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Correlates of non-adherence to antiretroviral therapy in a cohort of HIV-positive drug users receiving antiretroviral therapy in Hanoi, Vietnam

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Abstract

The HIV epidemic in Vietnam is concentrated, with high prevalence estimates among injection drug users and commercial sex workers. Socio-demographics, substance use and clinical correlates of antiretroviral therapy non-adherence were studied in 100 HIV-1 infected drug users (DUs) receiving antiretroviral therapy (ART) for at least 6 months in Hanoi, Vietnam. All study participants were men with a mean age of 29.9 ± 4.9 years. The median duration on ART was 16.2 ± 12.7 months. 83% reported 'very good' or 'perfect' adherence in the past 30 days on a subjective one-item Likert scale at time of study enrollment. 48% of participants reported drug use within the previous 6 months, with 22% reporting current drug use. Injection drug use with or without non-injection drug use in the past 6 months (95% C.I. 2.19, 1.30-3.69) and years on ART (95% C.I. 1.43, 1.14-1.78) were correlated with suboptimal adherence. These findings support Vietnam's ongoing scale-up of harm reduction programs for injection drug users and their integration with ART delivery. Moreover, results highlight the need to identify and implement new ways to support high levels of ART adherence as duration on ART increases.

Keywords

HIV; Vietnam; adherence; substance abuse; injection drug users

Introduction

The first case of human immunodeficiency virus (HIV) was reported in Vietnam in 1990. Twenty years later, the HIV prevalence among adults, aged 15–49, was estimated to be 0.44% with 254,000 people living with HIV.¹ Like several countries in Southeast Asia,^{2,3} injection drug users (IDUs) bear the burden of HIV infection in Vietnam with IDUs

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accounting for more than 56% of all reported infections in the country.⁴ Nationally, the HIV prevalence amongst IDUs is estimated at 29-34%, with wide geographical variation.⁵

In 2005, Vietnam began rapid scale-up of antiretroviral therapy (ART) with the support of the United States President's Emergency Plan for AIDS Relief (PEPFAR). In 2009, the country strengthened its commitment to provide ART to IDU and develop and scale-up harm reduction programs.⁶ As of December 2010, 49,492 people were receiving ART, an 18-fold increase from December 2005.⁷

Optimal adherence to ART is required for successful viral suppression and minimization of HIV drug resistance (HIVDR).^{8, 9, 10} Previously, we published an analysis documenting successful ART treatment of Vietnamese IDUs with rates of viral suppression comparable to other international populations.¹¹ However, not unexpectedly, we observed that self-reported poor adherence to ART was significantly and independently associated with viral non-suppression ($p<0.01$). Few studies to date have examined the factors associated with poor adherence among IDUs in Vietnam. Better understanding in this area is necessary to optimize HIV care and harm reduction in this important vulnerable population.

Studies have identified active drug use, poor social supports, and hazardous alcohol use as correlates of poor adherence to ART.^{12, 13, 14} Two recent studies examined predictors of ART non-adherence in Vietnam^{15, 16}. Although both of these studies involved larger cross-sections of HIV-infected patients than ours, both included only approximately 50% of patients with a history of opiate use. In addition, both studies used a 30-day visual analogue scale (VAS) of self-reported adherence to estimate adherence to ART. Our study uses a Likert rating scale^{17, 18, 19} as a measure of self-reported adherence and focuses exclusively on IDUs. The Likert rating scale may have advantages over other self-reported adherence measures and has been shown to be as good, if not better, than the VAS when assessing a 30-day interval¹⁸.

The purpose of this analysis was to explore factors related to poor ART adherence with an aim to understand and develop targeted interventions to improve adherence in this population. Specifically, we examined the effects of several socio-demographic, clinical, and substance use characteristics on poor ART adherence.

Methods

Study participants

The outpatient clinic at the National Hospital of Tropical Diseases (NHTD), which opened in May 2005, provides ART free of charge to approximately 700 patients, from Hanoi and surrounding provinces. NHTD's clinic population is approximately 70% male with 70% reporting current or former opiate injection drug use. At the time of study enrolment, the clinic used clinical staging or CD4 cell count to determine eligibility to initiate free ART following the Vietnamese National Guidelines for Treatment of HIV/AIDS.²⁰ To support adherence, patients attend group counseling sessions over a one month period prior to initiation of ART and subsequently receive individual adherence counseling from clinic and pharmacy staff at each follow-up visit.

