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Factors Associated with High Transmission Risk and Detectable Plasma HIV RNA in HIV-infected MSM on ART

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Abstract

HIV transmission risk is increased during ART use if individuals are not virologically suppressed and engage in high risk transmission behavior. Baseline data of HIV-infected MSM with recent history of risky behavior on ART for ≥3 months (n=139) was evaluated to assess predictors of detectable viremia and HIV transmission risk taking behavior. 24 subjects had VL>75 c/mL and 12 had VL>1000 c/mL. In multivariable regression analyses, subjects with VL>75 c/mL were more likely to be Black (OR 4.48, p=0.007), have lower CD4 cells (OR 0.727, p=0.005) and have used methamphetamines in the last month (OR 6.64, p=0.019). Subjects with VL>1000 c/mL were more likely to have lower CD4 cells (OR 0.494, p=0.004), report <90% adherence (OR 7.94; p=0.046) and have used methamphetamines in the last month (OR 10.01, p=0.034). Subjects with VL>75c/mL with the greatest transmission risk behavior (n=14) were more likely to be Black (OR 8.00, p=0.006), have lower CD4 cells (OR 0.657, p=0.009) and have used methamphetamines in the last month (OR 5.20, p=0.042). High risk HIV transmission behavior with viremia occurred in 10% of the cohort. Future efforts to reduce HIV transmission among MSM on ART will require combined interventions that target risk-taking behaviors and substance use.

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Introduction

Antiretroviral therapy (ART) is now being used globally not only to reduce individual risk of HIV progression in HIV-infected individuals but to also to reduce their infectiousness and prevent forward transmission. In the landmark HIV treatment as prevention (TasP) study HPTN 052, it was shown that earlier use of ART by HIV-infected heterosexuals in serodiscordant couples reduced HIV transmission by 96%.[1] This TasP strategy is currently at the forefront of a public health approach integral to controlling the HIV epidemic. However, in order for the TasP strategy to be widely effective, patients must be adherent to ART and maintain suppressed plasma HIV viral loads (VL).[2]

Despite improvements in efficacy, safety and tolerability of ART, only 72% of patients receiving ART have suppressed viral loads throughout the year.[3] Adherence to ART is critical to maintaining suppression and interventions to improve suppression rates at a population level will need to address the causes of nonadherence. In a retrospective review of HIV-infected adults, sustained viral suppression was shown to be lower for younger patients, Blacks, injection drug users and those without private insurance.[3] Individuals with alcohol and other substance use disorders have been shown to be at increased risk for poor adherence and virologic failure.[4–9]. Mental health disorders are common among HIV-infected individuals and are associated with poor ART adherence.[7,10,11] Combining all theses factors, multimodal approaches to clinical care are required to address all the co-morbidities and barriers to adherence.

While plasma HIV RNA suppression provides significant health benefit to HIV-infected individuals, viral suppression is also critical to reduce the risk of onward transmission, particularly among those with high transmission risk behavior. Some evidence suggests that lower adherence rates to ART have been associated with increased transmission risk behaviors.[12,13] Previous studies have shown that high-risk sex with HIV-uninfected partners persists among HIV-infected patients with viremia.[14–16] However, there is less known about what determinants may account for continued high transmission risk behavior in HIV-infected patients who are on therapy but not fully suppressed. In this analysis, we examined the baseline data of subjects with a recent history of transmission risk behavior enrolled in an internet-based prevention intervention study in order to determine factors associated with increased levels of VL and the association of those factors with high transmission risk sexual behavior. We hypothesized that demographic factors, methamphetamine use, depression, non-adherence and complexity of drug regimen would be associated with viral nonsuppression and high transmission risk behavior.

Methods

Study setting

This study focuses on the baseline data from an ongoing randomized controlled study of an internet intervention for HIV infected men who have sex with men (MSM) that was enrolled from November 2010 to July 2012 at three HIV primary care clinics at University of California San Diego, University of Southern California and Harbor-University of California

Los Angeles, which are part of the California Collaborative Treatment Group (CCTG), a multi-institutional, HIV clinical research network.

Eligibility criteria

Eligible subjects for the parent study (CCTG 592) were HIV-1-infected adults (age > 18 years) in stable health with no active opportunistic infection, MSM with a recent history of: potential exposure to an uninfected partner defined as reported unprotected anal sex with any partner in the past 3 months; more than 2 partners in the past year; having an HIV negative or unknown status partner in the past 3 months; or any sexually transmitted infection (STI) in the past year. Other eligibility criteria included English speaking, adequate computer skills for the study and no uncontrolled psychiatric condition. All study participants gave informed consent, and study procedures were approved by the institutional review board at each institution.

