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Baseline Clinical Characteristics, Antiretroviral Therapy Use, and Viral Load Suppression Among HIV-Positive Young Men of Color Who Have Sex with Men

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Abstract

Given the continued high incidence of HIV infection in the United States among racial/ethnic minority young men who have sex with men (YMSM), and an appreciation that antiretroviral therapy (ART) can provide personal and public health benefits, attention is needed to enhance the detection of HIV-infected youth and engage them in medical care and support services that encourage sustained HIV treatment and suppression of viremia. Poor retention in clinical care has been associated with higher mortality, an increase in HIV RNA, and decreased CD4 cell count. The goal of the current study was to evaluate the health care utilization and health outcomes of HIV-infected racial/ethnic minority YMSM enrolled in an outreach, linkage, and retention study funded by the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB). We hypothesized that among racial/ethnic minority YMSM, baseline CD4 counts and usage of ART are influenced by age, race, drug and alcohol use, and mental health symptoms. Overall, 155 subjects had at least a baseline CD4 count recorded at study entry. There was a low rate of ART use in this population with only one-half of the cohort with CD4 counts ≤ 350 cells/mm^3 being prescribed ART to treat their infection. However, of those youth who were started on ART, the majority (74%) did achieve undetectable viral loads (<400 copies). Given the continued increase in cases of HIV infection among racial/ethnic minority YMSM, efforts to increase both the provision of ART and support services that encourage adherence in this population are warranted.

Introduction

To optimize health outcomes, newly diagnosed youth and those already known to have HIV infection must be effectively linked to care and receive antiretroviral therapy (ART) as indicated with optimal adherence and suppression of viral replication. However, an estimated 42–59% of people living with HIV/AIDS are not in regular HIV care.[1] Moreover, despite the widespread availability of HIV screening programs, delayed diagnosis of HIV infection remains a substantial problem. Compared to adults, adolescents are more likely to be identified later in the course of their infection and delay entry into clinical care.[2,3]

Poor engagement and retention in care has been found to be a predictor of higher mortality.[4] Further, nonadherence to medical appointments is associated with both an increased HIV RNA and a decreased CD4 cell count.[5] To date, there is limited information on clinical outcomes in youth. However, it has been reported that young adults have poorer rates of retention in care than older adults, suggesting that young adults are more at risk for being lost to follow-up.[6,7]

For HIV-positive patients, adherence to ART to the point of viral suppression can lower the risks of disease progression and death,[8,9] reduce overall health care costs,[10] and, potentially, decrease HIV transmission.[11] Despite improvements in ART regimens with regard to dosing frequency, dosing constraints (*i.e.*, food restrictions), storage conditions, and adverse effects,[12] drug adherence remains a significant problem. While current ART regimens are less toxic, more tolerable, and simpler, suboptimal adherence remains common, and young age, active drug and alcohol use, and depression are associated with poor adherence.[13–15]

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The goal of the current study was to evaluate the health care utilization and outcomes of HIV-infected young racial/ethnic minority men who have sex with men (YMSM) enrolled in the outreach, linkage, and retention study described in greater detail previously.[16] We hypothesized that among racial/ethnic minority YMSM, baseline CD4 counts, as a marker of disease stage, delayed diagnosis of HIV or delayed entry or re-entry into HIV care, are influenced by age, race, drug and alcohol use, mental health symptoms, and time since HIV diagnosis. Further, we anticipated that usage of ART among racial/ethnic minority YMSM will be less than recommended by current U.S. Department of Health and Human Services (DHHS) guidelines[17] and influenced by age, race, drug and alcohol use, and mental health symptoms.

