

Brief report

Correlates of Adherence to Varenicline Among HIV+ Smokers

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Abstract

Introduction: Low rates of adherence to smoking cessation pharmacotherapy may limit the effectiveness of treatment. However, few studies have examined adherence in smoking cessation trials thus, there is a limited understanding of factors that influence adherence behaviors. This brief report analyzes correlates of adherence to varenicline among people living with HIV/AIDS.

Methods: Study participants were recruited from three HIV care centers in New York City and enrolled in a three-arm randomized controlled pilot study in which all subjects received varenicline. At the 1-month study visit, there were no significant differences in adherence by study condition, therefore we combined treatment arms to examine correlates of adherence ($n = 127$). We used pill counts to assess varenicline adherence, defined as taking at least 80% of the prescribed dose. We conducted a multivariate path analysis to assess factors proposed by the information-motivation-behavioral skills model to predict adherence.

Results: Only 56% of smokers were at least 80% adherent to varenicline at 1 month. Adherence-related information, self-efficacy, a college degree, and non-Hispanic white race/ethnicity were associated with increased varenicline adherence. In path analysis, information and motivation were associated with increased adherence self-efficacy, and adherence self-efficacy was associated with increased adherence, but with marginal significance. These associations with adherence were no longer significant after controlling for race/ethnicity and education.

Conclusions: Further exploration of the role of a modifiable correlates of adherence, such as adherence-related information, motivation and self-efficacy is warranted. Interventions are needed that can address disparities in these and other psychosocial factors that may mediate poor medication adherence.

Introduction

Smoking represents an important health risk for people living with HIV/AIDS (PLWHA) and is associated with suboptimal adherence to antiretroviral therapy (ART).^{1,2} PLWHAs are interested in quitting

and can achieve abstinence, particularly when pharmacotherapy is used.³⁻⁷ However, similar to findings in the general population, treatment adherence among HIV+ smokers is poor and declines over time.⁸⁻¹⁰ Despite the overwhelming burden of tobacco-related

disease, few studies have evaluated the delivery of smoking cessation interventions for HIV-infected adult smokers, and none have used objective measures to examine patterns of adherence to varenicline.^{6,7,10-12}

Varenicline is an efficacious smoking cessation medication, but poor adherence limits treatment effectiveness.¹³⁻¹⁷ Factors associated with adherence to cessation pharmacotherapy include demographics (female gender, older age, higher level of education), lower levels of nicotine addiction, fewer side effects, and early treatment adherence.^{14,16-18} PLWHAs may face additional obstacles to adherence including an already complex medication regimen, high rates of co-occurring drug and alcohol use and limited socioeconomic resources.^{7,19}

Most studies of adherence to cessation pharmacotherapy have lacked a theoretical framework for understanding predictors and have largely excluded measures of psychological and behavioral factors that may help explain lower rates of treatment adherence, particularly among disparate populations.¹⁸ The information-motivation-behavioral skills (IMB) model has been applied to a number of health behaviors, including medication adherence.^{20,21} The model posits that adherence is more likely if individuals have adequate adherence-related self-efficacy or confidence that they can use the treatment as prescribed (behavioral skills), information/knowledge about the treatment, and positive attitudes and beliefs towards adherence outcomes (motivation). It is further hypothesized that adherence-related behavioral skills (self-efficacy) mediate the relationship between information, motivation, and adherence behavior.

The purpose of this brief report was to describe rates of varenicline adherence and to assess the relationship among baseline measures of the IMB constructs and varenicline adherence after 1 month of treatment. The data are derived from a randomized controlled pilot study to assess the effect of an adherence-focused intervention on adherence to varenicline among HIV+ smokers.

