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Correlates of HIV-1 viral suppression in a cohort of HIV-positive drug users receiving antiretroviral therapy in Hanoi, Vietnam

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Summary

Injection drug users bear the burden of HIV in Vietnam and are a focus of national treatment programs. To date, determinants of successful therapy in this population are unknown. Substance use and clinical correlates of viral suppression were studied in 100 HIV-1 infected drug users receiving antiretroviral therapy (ART) for at least 6 months in Hanoi, Vietnam. Mean age of the cohort was 29.9 + 4.9 years; all were men. A majority of patients (73%) achieved viral suppression (HIV-RNA < 1000 copies/ml). Correlates of viral suppression include self-reported >95% adherence ($p < 0.01$) and current use of trimethoprim/sulfamethoxazole ($p < 0.01$); current or ever diagnosed with tuberculosis was associated with viral non-suppression ($p = 0.006$). Tobacco use was prevalent (84%), and surprisingly 48% of patients reported active drug use; neither was associated with viral non-suppression. This is the first study to document successful ART treatment in a population of Vietnamese drug users; rates of viral suppression are comparable to other international populations. The 28% of patients without HIV-1 suppression highlights the need for adherence promotion, risk reduction programs, and population based surveillance strategies for assessing the emergence of HIV drug resistance in settings where access to viral load and drug resistance testing is limited.

Keywords

HIV; Vietnam; antiretroviral therapy; substance abuse; adherence

INTRODUCTION

The first case of human immunodeficiency virus (HIV) in Vietnam was reported in 1990. By 2006 the number of reported cases had increased to 280,000 representing an overall prevalence estimate of 0.5% among adults (aged 15-49 years)¹. In Vietnam, the HIV epidemic began and remains largely concentrated in injection drug users (IDUs) and commercial sex workers [CSWs]. Heroin has replaced opium as the preferred illicit drug and the average age of drug users is declining². IDUs account for more than 56% of all reported HIV infections³. In 2005, national sentinel surveillance estimated the prevalence of HIV among intravenous drug users (IDUs), commercial sex workers and pregnant women at 34.0 %, 4.2%, and 0.38%

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respectively¹. Specifically in Hanoi, prevalence among IDUs in sentinel surveillance surveys rose from 0.11% to 34 % between 1994 and 2005⁴.

First published in 2000, the National Guidelines for Diagnosis and Treatment of HIV/AIDS in Vietnam recommended the use of two agent (“dual”) nucleoside reverse transcriptase inhibitor (NRTI) therapy⁵. The number of patients with access to ART was initially limited to a small number of patients in the national program. Non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs) became available more recently but were not consistently available, risking treatment interruptions and causing some patients to switch between dual and triple therapy.

In 2005, Vietnam began rapid ART scale-up supported by the US President’s Emergency Plan for AIDS Relief (PEPFAR) and revised its national guidelines with treatment based on the principal of 2 NRTIs and 1 NNRTI, with PIs being reserved for second line use⁶.

To date there have been no reports assessing the impact of past and current drug use on success of ART in Vietnam. The purpose of this analysis is to assess substance use and clinical determinants of HIV suppression in a cohort of patients with a history of drug use receiving ART at a large urban outpatient clinic in Hanoi, Vietnam.

METHODS

Study Participants

Between June and November 2006, 100 HIV infected patients were recruited from the outpatient clinic of the National Institute of Infectious and Tropical Diseases (NIITD) in Hanoi, Vietnam to participate in a longitudinal study of nutrition and HIV infection in injection drug users. These patients were recruited from a pool of 370 patients receiving ART at the clinic at that time. Patients were eligible to participate in the study if they were HIV seropositive, age ≥ 18 , had received ART at NIITD for at least six months, had a history of injection drug use within the previous 5-years (by self-report), understood and agreed to all study procedures, and signed written informed consent. Since there were few to no female drug users in the clinic population at the time of recruitment, the study population was restricted to men only. For the current analysis, we included data from baseline study visits only. The study was reviewed and approved by the Institutional Review Board of Tufts University (Boston) and the ethical review board of the Hanoi School of Public Health.