Study Design and Procedures

CCTG 592 is an ongoing randomized, controlled study comparing the efficacy of a web-based intervention to reduce high-risk sexual behavior by people with HIV. Baseline data was collected by confidential self-report for all enrolled subjects which included basic demographics, medical history, history of STIs, ART use, concomitant medications, medication adherence, psychiatric history, depression screen, illicit drug use, and laboratory assessments including STI screen, plasma HIV RNA and CD4 count. Medication adherence measures included the ACTG 4-day recall[17], last time missed medication over the course of 3 months question and a greater or less than 90% adherent question. Depression score was based on Center for Epidemiological Studies Depression Scale (CES-D)[18], a 20 item self-report scale with scores ranging from 0 to 60 (0–9 No depression, 10–15 Mild depression, 16–24 Moderate depression and >24 Severe depression).

Measurements

This analysis included baseline data from the subset of subjects enrolled in CCTG 592 that were on ART for at least three months, a time frame that viral suppression would usually be expected. Subjects were grouped according to their VL and transmission risk behavior. Data were evaluated to assess correlates of having VL > 75 copies/mL and > 1000 copies/mL). In addition, the baseline data for those with VL > 75 copies/mL and high transmission risk behavior, defined as having unprotected receptive or insertive anal sex with an unknown or HIV negative partner in the last 3 months, was also examined. Thus, three endpoints were studied: VL > 75 copies/mL, VL > 1000 copies/mL and VL > 75 copies/mL plus transmission risk behavior. We also examined VL > 1000 copies/mL plus transmission risk behavior but are not reported here due to low number of events.

Statistical Analysis

Descriptive analyses including Fisher’s exact test for categorical variables and Wilcoxon Rank-Sum test for continuous variables were conducted to assess the associations between each of the baseline predictors and each outcome measure. Multivariable logistic regression models were used to study which factors were associated with each outcome. Each of the

three outcomes was studied separately. A p-value of <0.05 was considered statistically significant. No adjustments were made for multiple testing. Statistical analyses were performed in R (http://cran.r-project.org), version 2.14.0.

Results

Study Sample

A total of 139 subjects (from the 181 MSM enrolled in the parent study) were on ART for more than 3 months and were included in this analysis. Twenty-four (18%) had VL > 75 copies/mL and 12 (9%) had VL > 1000 copies/mL. The median age of 46 years and median CD4 count was of 576 cell/uL. Thirty-five percent were Black and 31% Hispanic with 57% reporting an average household monthly income of less than $2000. Demographic data, background and medical characteristics of the sample are listed in Table 1.

Predictors of Detectable Viral Load

As summarized in Table 2, in univariate analysis, subjects with VL > 75 copies/mL were more likely to be Black (65 vs 29%, p=0.001), to have lower CD4 cells (307 vs 607, p<0.001) and to have reported missing a medication dose in the past 3 months (79 vs 54%, p=0.024) and more likely to have used methamphetamines in the last 30 days (29 vs 12%, p=0.05). The results from adjusted multivariable regression analysis for VL > 75 copies/mL found that being Black [OR (95% CI)=4.48 (1.50–13.39), p=0.007], CD4 count [OR= 0.727 (0.581–0.909), p=0.005], and methamphetamine use [OR= 6.64 (1.59–27.80), p=0.019] remained independently associated with the outcome. None of our nonadherence measures were found to be significant predictors for detectable VL > 75 copies/mL by multivariable analysis.

In univariate analysis, subjects with VL > 1000 copies/mL were significantly more likely to be Black (64 vs 33%, p=0.049) and less likely to be Hispanic (0 vs 35%, p=0.016). They were also significantly more likely to have lower CD4 cells with a median of 241 vs 604 cells/uL (p<0.001), to be on more total medications (6 vs 4, p=0.05), to be on a PI-based regimen (92 vs 54%, p=0.013) and to have reported <90% adherence (42 vs 11%, p=0.011). In addition, there was a statistical trend towards being on ART for less time (23 vs 39 months, p=0.054). The results from adjusted multivariable regression analysis for VL > 1000 copies/mL found that lower CD4 count [OR= 0.494 (0.305–0.802), p=0.004], reporting <90% adherence [OR= 7.94 (1.04–62.50), p= 0.046] and methamphetamine use [OR= 10.01 (1.19–83.88), p=0.034] remained independently associated with the outcome. The magnitude of increased risk of VL > 1000 copies/mL was similar to VL > 75 copies/mL for Black race but with a non-significant trend. Race, time on ART, total number of medications and type of ART regimen were not found to be significant predictors for virologic suppression by multivariable analysis (Table 2).

