherence to the nicotine patch and other treatments for tobacco dependence tends to be very low (< 40%; World Health Organization, 2003). The same has been found in two studies specifically reporting on nicotine patch adherence among PLWHA smokers trying to quit (Ingersoll et al., 2009; Stanton et al., 2015). Given that poor adherence to the nicotine patch significantly decreases the chances of quitting among PLWHA (Lloyd-Richardson et al., 2009; Stanton et al., 2015), similar to findings from studies of non-HIV positive smokers (Shiffman, Sweeney, Ferguson, Sembower, & Gitchell, 2008), it is critical to develop an intervention approach that improves nicotine patch adherence.

In the general population of smokers, commonly cited reasons for non-adherence to nicotine replacement include cost, side effects, and beliefs that nicotine replacement does not work (Balmford, Borland, Hammond, & Cummings, 2011). However, interventions that simply provide information to address these concerns have not been particularly effective (Hollands et al., 2015). There is little guidance in the literature on the best approach to improving adherence to nicotine replacement. This is especially true for understudied populations in that the small number of existing studies have used predominantly non-Latino White, healthy general population samples (Hollands et al., 2015). The ethnic disparities that exist in both smoking- and AIDS-related illnesses (Vega, Rodriguez, & Gruskin, 2009) create a clear need to improve nicotine replacement adherence (and thus smoking cessation) among HIV-positive Latino smokers. To address this need, we took a two-phase formative approach to developing a treatment module to improve nicotine patch adherence among Latino PLWHA smokers (Shadel, Galvan, & Tucker, in press). The first phase involved

interviewing smokers who had previously used the nicotine patch to better understand how, when, and why they used it; perceived barriers to using it; and suggestions for improving adherence to it. The second phase involved providing smokers with brief smoking cessation treatment and nicotine patches, then interviewing them in "near real time" over a two month period about their patch use during a quit attempt (e.g., barriers and facilitators). Results from this work identified three factors associated with adherence to the nicotine patch: high motivation for continued patch use; realistic expectations about patch side effects and efficacy; and linking patch use with established daily routines. In addition, we integrated standard cognitive behavioral therapy techniques for identifying and dealing with triggers, in this case for not using the patch. A 10-minute adherence-focused treatment module, which could be added to an existing brief smoking cessation treatment (Shadel & Niaura, 2003), was developed to address these key issues. Of note, participant feedback in the formative phases of our research indicated that it was not necessary to tailor the content of the adherence module to either HIV-positive smokers or Latino smokers (Shadel et al., in press).

This is the first study to evaluate the efficacy of a brief adherence-focused intervention module designed specifically to increase compliance with the nicotine patch. We present results from a Phase II pilot evaluation that compares an adherence-focused brief smoking cessation treatment and nicotine patch to a standard brief smoking cessation treatment and nicotine patch among Latino PLWHA smokers. The focus on Latino PLWHA smokers is important in that this is an understudied, yet high-priority population for improving smoking cessation (Levinson, Pérez-Stable, Espinoza, Flores, & Byers, 2004). Indeed, poor adherence to the nicotine patch in a recent randomized controlled trial involving 302 Latino PLWHA smokers prompted the authors to call for more research to improve compliance to nicotine replacement therapy (NRT) (Stanton et al., 2015). In the present study, we hypothesized that both compliance to the nicotine patch and smoking abstinence rates would be higher among smokers randomized to receive the adherence-focused brief smoking cessation treatment compared to those who received standard brief smoking cessation treatment.

Methods

Participants

Participants were age 18 or older, self-identified as both Latino/a and HIV-positive, smoked 20 days and 5 cigarettes per day in the past month, were ready to set a quit date within the next 30 days (score < 7 on the Readiness to Quit Ladder; Biener & Abrams, 1991), and were willing to use the nicotine patch. Ineligibility criteria included self-reporting any medical condition which would prevent using the nicotine patch, currently using e-cigarettes or tobacco products other than cigarettes, currently engaging in another smoking cessation treatment, or having participated in the formative phase of the project. The study was advertised at health clinics and social service agencies serving HIV-positive individuals in the study area, magazines targeting the LGBT Latino community, and social networking sites geared towards gay and bisexual men. We received calls from 107 individuals and were able to re-contact and screen 69 of them. Forty of the screened individuals were eligible the study. Six participants (four in standard condition, two in adherence condition) dropped out

between baseline and follow-up. There were no significant differences between drop-outs and completers.