Study measures

Data collected at baseline included a brief physical examination, an assessment of body composition (including weight and height) and a 45 minute lifestyle questionnaire, administered by trained study personnel. The lifestyle questionnaire elicited information on sociodemographics, medical history, alcohol, tobacco, drug use behavior, use of ART and other prescribed medications, adherence to ART, food security, and depressive symptoms. Blood specimens were obtained for determination of complete blood count, CD4+ cell count, HIV viral load, and Hepatitis B and C serologies. CD4 cell count was determined using Becton Dickinson Facscalibur (New Jersey, USA) and viral load was determined using the Versant b-DNA assay (Bayer, Thailand). All laboratory testing was conducted at NIITD. For this analysis, HIV viral load suppression was defined as $<1,000$ copies/ml; this threshold was used because transient viremia below this threshold is not typically associated with the development of HIV drug resistance (HIVDR) and importantly are not associated with virologic or clinical failure of previously adequate ART⁷.

Two types of correlates of viral suppression were examined in this analysis: substance use correlates and clinical/treatment correlates. Substance use variables included tobacco smoking,

alcohol, and illicit drug use. Frequency and amount of alcohol intake over the past 30 days was assessed. Responses were categorized as hazardous or non-hazardous using National Institute on Alcohol Abuse and Alcoholism guidelines.⁸

Clinical correlates included adherence to ART, CD4 cell counts, co-infections (hepatitis B, hepatitis C, and/or tuberculosis), other prescribed medications, and symptoms of illness. Adherence to currently prescribed antiretroviral regimen was assessed by two self-report methods: a 30-day visual analogue scale (VAS)⁹ assessing adherence to the entire prescribed regimen within the last 30 days (expressed as a percent) and the patient's subjective rating on a one-item Likert scale of how well he was able to take all his medications in the past 30 days (excellent, very good, good, fair, or poor). Adherence was analyzed both as a continuous and a binary variable with "adherent" defined as self-report of $\geq 95\%$ on the 30-day VAS.

Statistical Methods

To describe the overall study population, means ($\pm$ SD) for continuous variables, and proportions for categorical variables, were calculated. The study population was divided into two comparison groups according to HIV viral load: suppressed (viral load < 1000 copies/ml) vs. unsuppressed (viral load ≥ 1000 copies/ml). T-tests for continuous variables and chi-square tests for categorical variables were used to compare characteristics between the two viral load groups. All analyses were conducted in SAS v9.1 (Cary, NC, USA).

Results

Table 1 shows the baseline characteristics of the 100 study participants. The mean age was 29.9 ± 4.9 years. Seventy-three percent of the cohort was married. Ninety-six percent were heterosexual. Education levels were high with 34% completing tertiary education and 25% attending university or higher levels of education. Overall, 23% had been incarcerated at some point during their lifetime.

Tobacco smoking was highly prevalent among the participants, with 84% reporting current smoking. 5 % reported hazardous alcohol use and 73% non-hazardous alcohol use following National Institute on Alcohol Abuse and Alcoholism definitions⁸. Non-drinkers constituted 22% of the study population. Lifetime use of heroin (either smoked or injected) was reported by 90% of those enrolled. Other highly reported drugs used included marijuana (45%) and sedatives (77%). Within the 6 months prior to study enrollment, 48% of the cohort reported some illicit drug use (data not shown).