The study cohort has previously been described in detail.¹⁴ Briefly, between June and November 2006, 100 HIV infected patients were enrolled in a 30-month prospective study on HIV and nutrition. Consecutive patients attending scheduled clinic visits were approached by study staff to determine eligibility. Study inclusion criteria were: age 18 years, receiving ART at NHTD for at least six months, and history of IDU within the previous 5-years. Since there were very few female patients who reported a history of injection drug use in the clinic population at time of recruitment, the study population was restricted to men only. More than 95% of patients who met study eligibility criteria were enrolled. The Institutional Review Board of Tufts University, in Boston, and the Ethical Review Board at NHTD, in Hanoi, approved the research. All participants signed written informed consent.

Study measures

Data collected at study enrolment included information from a 45-minute lifestyle questionnaire, administered on a computer by trained study personnel with no prior or current affiliation to the ART clinic at NHTD. All responses were kept confidential and not returned to NHTD staff or patients' medical records. The questionnaire elicited information on socio-demographics, medical history, symptoms related to HIV infection or ART side effects, alcohol, tobacco and drug use behavior, ART and other medications, and adherence to ART. Socio-demographic information obtained included marital status; living arrangements (alone/with others, ownership/rental etc.), employment, and detainment status. The frequency and amount of alcohol consumed during the 30 days prior to questionnaire administration was elicited and responses were categorized as hazardous or non-hazardous drinking using National Institute on Alcohol Abuse and Alcoholism guidelines (>14 drinks per week or >4 drinks per occasion).²¹

Clinical correlates included years on ART, CD4 cell count, co-infections (hepatitis B, hepatitis C, and/or tuberculosis), other prescribed medications, and self-reported symptoms of illness (nausea, vomiting, stomach pain, fever, white patches in the mouth (thrush), mouth/lip/gum pain), which were deemed by the participant to be "moderately", "quite a bit", or "extremely bothersome" at follow-up visits.

Adherence to currently prescribed ART was assessed using the patient's subjective rating on a one-item Likert scale¹⁸ of how well he was able to take all his medications in the past 30 days (perfect, very good, good, fair, or poor). In analysis, a binary adherence variable was created with responses of *perfect or very good* indicating 'adherent' and responses of *good, fair, or poor* indicating 'non-adherent.'

Blood specimens were obtained for determination of complete blood count, CD4 cell count and HIV RNA quantitation. CD4 cell counts were determined using Becton Dickinson FacsCalibur (New Jersey, USA) and HIV RNA was measured using the Versant b-DNA assay (Bayer, Thailand). All laboratory testing was conducted at NHTD.

Statistical methods

To describe the overall study population, means (\pm SD) for continuous variables, and proportions for categorical variables, were calculated. Repeated measure generalized

estimating equation (GEE) models with logit link and binary distribution was used to examine bivariable associations of socio-demographic, clinical and substance use covariates with non-adherence. The full multivariable model included all covariates in the bivariable models with a p-value <0.20. Backwards elimination methods were then used to determine the final multivariable model. The missing indicator method²² was used for the variable drug use in the past 6 months, which was missing for four person visits. The unadjusted and adjusted odds ratios and 95% confidence intervals from these models are presented. All analyses were conducted using SAS v9.2 (Cary, NC, USA).

Results

In this analysis, we present data from 528 visits with complete questionnaire and adherence data (100 baseline visits and 96, 90, 85, 82, and 79 follow-up visits at months 6, 12, 18, 24, and 30, respectively). Over the 30 months of follow-up, 4 visits had missing viral load or adherence data. Twenty-one participants did not complete all six study visits: 6 died, 7 were imprisoned, 4 transferred care to other clinics and 4 were lost-to-follow-up. The characteristics of the study participants at time of enrolment are presented in Table 1. The mean age was 29.9 ± 4.9 years, 73% were married and 96% were heterosexual. Education levels were high with 34% completing tertiary education and 25% attending university or higher levels of education. Overall, 23% had ever been incarcerated. Almost one half reported drug use (DU) in the 6 months prior to enrolment and almost one quarter reported IDU during the same time period. Thirty-seven percent reported hazardous alcohol use per National Institute on Alcohol Abuse and Alcoholism definitions, while 22% reported not drinking at all. Ninety percent reported ever-injecting heroin, 77% reported using sedatives, and 45% reported marijuana use. 16% reported use of two or more illicit drugs simultaneously in the last 6 months. Smoking tobacco was common with 84% reporting current use. The median duration on ART at enrolment was 16.2 months \pm 12.7 and 95% of patients were receiving non-nucleoside reverse transcriptase inhibitor-based regimens in combination with two nucleoside reverse transcriptase inhibitors. At time of enrolment, the median CD4 cell count was 189 ± 110 cells/mm³ and 59% and 73% had HIV RNA < 50 copies/mL and < 1000 copies/mL, respectively. Eighty-three percent reported *perfect* or *very good* adherence in the previous 30 days.