Procedure

After completing the baseline survey, 20 participants were randomized to receive a standard brief smoking cessation treatment and nicotine patch, and 20 were randomized to receive an adherence-focused brief smoking cessation treatment and nicotine patch. The standard condition followed the 5 A's protocol (Ask; Advise; Assess; Assist; Arrange; Shadel & Niaura, 2003). The adherence treatment followed the same basic structure as the standard treatment, but included an additional module on improving adherence to patch use (available from the first author). The module was designed to help smokers: (a) build motivation to use the patch (e.g., by weighing the pros and cons of patch use through a decisional balance exercise); (b) establish realistic expectations about the patch (e.g., by understanding the extent to which withdrawal symptoms and urges will be reduced and how long it will take); (c) develop personalized strategies to remember to use the patch (e.g., by linking patch application to daily routine like brushing teeth); and deal with temptations to not use the patch (e.g., by identifying personal triggers for not using the patch, and devising a plan for avoiding or dealing with these triggers).

Both interventions involved a single in-person session, delivered in English or Spanish, at one of multiple locations of a social service agency serving the LGBT community in Los Angeles. Facilitators were bilingual Master-level project staff not affiliated with the agency. All participants received an 8-week supply of nicotine patches and a pamphlet on quitting smoking. Although contact time was slightly longer in the adherence (27 minutes) vs. standard (16 minutes) condition, the additional contact time in a brief intervention (overall, less than 30 minutes) is not likely to make a difference in cessation outcomes (Fiore et al., 2008). Participants were compensated for completing the surveys. Sessions were audio-recorded (with permission), with 30% of sessions reviewed by the 2nd or 3rd authors to ensure intervention fidelity. All procedures were approved by the Institutional Review Boards of RAND and Bienestar Human Services, and survey responses were protected by a Certificate of Confidentiality from the National Institutes of Health.

Measures

<u>Baseline variables</u> included demographics (age, gender, education, living situation), smoking and quitting history (age at first cigarette, number of days smoked and number of cigarettes per day in past month, smoking within 30 minutes of waking (Baker et al., 2007), number of times quit in past year, and ever used the nicotine patch), medical history (number of years since HIV diagnosis, number of pills taken per day, number of current medical comorbidities), and depressive symptoms (Radloff, 1977).

<u>Abstinence outcomes</u> were 7-day point prevalence and 90-day continuous abstinence (i.e., time since quit day) (Hughes et al., 2003). Participants who reported that they were abstinent at the follow-up point had their status confirmed via expired air carbon monoxide (CO; < 5 ppm). Given the possibility of CO false positives related to smoking other substances such as marijuana, we probed further about marijuana use if a participant reported no cigarette

smoking, but had a CO level > 5 ppm (one participant fell into this category; s/he was classified as abstinent from cigarettes even though s/he was not abstinence from marijuana).

Nicotine patch adherence was assessed both with self-report of number of days of patch use between baseline and follow-up and by asking participants to return at follow-up all of the patches they had been given and conducting a count of their used patches. Twenty-two of the 34 follow-up participants returned their patches; the remaining 12 participants provided only self-reports of number of patches used. Participants were classified as adherent with the nicotine patch if they used   6 patches per week (Schnoll et al., 2010).

Analytic Plan

Biochemically-verified 7-day point prevalence quit rates and continuous abstinence at 3 months (90 days) following the baseline visit, as well as nicotine patch adherence rates, are reported for each of two samples: an Intention to Treat sample (ITT: missing outcomes at the follow-up treated as "smoking"; $n = 40$) and a complete cases sample (participants who had complete data at baseline and follow-up; $n = 34$). Logistic regression was used to evaluate the effect of condition on these outcomes for each sample. To further investigate the impact of attrition, we conducted a multiple imputation sensitivity analysis based on the assumption that outcome data were missing at random (Heron et al., 2011; Rubin, 1987). We used all baseline variables in Table 1 in the imputation model (20 imputations). Qualitative comparisons between the main and sensitivity analyses were made. This Phase II pilot trial was not powered to detect significant differences between treatments, but rather to estimate effect sizes for potential larger future randomized trials. All p-values reported are from the Fisher's exact test in order to account for the small sample.