Predictors of Viremia plus Transmission Risk

The overall rate of HIV transmission risk behavior as defined in the methods section was 42%. Predictors of having VL > 75 copies/mL and HIV transmission risk factors are summarized in Table 3. There were 14 subjects (10%) with VL > 75 copies/mL who had

high HIV transmission risk. These subjects were more likely to be Black (71 vs 30%, p=0.002), to have lower CD4 cells (305 vs 604 cells/uL, p=0.002) and to have reported missing a medication dose in the past 3 months (89 vs 54%, p=0.004). This group had higher depression scores (23 vs 19, p=0.036) and had used methamphetamines in the last 30 days (39 vs 11%, p=0.006). These subjects were also more likely to report having regular HIV-infected sex partners (72 vs 40%, p=0.011). Having a casual HIV-uninfected/unknown status sex partners (50 vs 26%, p=0.051), having an STI in the past 30 days, being on a PI-based regimen and reporting <90% ART adherence were associated with viral non-suppression and transmission risk but statistical significance was not reached. The results from adjusted multivariable regression analysis for an association with viral non-suppression and HIV transmission risk behavior found that Black race [OR (95% CI)=8.00 (1.83–34.92), p=0.006], CD4 count [OR= 0.657 (0.479–0.902), p=0.009], and methamphetamine use [OR= 5.20 (1.06–10.23), p=0.042] remained independently associated with the outcome.

Discussion

This analysis of HIV-infected MSM on ART in Southern California explored the factors associated with viremia and ongoing HIV transmission risk behavior. The rate of high transmission risk behavior was 42%. High transmission risk behavior with increased VL occurred in 10% of the cohort and of those individuals, 64% had viral loads above 1000. This finding suggests that there is risk for potential HIV transmission from individuals on ART and therefore a need to understand the factors associated with this risk in order to fully utilize treatment for prevention strategies.

Among MSM on ART, having a detectable viral load with high transmission risk behavior was found to associated with being Black, having lower CD4 counts and having used methamphetamines in the last month. The association of nonsuppression with Black race is a finding that has been previously reported and may represent disparities in access to ART and care.[19–21] However, an analysis of subjects from several large randomized clinical trials found that black subjects had a 40% higher virologic failure rate than white subjects; the results remained significant in multivariate models after accounting for known confounders.[22] As all subjects in the clinical trial had access to medication and aggressive follow-up, factors other than access to care may be important including genetic factors, metabolic differences, and social variables. Not surprisingly, low CD4 count was significantly associated with viral nonsuppression across all groups which likely represents the known association between lower CD4 count and detectable viral load.

Methamphetamines use was consistently found to be a significant predictor of all endpoints studied. This suggests that methamphetamines use could be a major contributor to HIV transmission from MSM on ART. Whether methamphetamines use alone is responsible for risky behavior or there are particular psychological characteristics that drive both drug use and risky behavior as has been previously noted[12] is not evident from our data.

The distinction made in this study between VL > 75 copies/mL vs high level of > 1000 copies/mL may be an important one. A low level viral load may represent a “blip,” which data has shown not to be associated with virologic failure of previously adequate ART.[23] In

contrast, higher VLs are more concerning for true virologic failure and ongoing risk of transmission in general and of drug resistant virus in particular.

Nonadherence to ART has been previously shown to be one of the key predictors of virologic failure. Several factors including younger age, Black race, Hispanic ethnicity, drug use in the past 12 months, homelessness, depression, time on ART, number of previous regimens and boosted PI regimens have been found to be independent factors associated with nonadherence.[24–26] In our study, several self-reported adherence questions were used including 4-day recall, last time a medication was missed and 90% adherence assessment. In the univariate analysis, missing a medication dose in the last 3 months was predictive of VL > 75 copies/mL as well as VL > 75 copies/mL with HIV transmission risk, and reporting less than 90% adherence was associated with VL > 1000 copies/mL. While this finding underscores the need for standardization of adherence questions, it also suggests an association between varying levels of nonadherence and virological failure.