Table 2 shows the results of repeated measures logistic regression models assessing the effects of clinical, socio-demographic, and substance use correlates on non-adherence. "Living alone", a measure of social isolation, was not associated with ART non-adherence, 2.98 (95% CI 0.91, 9.8). Of the substance use correlates analyzed, alcohol intake in the past 30 days and hazardous alcohol use in the past 6 months were not significant correlates of non-adherence: 1.16 (95% CI 0.78, 1.74) and 0.94 (95% CI 0.64, 1.38), respectively. Tobacco use at the time of study enrolment was a significant correlate of non-adherence in the bivariable analysis, but not in the final multivariable model. When disaggregated according to mode of substance intake, non-injection drug use was not a significant correlate of non-adherence; however, injection drug use with or without concomitant use of non-injection drugs was significantly correlated with non-adherence 2.19 (95% CI 1.30, 3.69). Duration on ART was also a correlate of non-adherence, 1.43 (95% CI 1.14, 1.78), with increased risk non-adherence for each additional year on treatment. Co-infections (acute or

chronic hepatitis B or hepatitis C) and tuberculosis were not found to increase the risk of non-adherence nor were symptoms of illness.

Discussion

As we previously report, overall levels of self-reported ART adherence in this cohort were high (83% reporting *perfect/very good* adherence at time study enrolment); however, self-reported *good/fair/poor* adherence was associated with viral non-suppression ($p=0.05$).¹⁴ To further characterize factors associated with non-adherence, we assessed socio-demographic, clinical and substance use correlates of adherence in this cohort. In this analysis, we observe that active drug use and duration on ART increase the odds of suboptimal ART adherence. Although rates of virological suppression in our population were similar to drug using and non-drug using populations in other international settings²³, our findings suggests that those who injected drugs in the previous six months were more than twice as likely to report poor ART adherence than those who did not inject drugs in the previous six months, when controlling for other covariates. These findings underscore the need to develop and implement integrated care models, which provide harm reduction to IDUs receiving ART and to develop new methods for providing long-term adherence support in this vulnerable population.

Interventions, such as methadone maintenance therapy (MMT) decrease concurrent opioid use²⁴ and MMT programs have been shown to significantly facilitate effective ART among DU in Vietnam.²⁵ In 2008, MMT was piloted in Haiphong and Ho Chi Minh City, and was proven effective as a harm reduction method for IDUs in Vietnam.²⁶ In one large multisite Vietnamese study patients participating in MMT programs, while receiving ART, were more likely to decrease opioid use as confirmed by self-report and positive heroin-urine tests.²⁷ Subsequently, MMT has been scaled-up, and as of 2012, 44 designated MMT sites in 11 provinces offered methadone.²⁶ Given these positive early experiences, MMT should be scaled up to all provinces with emphasis given to the integration of MMT and other harm reduction strategies into routine clinical practice at ART clinics.

The median duration on ART at enrollment for this cohort was 16.2 months (range 6-85 months). Each additional year on ART was associated with a 40% increase in risk of poor ART adherence. This finding is similar to some reports^{28, 29} and contrary to others.^{30, 31} Possible explanations for our observation may include treatment fatigue and/or re-initiation of prior injection drug use. High long-term levels of adherence to ART are required to maximize population-level ART outcomes. The determinants of non-adherence and their relative contribution are likely to vary between populations, emphasizing the need for local assessment of factors associated with non-adherence and the development of locally relevant solutions. A recent publication suggests that mobile phone text messages and direct calls from health workers were methods accepted by patients in Vietnam to support ART adherence.³² This approach combined with active identification and treatment of relapse of IDU warrants study at NHTD.

Contrary to a recent publication demonstrating association between alcohol use, with or without illicit drug use, and suboptimal ART adherence, we observed no such association in

our population.¹¹ This discrepant finding may be due to differences in the type of alcohol consumed (i.e. % alcohol by volume), differences in the methods used to assess alcohol consumption and/or differences in the definitions of hazardous drinking used in analysis. The majority of our participants drank alcohol in the past 30 days (nearly 80%) and a high proportion of these participants were classified as hazardous drinkers (37%). Further studies should be done in this and comparable populations in Vietnam to collect more detailed information on the specific types of alcoholic beverages consumed and the alcoholic content of the beverages in order to more precisely assess the relationship between alcohol intake and non-adherence. Additionally, it is important to note that the alcohol assessment tool which we used was developed and validated in a high income country setting and development of a culturally specific alcohol assessment tool for use in this population should be considered for future research.