Methods

Study Design

This is an analysis of 1-month varenicline adherence among subjects enrolled in a three-arm randomized controlled pilot study. Medically eligible patients were randomized to receive 12 weeks of varenicline either alone or in combination with one of two adherence-focused support options: twice daily text message support or text message plus seven cell phone-delivered counseling sessions. A total of 841 patients were screened for eligibility, 158 were randomized and 131 completed the 1-month study visit. We combined data across the three treatment arms because no significant differences were found in varenicline adherence at the 1-month study visit. Participants provided written informed consent. The New York University School of Medicine and St Luke's Roosevelt Hospital Institutional Review Boards approved study procedures.

Setting and Participants

Between July 2013 and March 2014, we recruited study participants in the waiting area of three HIV care centers, St Luke's-Roosevelt Hospital Spencer Cox Centers for Health, located in New York City. Smokers were eligible if they were 18 years or older, smoked at least five cigarettes daily in the past week, were willing to quit within the next 2 weeks, and were cleared by their physician for varenicline use (ie, did not have major depression, schizophrenia or bipolar disorder, or renal impairment). Individuals were excluded if

they were pregnant or nursing, using another FDA-approved smoking cessation medication, had a PHQ 9 depression score less than 5 and a substantial to severe drug use disorder defined as a score of at least 6 on the Drug Abuse Screening Test-10 and/or a hazardous or active alcohol use disorder defined as at least 7 for men and at least 5 for women on the Alcohol Use Disorders Identification Test-Consumption.^{22,23}

Measures

Adherence

Consistent with previous studies, adherence was defined as taking at least 80% of prescribed varenicline in the previous 4 weeks (ie, at the 1-month follow-up visit), as determined by pill count.^{15,16,18,24} There is evidence for an association between short-term adherence and cessation outcomes.¹⁶ For example, adherence to varenicline and nicotine patch during the first 3 weeks of treatment has been linked to longer-term abstinence outcome.^{14,25} Participants who did not bring their medication bottles for pill count were considered nonadherent ($n = 9$).

Baseline Measures

Nicotine dependence was measured using the single-item of time to first cigarette after waking taken from the Fagerstrom Test for Nicotine Dependence.²⁶ Alcohol and drug use were measured using the Alcohol Use Disorders Identification Test-Consumption and the Drug Use Disorders Identification Test.^{27,28} We used a visual analog scale (VAS), as a measure of self-reported adherence to ART in the past month with responses ranging from 0%–100% (coded 1–10).²⁹

Constructs of the IMB model were assessed using three scales (Supplementary Appendix). To measure beliefs and attitudes (motivation), we adapted Fucito's 6-item beliefs and attitudes about bupropion measure (Cronbach's $\alpha = .86$) which uses a 5-point likert scale.⁸ The 8-item varenicline information scale was adapted from the Life Windows IMB Adherence Assessment Questionnaire (Cronbach's $\alpha = .65$) and was assessed on a 5-point likert scale (1 = strongly disagree, 5 = strongly agree).³⁰ Varenicline adherence self-efficacy (behavioral skills) was assessed with a 17-item survey using 4-point likert scale (1 = not at all sure, 4 = extremely sure), with 12 items adapted from the Medication Adherence Self-Efficacy Scale and 5 items from the Adherence Self-Efficacy Scale (Cronbach's $\alpha = .92$).^{31,32} All negative questions were reverse coded before data analysis. To test internal consistency of each scale, Cronbach's alpha was calculated based on all participants who completed the baseline survey ($n = 158$).

Analysis

We included the 127 participants with complete data on all measures for the 1-month study visit in the analysis. *T*-tests, Fisher's exact tests and chi-square analyses were used to compare associations between baseline variables and adherence (Table 1). Baseline variables with a significant bivariate association with varenicline adherence, as well as variables indicating study treatment condition, were included in Table 2 analyses.