The mean body mass index (BMI) was 20.2 ± 2.1 kg/m². ART duration ranged from 6.2 to 85.7 months with a median duration of 13.6 months and an average duration of 16.2 ± 2.7 months. The mean absolute CD4+ cell count at initiation of ART for 95 of the 100 subjects was 115 ± 78 cells/mm³. At study entry, the average CD4+ cell count for the overall group was 189 ± 110 cells/mm³ and 86 % of participants were receiving one of four standard first-line ART regimens as defined by the National Guidelines for Diagnosis and Treatment of HIV/AIDS: D4T/3TC/NVP, ZDV/3TC/EFV, ZDV/3TC/NVP, or D4T/3TC/EFV⁶. The remaining patients were receiving the following other regimens: TDF/3TC/EFV, ZDV/3TC/IND, or DDI/ABC/NFV. (Abbreviations in footnote, Table 1)

Based on hepatitis B serologies, 14% of the cohort was hepatitis B seronegative at baseline, 35 % demonstrated immunity from previous infection, 13% were immune from previous vaccination, and 14% had serologic evidence of acute or chronic hepatitis B infection. Eighty-five percent of the cohort was hepatitis C antibody positive. Based on self-reports, 22% had current or prior tuberculosis and 13% had been diagnosed and treated for tuberculosis since initiation of ART.

Table 2 shows ART adherence and substance use characteristics by viral load suppression. Overall, 73% of patients were virally suppressed at baseline. No differences were observed between patients with viral suppression and non-suppression in terms of current tobacco use; however, there was a trend towards significance among smokers, with those in the non-suppressed group smoking a higher number of cigarettes per day on average ($p=0.09$). There was no difference between viral load suppression groups in terms of alcohol consumption or active drug use within the last 6-months.

Based on the VAS, the mean level of adherence within the last 30 days was 96.3% overall with a median adherence of 100% (range 30% to 100%); 85% of patients reported being adherent at a level of 95% or higher. While there was no significant difference in mean levels of reported adherence between viral load suppression groups ($92.6\% \pm 16.5\%$ vs. $97.7\% \pm 9.6\%$; $p=0.13$), patients whose viral loads were not suppressed were more likely to report less than 95% adherence than those who achieved suppression (29.6% vs. 9.6% ; $p=0.002$). In addition, patients achieving viral suppression reported higher levels of adherence to ART in the past 30-days than patients not achieving viral suppression ($p=0.05$).

Table 3 shows clinical characteristics by viral load suppression. Mean duration of ART did not differ between viral load suppression groups, although a smaller proportion of those on ART for more than 24 months were suppressed compared to those who had been on ART only 6-12 months (62% vs. 79% ; $p=0.22$). While mean CD4+ cell counts did not differ between viral load suppression groups, either at initiation of ART or at baseline visit, those who achieved suppression had significantly larger increases in their CD4 counts compared to those who did not achieve suppression. Active or chronic Hepatitis B and C co-infection was not associated with viral suppression; however, patients demonstrating hepatitis B susceptibility were more likely to not achieve viral suppression (26% vs. 10% $p=0.05$). Interestingly individuals ever diagnosed with tuberculosis were more likely to have viral loads $>1,000$ copies/ml (41% vs. 15% ; $p=0.0006$) with a trend toward non-suppression in individuals treated for tuberculosis since initiation of ART (26% vs. 8% ; $p=0.06$). Patients reporting current trimethoprim/sulfamethoxazole use were more likely to achieve viral suppression (85% vs. 56% ; $p=0.002$).

Discussion

In June 2004, Vietnam was added to the list of countries eligible for funding through PEPFAR with development of a national plan for ART scale-up. The outpatient clinic at NIITD opened in May 2005 and began providing antiretroviral therapy free of charge. The HIV infected population at NIITD consists of approximately 700 patients from Hanoi and surrounding provinces referred for outpatient care. The clinic population is approximately 70% male with 70% reporting current or former opiate injection drug use. NIITD follows the Vietnamese National Guidelines for Treatment of HIV/AIDS with eligibility to initiate ART based on WHO clinical staging or CD4 cell count⁶. Prior to initiation of ART, all eligible patients attend one month of group and individual adherence counseling. After initiation of ART, patients are seen at two week intervals for the first month and then monthly thereafter. At clinic each visit, patients are seen by a physician and receive ART adherence counseling from both clinic and pharmacy staff. Patients included in this study had been receiving ART for a mean of 16.2 months (range 6 - 85 months).