Results

Table 1 presents baseline descriptive demographic and smoking and quitting history variables for each condition. Randomization was largely successful in equating participants on these variables at baseline. Participants in the adherence condition reported significantly greater past year quit attempts; as such, this variable is treated as a covariate in the regression analyses.

Effects of adherence intervention on abstinence outcomes

The top half of Table 2 presents the raw (unadjusted) abstinence outcomes for each of the two outcomes for each sample. Across both the treatment completers sample and ITT sample for both 7-day point prevalence abstinence and continuous abstinence outcomes, abstinence rates for participants assigned to the adherence condition were 2–3 times larger than abstinence rates for those in the standard condition. The intervention effects are clinically meaningful, although they did not reach a conventional level of statistical significance given the small sample size for this pilot. For 7-day point prevalence abstinence, the odds ratio for the effect of treatment condition was $OR = 3.71$ (95% $CI = 0.67 – 20.49$) for the ITT sample, and $OR = 4.01$ (95% $CI = 0.63 – 25.79$) for the completers sample. For 90-day continuous abstinence, the odds ratio for the effect of treatment condition was $OR = 5.40$ (95% $CI = 0.79 – 37.14$) for the ITT sample, and $OR = 6.17$ (95% $CI = 0.78 – 48.86$)

for the completers sample. The multiple imputation sensitivity analysis produced qualitatively the same results; for the 7-day point prevalence abstinence, the effect of the treatment was estimated at $OR = 2.14$ (95% $CI = 0.36 – 12.74$) and for the 90-day continuous abstinence, the effect was $OR = 7.58$ (95% $CI = 0.94– 61.32$).

Effects of adherence intervention on patch use

The bottom half of Table 2 presents the raw (unadjusted) proportion of participants who were compliant in using the nicotine patch in each condition. The table reports overall levels of patch compliance for the 8 weeks, and then compliance for first four weeks and the last four weeks that participants were asked to use the patch. Across these indices, a greater proportion of participants assigned to the adherence condition were compliant in using the nicotine patch compared to participants in the standard condition. The compliance rate was about 1.75 times larger in the adherence condition than the standard condition over the entire 8 week period, with this intervention effect being even stronger for the last four weeks that participants were asked to use the nicotine patch. Logistic regression analyses was used to predict these indices of patch compliance from treatment condition while controlling for number of quit attempts in the past year. The odds ratio for the effect of treatment condition on patch compliance for the full 8 weeks was 3.60 (95% $CI = 0.62 – 20.91$), for the first 4 weeks was 2.08 (95% $CI = 0.37 – 11.71$), and for the last 4 weeks was 5.87 (95% $CI = 0.90 – 38.47$). Again, the magnitude of intervention effects is clinically meaningful, although they did not reach a conventional level of statistical significance given the small sample size for this pilot.

Discussion

The lack of strong results from randomized trials of smoking cessation interventions for PLWHA smokers have led experts to call for more research to improve adherence to the nicotine patch (Lloyd-Richardson et al., 2009; Stanton et al., 2015). Efficacious adherence-based interventions for nicotine patch use are needed, and results from this Phase II pilot study are very promising. Quit rates in the standard condition were of a magnitude consistent with other studies of brief counseling combined with nicotine replacement (Fiore et al., 2008). However, adding a 10-minute module focused on patch adherence to the standard 5 A's protocol led to an improvement in adherence to the patch, verified 7-day point-prevalence abstinence at 3-months, and continuous abstinence over the follow-up period. Although not statistically significant (this small pilot was conducted to estimate effect sizes), the magnitude of the effect is greater than the relative risks reported in other evaluations of the short-term efficacy of interventions to increase adherence to medications for tobacco dependence (Hollands et al., 2015).