Bivariate analyses (Table 2) were conducted to examine the correlates of each IMB model construct and the relationship between the three IMB constructs and adherence. To further investigate relationships among varenicline information, varenicline attitudes/beliefs, adherence self-efficacy and the adherence outcome, a path model was estimated using Mplus Version 7.3.³³ We used the robust weighted

Table 1. Characteristics of Study Participants and Correlates of 1-Month Adherence to Varenicline

Baseline variable	M ± SD, N (%) ^a			P ^c
	Total, N = 127 ^b	Adherence N = 71	Nonadherence N = 56	
Age	46.94 ± 9.75	47.21 ± 10.35	46.58 ± 9.00	.720
Gender				1.000
Female	17 (13.4%)	10 (14.1%)	7 (12.5%)	
Male	106 (83.5%)	59 (83.1%)	47 (83.9%)	
Transgender	4 (3.1%)	2 (2.8%)	2 (2.8%)	
Education				.003
<HS	27 (21.3%)	12 (16.9%)	15 (26.8%)	
HS degree or General Equivalency Diploma	36 (28.3%)	22 (31.0%)	14 (25.0%)	
Some college	39 (30.7%)	16 (22.5%)	23 (41.1%)	
College or post-graduate degree	25 (19.7%)	21 (29.6%)	4 (7.1%)	
Race/ethnicity				.008
Non-Hispanic African American/black	61 (48.0%)	30 (42.3%)	31 (55.4%)	
Non-Hispanic white	17 (13.4%)	15 (21.1%)	2 (3.6%)	
Other non-Hispanic	6 (4.7%)	5 (7.0%)	1 (1.8%)	
Hispanic of any race	43 (33.9%)	21 (29.6%)	22 (39.3%)	
DUDIT	4.22 ± 6.60	3.78 ± 6.86	4.77 ± 6.28	.409
AUDIT-C	1.81 ± 1.84	1.62 ± 1.74	2.05 ± 1.95	.191
Baseline number of cigarettes per day	15.03 ± 9.56	14.93 ± 8.44	15.16 ± 10.89	.896
Time to first cigarette				.183
5 minutes or less after waking	68 (53.5%)	33 (46.5%)	35 (62.5%)	
6–30 minutes after waking	43 (33.9%)	27 (38.0%)	16 (28.6%)	
>30 minutes after waking	16 (12.6%)	11 (15.5%)	5 (8.9%)	
Quit attempts for ≥24 hours in last year	2.01 ± 5.27	2.07 ± 6.13	1.93 ± 3.96	.881
^d HIV antiretroviral meds taken past 4 weeks (mean VAS score)	9.22 ± 1.99	9.49 ± 1.52	8.87 ± 2.44	.101
^e Beliefs and attitudes about varenicline	4.35 ± .59	4.39 ± .59	4.29 ± .59	.360
Adherence self-efficacy (MASES and ASES)	56.72 ± 8.60	58.46 ± 7.76	54.52 ± 9.17	.010
Varenicline Information Scale (LW-IMB-AAQ)	34.96 ± 4.24	35.63 ± 3.83	34.11 ± 4.61	.044

AAQ = Adherence Assessment Questionnaire; AUDIT-C = Alcohol Use Disorders Identification Test-Consumption; DUDIT = Drug Use Disorders Identification Test; HS = high school; IMB = information-motivation-behavioral skills; LW = Life Windows; MASES = Medication Adherence Self-Efficacy Scale; VAS = visual analogue scale.

Bold values represent significant associations ($P < .05$) between independent and dependent variables.

^aValues are presented as means with standard deviations or %s with percentages in each column.

^b131 participants completed the week 4 study visit. Four subjects were excluded from analysis because of either missing data from the IMB measures or because of a varenicline associated side effect for which continued varenicline is contradicted.

^cT tests were used for continuous variables and Fisher's exact tests were used for categorical variables, with the exception of the time to first cigarette variables where chi-square analysis was conducted.

^dVAS score was 0%–100% and coded as 1–10

^eMean score was used for beliefs and attitudes about Varenicline scale and sum scores for MMAS-4, Adherence Self-Efficacy (MASES and ASES combined) and Varenicline Information Scale.