The vanguard of the HIV epidemic remains among injection drug users, and they remain a core group of transmitters in Vietnam. The benefits of ART are undisputed^{10, 11} and there is growing evidence that successful ART outcomes can be achieved for drug users.¹² The observed 73% of the cohort with viral suppression, in this cross sectional analysis, is consistent with reports from other resource-limited settings for individuals receiving ART for varying lengths of

time¹³⁻¹⁵ and attests to the possibility of successful ART outcomes in drug users in resource-limited settings.

Forty-eight percent of patients reported active drug use within 6-months of study entry, a surprising finding given the generally sensitive nature of drug use disclosure in Vietnam. Among active users, the drugs of choice were sedatives (28%) closely followed by injected heroin (22%). The majority of active drug users were well-educated and typically living with their families. We observed a slightly higher proportion of active drug use among the proportion not achieving viral suppression (52% vs. 47% $p=0.68$). Although these results are not significant, acknowledged active drug use is strongly linked to poor medication adherence^{16, 17} and continued adherence support and drug treatment is therefore of particular importance in this population. Interestingly, there was a trend toward viral non-suppression among tobacco smokers with higher levels of daily cigarette use ($p=0.09$), but no differences were noted across the alcohol consumption categories.

In this sample of current and former drug users with a high prevalence of hepatitis C, co-infection was not associated with lack of viral load suppression ($p=0.22$) as has been reported in other studies¹⁸. Interestingly, current or previous tuberculosis (by self-report) was associated with non-suppression ($p=0.006$) and having received tuberculosis treatment since ART initiation approached significance ($p=0.06$). Clinicians follow national treatment guidelines when providing concurrent ART and tuberculosis therapy. These combinations are lifesaving, but prone to pharmacokinetic interactions and side effects that may interfere with ART adherence. Since we did not monitor drug levels, the impact of these potential interactions cannot be evaluated¹⁹. Finally, patients reporting concurrent trimethoprim/sulfamethoxazole use were more likely to achieve viral suppression ($p=0.002$); this finding likely relates to duration on ART: patients taking this agent had been receiving ART for a significantly shorter amount of time (13.6 ± 9 months vs. 24.7 ± 19 months; $p=0.01$), suggesting a loss of viral suppression over time.

Adherence to antiretroviral therapy is closely associated with viral suppression²⁰⁻²². Overall, self-reported ART adherence was high (96.3%) and there was no difference in response to the 30-day VAS between patients with and without viral suppression when examined as a continuous variable; however, more patients in the non-suppressed category reported being less than 95% adherent on the VAS compared to those who were suppressed ($p=0.002$). The high level of reported adherence observed in this cohort may be due to the rigor by which individuals are screened for eligibility to initiate ART; individuals must not only meet WHO staging criteria but must attend group and individual adherence counseling, must demonstrate a willingness for follow-up care, and must designate an ART support partner. Importantly, we observe that 22% of patients reporting >95% adherence still had viral loads greater than 1,000 copies/ml (data not shown). It is possible that these patients are over-estimating their adherence or may harbor drug resistant mutants. One of the limitations of this analysis is the lack of surrogate measures of adherence which have been shown in other populations to correlate with pill taking behavior, such as on-time drug pick-up and on-time appointment keeping²³⁻²⁵ and history of ART drug stock-outs at the site resulting in patient treatment interruption¹⁰. Viremia was suppressed in a smaller proportion of patients after 24+ months of therapy compared to those who had been on therapy for only 6-12 months; however the difference was not significant and could possibly be explained by adherence fatigue, a waning of adherence to ART with increasing duration of therapy²⁶.

The triple drug regimens used in Vietnam are known to be potent and durable. Results from this analysis demonstrate success in treating this challenging population of HIV- infected men, many with ongoing active drug use, when care is delivered within a clinical setting with adherence support. The vast majority (86%) was receiving standard first-line regimens and

72% of these patients had virologic suppression, an important observation as individuals maintaining viral suppression while on therapy are unlikely to develop HIVDR or to transmit virus to others.