Unlike other studies^{12, 13, 14} in which poor social support systems, hazardous alcohol use and active drug use were significant correlates of non-adherence, social support systems and hazardous drug use were not significant predictors of non-adherence among our study population. An explanation for this finding may be due to the overall higher socio-economic status of our study population. In general, participants in this study had high levels of education and rarely lived alone (4% at enrollment), which may have contributed to their ability to adhere to their medications.

This study has several important limitations. Notably, it relies on self-reported measures of adherence rather than on the assessment of objective measures such as on-time pharmacy refill, which has been shown in other populations to correlate with pill taking behavior³³ and viral load suppression.³⁴ Additional limitations include lack of laboratory-based confirmation of drug use, limited assessment of socio-demographic characteristics, no assessment of changes in socioeconomic characteristics over time and no assessment of type of alcoholic beverage consumed; i.e., percent alcohol by volume. Nonetheless, results highlight the need to identify and implement new ways to sustain high levels of ART adherence as duration on ART increases in this population. In addition, more studies are needed to assess determinants of ART non-adherence in larger and more representative populations of DUs in Vietnam.

Conclusion

Given the survival benefit of ART, the strengthening of harm reduction programs for HIV infected DU and scale-up of MMT may support long-term adherence to ART among IDUs in Vietnam. New programmatic supports for adherence beyond the first 12 months of therapy are needed as is additional research to characterize changes in patterns of adherence over time and associated determinants in order to further maximize the long-term benefits of ART in this important population.

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Table 1
Characteristics of study participants at time of enrolment

Characteristic	N= 100
Age (years)	29.86± 4.86
Male gender	100
Prison (ever)	23
Married	73
Live alone	4
Heterosexual	96
> 13 years education	78
Any drug use in last 6 months	48
Current injection drug use (last 6 months)	22
Drug Use in Lifetime (ever)	
Marijuana	45
Heroin (injected)	90
Heroin (smoked)	91
Sedatives	77
Amphetamines	9
Current Cigarette smoker	84
Alcohol use in past 30 days	78
Hazardous drinker (NIAAA) *	37
Duration on ART at baseline (months)	16.2± 12.7
ART regimen	
First-line	95%
Second-line	3%
Other	1%
Hepatitis B (acute or chronic)	15%
Hepatitis C	85%
CD4 cells/mm ³ at study baseline	189± 110
HIV RNA at study baseline	
HIV RNA >50 copies/ mL	59 (59%)
HIV RNA < 1000 copies/mL	73 (73%)
Ability to take all prescribed ART in past 30 day Likert- scale)	
Perfect	59
Very good	24
Good	10
Fair	5
Poor	2

* NIAAA= National Institute on Alcohol Abuse and Alcoholism

Table 2
Repeated measures logistic models* with outcome of non-adherent by Likert(*Good/Fair/Poor*); N=528

Characteristic	Unadjusted OR (95% CI)	Adjusted OR (95%)
CD4 cell count	1.00 (0.998, 1.002)	—
Live alone	2.98 (0.91, 9.80)	—
Tobacco smoker at enrolment	2.24 (1.21, 4.16)	—
Drug use last 6 months **		
None	Ref.	Ref.
Non-injection only	1.56 (0.99,2.48)	1.52 (0.95,2.44)
IDU *** with or without non-injection	1.85 (1.16, 2.96)	2.19 (1.30, 3.69)
Drink alcohol in past 30 days	1.16 (0.78, 1.74)	—
Hazardous alcohol usage in last 6 months	0.94 (0.64, 1.38)	—
Years on ART ****	1.39 (1.11,1.74)	1.43 (1.14,1.78)
Tuberculosis ever	0.83 (0.50, 1.39)	
Hepatitis B (acute/chronic)	1.63 (0.87, 3.06)	—
Hepatitis C co-infection at enrolment	0.97 (0.55, 1.70)	—
Bothersome symptoms		
Oral White Patches (thrush)	0.47(0.13, 1.69)	—
Mouth, Lip, Gum Pain	1.09 (0.61, 1.93)	—
Nausea	1.30 (0.83, 2.02)	—
Vomiting	1.22 (0.68,2.19)	—
Stomach pain	1.13 (0.69, 1.85)	—
Fever	1.55 (0.95, 2.54)	—

* Repeated measures GEE models with a logit link and binary distribution.

** Seven person-visits are missing either current drug use or injection drug use, but are including using missing indicator methods

*** IDU= injection drug use;

**** ART = antiretroviral therapy