Table 2. Bivariate and Multivariate Analysis of Correlates of IMB Model Constructs and Varenicline Adherence

	Bivariate			Model 1			Model 2		
	Coefficient	P	95% CI	Coefficient	P	95% CI	Coefficient	P	95% CI
1. Information^a (I)									
College ^b	0.15	.444	-0.24, 0.55						
Non-Hispanic white ^c	0.35	.065	-0.02, 0.72						
SC ^d	0.00	.982	-0.42, 0.43						
SC+TXT	-0.10	.651	-0.54, 0.34						
2. Attitude/belief (M)									
College	-0.18	.433	-0.65, 0.28						
Non-Hispanic white	0.33	.149	-0.12, 0.78						
SC	0.31	.138	-0.10, 0.71						
SC+TXT	0.08	.724	-0.36, 0.52						
3. Self-efficacy (B)									
Information	0.50	<.001	0.35, 0.65	0.39	<.001	0.24, 0.52	0.38	<.001	0.23, 0.51
Attitude/belief	0.49	<.001	0.32, 0.66	0.38	<.001	0.21, 0.53	0.39	<.001	0.21, 0.54
College	0.28	.184	-0.13, 0.69				0.30	.238	-0.21, 0.80
Non-Hispanic white	0.41	.005	0.13, 0.69				-0.03	.897	-0.49, 0.43
SC	0.15	.473	-0.26, 0.56				0.03	.877	-0.31, 0.38
SC+TXT	-0.02	.913	-0.48, 0.43				-0.02	.934	-0.35, 0.34
4. Varenicline adherence									
Information	0.23	.045	0.01, 0.45	0.12	.397	-0.14, 0.40	0.12	.473	-0.18, 0.46
Attitude/belief	0.10	.356	-0.12, 0.32	-0.06	.665	-0.33, 0.21	-0.06	.750	-0.39, 0.28
College	1.02	.002	0.38, 1.66				0.74	.385	-0.15, 1.72
Non-Hispanic white	1.16	.005	0.35, 1.98				0.80	.607	-0.24, 5.25
SC	0.39	.157	-0.15, 0.94				0.35	.286	-0.31, 0.95
SC+TXT	-0.12	.663	-0.66, 0.42				-0.17	.579	-0.79, 0.45
Self-efficacy	0.30	.011	0.07, 0.52	0.26	.065	-0.03, 0.53	0.21	.206	-0.13, 0.52

ABT = adherence-focused behavioral therapy; CI = confidence interval; IMB = information-motivation-behavioral skills; SC = standard care; TXT = text messaging. IMB constructs are measured at baseline and varenicline adherence at 1 month. IMB predictors and IMB dependent variables are standardized. Thus, when IMB variables are dependent, coefficients for dichotomous predictors (college, non-Hispanic white, SC, and SC+TXT) are standardized mean differences (ie, Cohen's *d*) and coefficients for IMB predictors (information and attitude/belief) are standardized regression coefficients (β). When adherence is dependent, coefficients represent the change in adherence probability Z-score associated with a one standard deviation increase in IMB predictors and a contrast of groups for categorical covariates.

^aNumbered variables in the first column are dependent variables. Indented variables in the first column are independent variables.

^bParticipants who completed college are compared to those who did not.

^cNon-Hispanic White participants are compared to all other racial/ethnic groups.

^dThe SC treatment condition is compared with SC+TXT+ABT. The SC+TXT treatment condition is compared with SC+TXT+ABT.

least squares estimator (WLSMV), the default for models with continuous and binary dependent variables, to estimate the direct effects of varenicline information and attitudes/beliefs (ie, motivation) on adherence self-efficacy and the direct effects of each construct in the IMB model on varenicline adherence. We then estimated the indirect effects on varenicline adherence of adherence-related information and attitudes/beliefs (ie, their effect via adherence-self efficacy) as the product of component direct effects, tested using bootstrapped 95% confidence intervals with 50 000 resamples with replacement of the data. We tested the path model with only the three IMB constructs (Table 2, Model 1), then controlled for potential confounders by adding direct effects from them to the adherence self-efficacy and varenicline adherence dependent variables (Table 2, Model 2). All three IMB variables were standardized prior to bivariate and path analysis.