Of those subjects with high transmission risk (VL > 75 copies/mL and HIV transmission behavior), nearly three-quarters reported having a regular HIV-infected partner as compared to 40% of those with low transmission risk (VL < 75 copies/mL and/or low HIV transmission behavior) (See table 3). This finding might suggest serosorting to have unprotected sex, which can be adaptive within relationships with seroconcordant partners but can be risky with an outside partner.[27] Subjects with HIV transmission risk were also more likely to have casual unprotected sex with HIV-uninfected or unknown HIV status partners. This could indicate these individuals are seeking unprotected sex with all partners regardless of serostatus.[28–30] The relationship with types of partners was no longer significant in multivariable modeling, which suggest that other risk factors such as methamphetamines use may be driving the association of partnership type with high risk transmission behavior. However, interventions could still target partnership dynamics in these individuals.

Limitations of this analysis include small sample size, self-report biases in adherence, self-report biases of sexual activity and errors in recall of treatment regimens. As data on sexual behaviors were self-reported, it is subject to recall and desirability biases, although this is somewhat less likely with direct patient entry of data with our web-based subject self-reporting system. It is also not known how participants determined the serostatus of their male sex partner. In addition, it is well known that any self-reported adherence levels may overestimate true medication use.[31] Finally, these results cannot necessarily be extrapolated to non-MSM or MSM that are not on ART.

This analysis confirms that despite being in care and on ART, there are still individuals that do not achieve virologic suppression. What makes our analysis unique is that we defined subjects as being at greatest risk for HIV transmission from both a virologic and behavioral perspective. We found that many subjects not suppressed on ART are still engaging in risky sexual behavior. Moreover, similar to what has been seen in prior studies, we showed that factors associated with poor viral control in MSM on ART included demographics and drug use. Notably, Black race, methamphetamines use and low CD4 count had strong associations with HIV transmission risk from MSM on ART. To truly reduce the risk of

HIV transmission from this patient population it will be vital to target high risk populations to maximally address the factors associated with having poor virologic control and ongoing HIV transmission risk. Consequently, a successful HIV TasP program will require multifaceted approaches to manage these challenges.

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Table 1

Baseline Characteristics*

	N=139
Age (IQR)	46 (39–50)
Race/Ethnicity	
White	44 (32%)
Black	48 (35%)
Hispanic	43 (31%)
Other	4 (2%)
Education	
Less than high school diploma	9 (6%)
High school diploma (or GED)	27 (19%)
Some college	66 (47%)
Bachelor's degree	21 (15%)
Some post graduate	12 (9%)
Advanced degree	4 (3%)
Household average monthly income	
<999	53 (38%)
1000–1999	27 (19%)
2000–2999	10 (7%)
3000–3999	3 (2%)
4000–7999	6 (4%)
>=8000	5 (4%)
Refused to answer	35 (25%)
Median CD4 absolute count (IQR)	576 (357–745)
Medial viral load (copies/mL) (IQR)	50 (40–50)
Months on ART**	36 (15–62)
STI in past 30 days	13 (9%)
Drug use in the past 30 days	51 (37%)
Depression score	19 (14–25)
Regular HIV+ partner	9 (7%)
Regular HIV- or unknown partner	9 (7%)
Casual HIV+ sex partner	9 (7%)
Casual HIV- or unknown partner	9 (7%)
HIV transmission risk	58 (42%)

*All categorical assessments are depicted as n (%) and continuous variables as median (Interquartile Range)