The fact that nearly 30% of patients do not show viral suppression is concerning as these patients may harbor true or possible drug resistance mutations which may reduce treatment response to subsequent regimens and place them at risk for transmitting HIVDR to uninfected individuals. Undoubtedly, there exists a greater risk of HIVDR among patients with prior, irregular, or unmonitored therapy, including the dual nucleoside regimens available before the recent scale-up; however, the frequency of these exposures could not be definitively confirmed by verbal history or chart abstraction for all study participants. Additionally, because HIVDR testing is not routinely performed in Vietnam, HIV genotypic data were not available on this group of subjects. A study of the level of preexisting resistance to antiretroviral drugs and their association with viral suppression is planned in a different subgroup of patients at NIITD.

In summary, in this population of Vietnamese drug users treated on ART for six months or more, we observed an overall higher level of adherence to prescribed ART than that reported in American cohorts of drug users²⁷⁻²⁹. We also observed rates of viral suppression consistent with other international cohorts.^{13, 14} Adherence at a level of $\geq 95\%$ to prescribed ART and concurrent trimethoprim/sulfamethoxazole use were significantly correlated with HIV viral suppression.

To our knowledge, this is the first paper documenting successful treatment of HIV infected drug users and related correlates of viral suppression in Vietnamese drug users. This study highlights substantial progress in HIV treatment in Vietnam, and the need for ongoing risk reduction programs, hepatitis B screening and vaccination, and substance abuse prevention and treatment programs. Furthermore, this study highlights the need for operational research and programs to promote adherence to ART. Importantly, viral load and HIVDR testing are not routinely available in most resource-limited countries, including Vietnam, where ART is provided using a population-based model of care rather than an individual model of care. Our study highlights the need for prospective population based surveys of HIVDR prevention using internationally recognized standardized tools^{30, 31} to maximize the long term durability and efficacy of available first and second-line regimens. The ongoing development of this cohort will be valuable to future qualitative and behavioral science research into methods to decrease barriers to successful treatment outcomes for this focal population in Vietnam's HIV epidemic.

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Table 1

Baseline characteristics of cohort: 100 HIV positive men in Hanoi, Vietnam

Characteristic	Mean $\pm$ SD or %
Age (years)	29.9 $\pm$ 4.9
Marital Status ^(a)	
Single/never married	23
Married / common-law married	73
Divorced/Separated/Widowed	2
Geographic Region of Residence	
Eastern Northern Uplands	40
Western Northern Uplands	2
Red River Delta	53
North Central	4
Southeast	1
Sexual Orientation/Identity	
Heterosexual/straight	96
Bisexual/Homosexual/Lesbian	1
Refused to answer	3
Education	
≤ 9 years of education	22
10-12 years (tertiary)	34
Vocational training	19
University or more	25
Jail or prison (ever)	23
Current Smoker	84
# of Cigarettes smoked per day (smokers only)	7.4 $\pm$ 5.9
Alcohol Drinker Categories ^(b)	
Non-drinkers	22
Non-hazardous	73
Hazardous	5
Drug Use in lifetime ^(c)	
Marijuana	45
Heroin (injected)	90
Heroin (smoked)	91
Cocaine (inject, smoke or snort)	1
Sedatives	77
Amphetamines	9
Ecstasy (MDMA)	3
Any illicit drug use in lifetime	100
<i>Clinical status</i>	
BMI (kg/m ²)	20.2 $\pm$ 2.1
Duration on ART (months) ^(d)	16.2 $\pm$ 12.7

Characteristic	Mean $\pm$ SD or %
CD4 absolute (cells/mm ³)	
At initiation of ART ^(e)	115 $\pm$ 78
At baseline visit	189 $\pm$ 110
Viral load copies/mL (HIV RNA log ₍₁₀₎)	
At baseline study visit	2.4 $\pm$ 1.1
ART regimen at study baseline ^(f)	
D4T, 3TC, NVP	27
ZDV, 3TC, EFV	22
ZDV, 3TC, NVP	19
D4T, 3TC, EFV	19
TDF, 3TC, EFV,	9
ZDV, 3TC, IND	2
DDI, ABC, NFV	2
Hepatitis B exposed	86
Hepatitis C Antibody present	85
Tuberculosis (self-report)	
Diagnosed and ever treated	22
Treated since starting ART	13