Results

Fifty-six percent were at least 80% adherent to the prescribed varenicline dose. Table 1 displays associations between baseline measures and varenicline adherence. Higher levels of education, greater baseline varenicline adherence self-efficacy and higher baseline scores on the varenicline information scale were positively associated with taking greater than 80% of prescribed varenicline. Non-Hispanic white participants were more likely to be adherent compared to other race/ethnicities. Participants completing college were more likely to be adherent compared to participants with less education.

Bivariate analyses in Table 2 show race/ethnicity and education were not associated with varenicline information or varenicline attitudes/beliefs (motivation). However, non-Hispanic whites had significantly higher varenicline adherence self-efficacy ($d = 0.41, P = .005$) and were more likely to be at least 80% adherent to varenicline ($P = .005$) than other race/ethnicities. Completion of college and treatment condition was not related to adherence self-efficacy.

Regression analyses in Table 2 show that varenicline information and attitudes/beliefs each had positive and significant direct effects on adherence self-efficacy (Model 1), even after adjusting for potential confounders (Model 2; varenicline information: $\beta = 0.38, P < .001$; varenicline attitudes/beliefs: $\beta = 0.39, P < .001$), but not on the adherence outcome in the unadjusted (Model 1) or adjusted analysis (Model 2). The direct effect of adherence self-efficacy on the adherence outcome was positive and marginally significant in unadjusted analysis (Model 1; $B_{\text{probit}} = 0.26, P = .065$); however, the effect was no longer significant after education, race/ethnicity and treatment condition were included in the model (Model 2; $B_{\text{probit}} = 0.21, P = .206$, a 21% reduction in direct effect compared to the unadjusted model). We also found positive and marginally significant indirect effects of varenicline information (not shown; $B_{\text{probit}} = 0.10$, 90% confidence interval [CI] = 0.01% to 0.21%) and varenicline attitudes/beliefs ($B_{\text{probit}} = 0.10$, 90% CI = 0.01% to 0.22%) on the adherence outcome through adherence self-efficacy in unadjusted analyses (Model 1). These indirect effects became nonsignificant after controlling for education, race/ethnicity, and treatment condition (Model 2; varenicline information: $B_{\text{probit}} = 0.08$, 90% CI = -0.02% to 0.19%; varenicline attitudes/beliefs: $B_{\text{probit}} = 0.07$, 90% CI = -0.02% to 0.15%).

Discussion

Failure to attend adequately to the issue of medication adherence poses a threat to pharmacotherapy effectiveness. Moreover, reaching

the commonly used cutoff point of 80% adherence appears important given the growing evidence that it is clinically relevant.^{14,16,18} For example, both the COMPASS study and a recent retrospective cohort study found that less than 80% adherence to varenicline was associated with a twofold increase in quit rates compared with poor adherence.^{14,34} In this sample of HIV-infected smokers, only 56% of participants were consistently adherent to varenicline at the 1-month follow-up visit. This is much lower than adherence rates reported in previous cessation trials that included this medication (70%–90%) and concerning given the association of early adherence to long-term cessation.^{14,16,18}

Lower adherence rates in the current study are likely explained by important differences in the study populations. With the exception of the study conducted by Nollen et al.,¹⁸ participants in the previous trials of varenicline were primarily White and did not include PLWHA.^{14,16} This is relevant because we found, in bivariate analyses, that both non-Hispanic blacks and Hispanics had lower rates of varenicline adherence and adherence self-efficacy compared to non-Hispanic whites. This is worth further study as the large literature on adherence to ART has demonstrated similar racial disparities in adherence self-efficacy, which is a strong predictor of ART adherence.^{18,21,35}