**Total time since initiation of ART

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Table 2

Plasma HIV RNA>75 copies/mL and >1000 copies/mL on ART*

	VL<75 copies/ml	VL>75 copies/ml	P-value	MV OR (95% CI)	P-value	VL<1000 copies/ml	VL>1000 copies/ml	P-value	MV OR (95% CI)	P-value
Total	115 (82%)	24 (18%)	--	--	--	127 (91%)	12 (9%)		--	--
Age (IQR)	46 (38–50)	47 (40–50)	0.654	--	--	46 (38–50)	50 (45–51)	0.173	--	--
Black Race	33 (29%)	15 (65%)	0.001	**4.48 (1.50–13.39)**	**0.007**	41 (33%)	7 (64%)	0.049	4.71 (0.81–27.55)	0.085
Hispanic Ethnicity	37 (35%)	4 (19%)	0.138	--	--	41 (35%)	0 (0%)	0.016	--	--
High school diploma	30 (26%)	6 (25%)	>0.999	--	--	33 (26%)	3 (25%)	>0.999	--	--
Household Income** <$2000 ≥$2000	62 (54%) 23 (20%)	18 (75%) 1 (4%)	0.106	--	--	71 (56%) 23 (18%)	9 (75%) 1 (8%)	0.532	--	--
CD4 count (cell/uL)	607 (439–758)	307 (221–525)	<0.001	**0.727 (0.581–0.909)**	**0.005**	604 (437–756)	241 (119–305)	<0.001	**0.494 (0.305–0.802)**	**0.004**
Months on ART	37 (16–63)	25 (10–46)	0.215	--	--	39 (16–64)	23 (9–34)	0.054	--	--
Total # medications	4 (3–6)	5 (3–6)	0.234	--	--	4 (3–6)	6 (3–8)	0.05	0.42 (0.047–3.34)	0.437
PI-based regimen	61 (53%)	18 (75%)	0.069	1.20 (0.38–3.81)	0.762	68 (54%)	11 (92%)	0.013	9.04 (0.09–903.81)	0.349
Missed med within 3 months	**62 (54%)**	**19 (79%)**	**0.024**	**1.84 (0.55–6.12)**	0.320	72 (57%)	9 (75%)	0.359	--	--
Self-reported ARV status <90% adherent	12 (11%)	6 (25%)	0.092	1.37 (0.37–5.10)	0.643	13 (11%)	5 (42%)	**0.011**	**7.94 (1.04–62.50)**	**0.046**
STI in past 30 days	9 (8%)	4 (17%)	0.243	--	--	12 (9%)	2 (13%)	>0.999	--	--
Psychiatric Diagnosis	64 (56%)	14 (58%)	>0.999	--	--	71 (56%)	7 (58%)	>0.999	--	--
Depression score	19 (14–25)	20 (15–27)	0.421	--	--	19 (14–25)	22 (17–27)	0.463	--	--
Drug use in past 30 days	39 (35%)	12 (50%)	0.169	--	--	44 (35%)	7 (58%)	0.129	--	--
METH use in past 30 days	13 (12%)	7 (29%)	0.05	**6.64 (1.59–27.80)**	**0.019**	16 (13%)	4 (33%)	**0.076**	**10.01 (1.19–83.88)**	**0.034**

* All categorical assessments are depicted as n (%) and continuous variables as median (Interquartile Range)

** Remainder refused to answer

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Table 3

Plasma HIV RNA > 75 copies/mL plus Transmission Risk Behavior on ART*

	VL <75 and/or low risk	VL >75 + high risk	P-value	MV OR (95% CI)	P-value
Total	125 (90%)	14 (10%)	--	--	--
Age (IQR)	46 (39–51)	44 (38–50)	0.704	--	--
Black Race	36 (30%)	12 (71%)	0.002	**8.00 (1.83–34.92)**	**0.006**
Hispanic Ethnicity	37 (33%)	4 (24%)	0.579	--	--
Education ≤ HS diploma	30 (25%)	6 (33%)	0.564	--	--
Household Income **<2000** **>=2000**	67 (74%) 23 (26%)	13 (93%) 1 (7%)	0.18	--	--
CD4 count	604 (435–755)	305 (150–501)	0.002	**0.657 (0.479–0.902)**	**0.009**
Months on ART (IQR)	36 (15–63)	29 (13–45)	0.314	--	--
# of meds (IQR)	4 (3–6)	5 (3–6)	0.143	1.76 (0.54–5.78)	0.353
PI-based regimen	65 (54%)	14 (78%)	0.074	0.36 (0.7=22–5.88)	0.471
Last time missed med **> 3m ago** **Within last 3m**	56 (46%) 65 (54%)	2 (11%) 16 (89%)	0.004	5.10 (0.73–35.69)	0.100
Self-reported ARV status <90% adherent	13 (11%)	5 (28%)	0.067	--	--
STI in past 30 days	9 (8%)	4 (22%)	0.07	5.25 (.74–37.43)	0.098
Psychiatric Dx	67 (55%)	11 (61%)	0.8	--	--
Depression Score	19 (13–24)	23 (18–31)	0.036	1.01 (0.93–1.09)	0.811
Drug use in past 30d	42 (35%)	9 (50%)	0.296	--	--
Meth use in past 30d	13 (11%)	7 (39%)	0.006	**5.20 (1.06–10.23)**	**0.042**
IVDU in past 30 days	3 (3%)	2 (11%)	0.128	--	--
Regular HIV+ partner	47 (40%)	13 (72%)	0.011	2.48 (.060–10.23)	0.208
Regular HIV- or unknown partner	55 (46%)	6 (33%)	0.446	--	--
Casual HIV+ sex partner	25 (21%)	7 (39%)	0.132	0.49 (0.096–2.44)	0.380
Casual HIV- or unknown partner	31 (26%)	9 (50%)	0.051	2.52 (0.61–10.46)	0.204

*All categorical assessments are depicted as n (%) and continuous variables as median (Interquartile Range)