^(a) Marital status is missing two participants

^(b) Alcohol drinker categories missing three participants

^(c) Marijuana and any illicit drug both are missing one participant

^(d) ART = antiretroviral therapy

^(e) Initial CD4 at ART initiation is missing for 5 participants

^(f) NVP = nevirapine; EVF = efavirenz; TDF = tenofovir; IND = indinavir; NFV = nelfinavir; ABC = Abacavir; ZDV = zidovudine; DDI = didanosine; 3TC = lamivudine

Table 2

Adherence and substance use characteristics by VL suppression among 100 HIV positive patients in Hanoi, Vietnam, Mean $\pm$ SD or n (%)

Characteristic	Not suppressed (VL >=1000 copies) n=27	Suppressed (VL <1000 copies) n=73	P-value
Smoking/Drug/Alcohol Usage			
Current Smoker	22 (81)	62 (85)	0.76*
# of cigarettes smoked per day (smokers only)	9.6 ± 7.7	6.6 ± 4.9	0.09
Alcohol Drinker Categories			
Non-drinkers	7 (26)	15 (21)	0.811
Non-hazardous	19 (70)	54 (74)	
Hazardous	1 (4)	4 (5)	
Drug Use in Last 6 months			
Marijuana ^(a)	3 (11)	4 (6)	0.39*
Heroin (injected)	8 (30)	14 (19)	0.26
Heroin (smoked)	4 (15)	8 (11)	0.73*
Cocaine (inject, smoke or snort)	0 (0)	0 (0)	-
Sedatives	8 (30)	20 (27)	0.83
Amphetamines	2 (7)	2 (3)	0.29*
Ecstasy (MDMA)	1 (4)	1 (1)	0.47
Any illicit drug use ^(a)	14 (52)	34 (47)	0.68
HIV medication adherence			
Visual Analog Scale (VAS) (% of med dosages taken in past 30d)	92.6 ± 16.5	97.7 ± 9.6	0.13
Not adherent (VAS <95)	8 (29.6)	7 (9.6)	0.002*
Ability to take all meds in past 30d			
Excellent	11 (41)	48 (66)	0.05*
Very Good	10 (37)	14 (19)	
Good	2 (7)	8 (11)	
Fair	3 (11)	2 (3)	
Poor	1 (4)	1 (1)	

Table 3

Clinical characteristics by VL suppression among 100 HIV positive patients in Hanoi, Vietnam

Characteristic	Mean $\pm$ SD or n (%)		P-value
	Not suppressed (VL $\geq$ 1000 copies) n=27	Suppressed (VL <1000 copies) n=73	
Duration on ART (months)	17.7 $\pm$ 12.6	15.6 $\pm$ 12.8	0.48
CD4 absolute (cells/mm ³)			
At initiation of ART ^(b)	119 $\pm$ 92	114 $\pm$ 73	0.77
At baseline visit	162 $\pm$ 94	199 $\pm$ 114	0.13
Increase in CD4 absolute (baseline – initial) ^(b)	43 $\pm$ 65	89 $\pm$ 98	0.009
Hepatitis B Susceptible	7 (26)	7 (10)	0.05*
Hepatitis C Antibody present	21 (78)	64 (88)	0.22*
Tuberculosis			
Diagnosed and treated ever	11 (41)	11 (15)	0.006
Treated since starting ART ^(c)	7 (26)	6 (8)	0.06*

* Fisher's Exact used (in lieu of Chi-square test) when 25% or more of cells had expected counts less than 5.

^(a) As defined by the inclusion criteria, all participants on ART for at least 6 months.

^(b) Initial CD4 at ART initiation is missing for 5 participants.

^(c) One patient responded that they "did not know" about TB treatment since commencing ART. HIV= human immunodeficiency virus; VL= viral load; ART= antiretroviral therapy