Lower adherence rates in this population may also be explained by the myriad social, economic and medical challenges HIV-infected smokers face may negatively impact adherence self-efficacy and pose additional challenges to varenicline adherence. These include a lack of social support, co-occurring substance use, an already complicated medication regimen and negative beliefs about pharmacotherapy.^{36,37} Few studies have prospectively tested interventions to improve adherence to smoking cessation medication, and none have included PLWHA.^{38,39} Moreover, there is little understanding of how these interventions may work to improve adherence. Our data suggest the need for additional research to test adherence-focused interventions among PLWHA and to explore the role of self-efficacy as a target of these interventions, particularly among racial/ethnic minorities. It is also worth exploring whether techniques that are effective for increasing ART adherence can be applied for cessation pharmacotherapy including cognitive behavioral education interventions based on self-efficacy theory, contingency management, cue dose training, and technology driven options like medication vials equipped with alarms and studying whether these intervention effects are mediated by increases in adherence self-efficacy.⁴⁰

Consistent with other empirical tests of the IMB model of adherence, the path analysis, which included only IMB variables only (Table 2, Model 1), suggests the effects of information and motivation on adherence may be mediated by adherence self-efficacy.²¹ In multivariate analysis, even when controlling for race/ethnicity and education, information and motivation remained associated with adherence self-efficacy. This finding suggests interventions targeting those IMB constructs may be especially efficacious by addressing knowledge gaps about the purpose of and use of medication and negative attitudes and beliefs related to pharmacotherapy. However, despite validation of the IMB model in predicting adherence to ART, there may be limitations to using a behavioral model like the IMB model in trying to understand the factors influencing adherence to smoking cessation pharmacotherapy. The only other smoking cessation study to apply the IMB conceptual model did not find any association between IMB variables and adherence.¹⁸ There were inconsistencies in how the constructs were measured across studies but findings from this pilot and Nollen's study indicate the need

to better understand how effects of IMB variables on medication adherence may be conditional on sample characteristics. In addition, expanding the model to include other factors associated with ART adherence, like social support and stress, may help create a more accurate picture of modifiable factors and mediators of disparities in adherence to smoking cessation medication.

Given the modest sample size, the loss of significance when expanding the basic model to include race/ethnicity and education may simply be due to reductions in power, since several significant associations were observed among race/ethnicity, education, IMB variables, and varenicline adherence. The fact that race/ethnicity and education were no longer significantly associated with varenicline adherence in the expanded model (Model 2) suggests IMB variables may have some role in explaining the disparities observed.

There are several limitations. First, this analysis presents data at an interim time period. A future longitudinal analysis will provide a more complete assessment of factors that influence adherence over the 12-week intervention period. However, identifying key factors impacting early abstinence may be important to improving treatment.¹⁶ Second, cross sectional IMB data are not definitive in establishing a causal sequence from information and motivation, through adherence self-efficacy, and ultimately to the adherence outcome. Third, we excluded patients with serious mental illness which may limit the generalizability of the findings. Finally, due to the modest sample size, we were not able to assess whether the IMB model is supported in a similar fashion across racial/ethnic groups or different levels of educational attainment. The moderation of IMB pathways to medication adherence by race/ethnicity is a critical question requiring further study.

In conclusion, greater emphasis is needed on improving cessation medication adherence among PLWHA, particularly among non-Hispanic black and Hispanic smokers. Among HIV+ smokers, adherence-related information, attitudes/beliefs, and self-efficacy may be important targets for interventions promoting adherence to varenicline. However, additional research is needed to identify modifiable predictors of adherence and cessation outcomes in this high risk population.

Supplementary Material

Supplementary Appendix can be found online at <http://www.ntr.oxfordjournals.org>

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Declaration of Interests

None declared.

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