Prior research has shown that simply addressing smokers' concerns about the cost, side effects, safety, and effectiveness of NRT is insufficient to significantly improve NRT adherence (Hollands et al., 2015). In contrast, our adherence-focused treatment module placed more emphasis on building motivation to use the patch, establishing realistic expectations for patch efficacy, and developing concrete strategies for remembering to use the patch and dealing with triggers and temptations to not use the patch. It is important to

note that none of these intervention targets is unique to HIV-positive smokers or to Latino smokers, and none of the elements of treatment was specifically tailored to these populations. In developing the adherence module, we anticipated that there may be a need for tailoring its content – especially in light of smoking cessation interventions that have been tailored for PLWHA smokers (Humfleet et al., 2013; Moadel et al., 2013), Latino smokers (Wetter et al., 2007; Woodruff, Talavera, & Elder, 2002), and Latino PLWHA smokers (Stanton et al., 2015). However, the feedback we received from the Latino PLWHA smokers who participated in the formative phases of this project did not indicate a need for tailoring. As such, future research should examine whether this adherence-focused treatment may be a promising approach for improving use of the nicotine patch in the general population of smokers.

This study has a number of strengths that should be noted. Improving smoking cessation in Latino HIV-positive smokers deserves greater attention, given the continuing growth of the Latino population in the U.S. and the high likelihood that disparities in both smoking- and AIDS-related illness will increase further (Vega et al., 2009). Thus, our specific focus on this understudied population is an important strength of the study. Further, the generalizability of our results is enhanced by offering the program in both English and Spanish, and recruiting participants from diverse settings within the community. Other strengths of the study include the use of a patch count to verify self-reported adherence, as well as the excellent retention rate. Despite these strengths, the study is limited by its small sample size which, although by design for this pilot trial, diminished our capacity to detect significant treatment effects. In addition, the 3 month follow-up period leaves open the question of whether the positive effects of this brief adherence-based intervention are sustained over time.

This is the first study to provide results of a brief adherence-focused module to increase adherence to the nicotine patch that can be added to a standard brief smoking cessation intervention. This module was developed in response to a significant need to improve NRT adherence and thus abstinence rates in smoking cessation programs. Developed with stakeholder input, including Latino PLWHA smokers who were tracked in near "real time" while using the patch, results from this pilot evaluation are promising. Smokers who received the adherence module showed better nicotine patch compliance over an 8-week period, and had abstinence rates that were 2–3 times higher compared to those who did not receive the adherence module. Next steps in this line of research include evaluating the efficacy of the adherence-focused intervention in a larger sample, with a longer follow-up, and in other populations of smokers.

Acknowledgments

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Table 1

Background Characteristics of the Baseline Sample (N=40)

Variable	Standard (*n*=20)	Adherence (*n*=20)	*p*
M Age *(SD)*	42.2 (8.1)	43.5 (9.4)	0.65
% male	95	90	1.00
Education			
% not high school graduate	35	50	0.54
% high school graduate / GED	40	25	
% more than high school	25	25	
% live alone	30	30	1.00
Smoking and quitting history			
M age at first cigarette *(SD)*	17.7 (7.0)	16.9 (5.5)	0.68
M days smoked in past 30 days *(SD)*	27.5 (6.7)	29.7 (1.0)	0.15
M number cigarettes smoked/day in past 30 days *(SD)*	13.1 (15.6)	12.8 (9.2)	0.95
Time to first cigarette (% who smoke within 30 minutes)	57.9	70.0	0.43
M number times quit in past year *(SD)*	0.60 (0.8)	1.7 (1.3)	< 0.05
% ever used nicotine patch	20.0	20.0	1.00
Medical and medication history			
M number of years since HIV diagnosis *(SD)*	13.1 (8.2)	12.2 (8.5)	0.67
M number pills taken per day *(SD)*	5.9 (5.5)	5.6 (3.6)	0.84
M number of current medical comorbidities *(SD)*	2.5 (2.9)	2.6 (3.8)	0.79
M depressive symptoms score *(SD)*	11.3 (7.2)	13.2 (6.1)	0.79

Table 2

Raw (Unadjusted) Abstinence Outcomes and Patch Adherence at the Three Month Follow-Up

Outcome	N	Standard	Adherence	p-value
ITT				
% abstinent (7-day point prevalence)	40	15.0	35.0	0.140
% abstinent (90-day continuous)	40	10.0	30.0	0.107
Complete cases				
% abstinent (7-day point prevalence)	34	18.8	38.9	0.193
% abstinent (90-day continuous)	34	12.5	33.3	0.115
Nicotine patch adherence				
% adherent to the nicotine patch (full 8 weeks)	34	25.0	44.4	0.233
% adherent to the nicotine patch (first 4 weeks)	34	56.3	61.1	0.774
% adherent to the nicotine patch (last 4 weeks)	34	18.8	44.4	0.105