Methods

Study population

Participants for the study were enrolled at one of eight demonstration sites funded by the Health Resources and Services Administration's HIV/AIDS Bureau through its Special Projects of National Significance (SPNS) program. These sites were located throughout the U.S. (Bronx and Rochester, NY; Chapel Hill, NC; Chicago, IL; Detroit, MI; Houston, TX; Los Angeles, CA; and Oakland, CA). Each site had its own outreach, linkage, and retention strategies. In order to be eligible for participation in the multisite cohort, participants had to be born male; HIV-infected and not currently in care; have sex with men, or the intent to have sex with men; self-identify as nonwhite, be between the ages of 13 and 24 years at the time of the first interview; be willing and able to provide full written informed consent; and agree to release of medical records. For new-to-care participants, three sites (Bronx, NY; Chapel Hill, NC; and Rochester, NY) enrolled youth who were diagnosed with HIV within the past 6 months; one site (Chicago, IL) enrolled youth diagnosed within the past 3 months; three sites enrolled all youth who had never been in care (Detroit, MI; Houston, TX; Los Angeles, CA) and one site (Oakland, CA) only enrolled youth who had been newly diagnosed within 30 days. Six sites (Bronx, NY; Chapel Hill, NC; Detroit, MI; Los Angeles, CA; Oakland, CA; and Rochester, NY) also enrolled youth who were not new to care but had received either intermittent or no care for at least 6 months. Institutional Review Boards (IRBs) of the George Washington University, as well as site-specific IRBs, approved all instruments and protocols. This included parent/guardian consent, if required by local IRB.

Data collection

Data for this study were collected between June 1, 2006 and August 31, 2009. Eligible participants underwent standardized face-to-face interviews by local study staff at baseline and every 3 months thereafter. Demonstration site administrators were trained at biannual grantee meetings and then provided with an interviewer and chart abstraction manual to assist in training staff. When needed, evaluation and support faculty conducted site visits for training and quality assurance. All clinical data were abstracted by trained local personnel. De-identified data were entered into a secure web-based data portal by study staff, reviewed for quality, and maintained by evaluation center staff at The George Washington University.

Statistical analysis

Clinical data were assigned to the appropriate time window (baseline, 6-month follow-up, 12-month follow-up) based on the participant's date of entry into the study. Baseline values were required to be within 2 months of study entry; 6-month follow-up values were required to be between 4 and 8 months after study entry; and 12-month values were required to be between 10 and 14 months after study entry. If there were two clinical values within a window, the average of the two was used for analysis. Any participants who entered the study after August 31, 2008 were censored since they had less than 1 year of follow-up time before the end of the study.

Participants were stratified into two groups based on baseline CD4 counts (≤ 350 and >350 cells/mm^3) and compared by age, race/ethnicity, sexual identity, education, drug and alcohol use, and depression defined by the Center for Epidemiologic Studies Depression Scale (CES-D)[17a] using Pearson's Chi-square tests. For those persons with a CD4 count ≤ 350 cells/mm^3 at any time during the first 12 months, Chi-square tests were used to compare those who started ART with those who did not start ART on the same set of demographic and behavioral characteristics. All analyses were performed using SAS v9.1 (Cary, NC).

Results

There were 227 racial/ethnic minority YMSM who completed a baseline survey and had at least 1 year of follow-up time. Overall, 155 subjects (68%) had at least a baseline CD4 count recorded at study entry (Table 1). The only significant difference between subjects with clinical data and those without was race, with African Americans being more likely than other races to have clinical data (data not shown). Of the 155 clients, 42 (27%) had only a baseline value, 44 (28%) had baseline and only 6-month follow-up values, and 69 (45%) had baseline, 6-month, and 12-month follow-up values. There were no significant demographic differences between those with more follow-up data in terms of race, sexual identity, age, site of enrollment, CES-D score or drug use. The only factor of significance was that those subjects with more education were more likely to have follow-up data (data not shown).

There were no significant differences between those subjects with baseline CD4 counts ≤ 350 and >350 cells/mm^3 except that those subjects who were new to care (compared to those who were re-engaging after intermittent or poor adherence to medical visits in the past) had higher CD4 counts at baseline (Table 1). Among those with CD4 counts ≤ 350 cells/mm^3 at baseline ($n=55$), 55% ($n=30$) were either on ART or were prescribed ART the day of enrollment into the study. Of those on ART, 63% were on an non-nucleoside reverse transcriptase inhibitor (NNRTI)-based regimen, and 27% on a boosted-Protease Inhibitor (PI)-based regimen. Regimen information for 10% of those receiving treatment was not reported.

Among those with CD4 counts ≤ 350 cells/mm^3 at baseline with at least a 6-month follow-up appointment ($n=40$), 27 (67%) were either on or initiated ART at baseline and of those 17 (63%) had an undetectable viral load (<400 copies) at their 6-month follow-up. Of the 13 subjects not on ART at baseline, none were started on therapy at their 6-month follow-up visit ($n=7$) or their 12-month follow-up visit ($n=6$).

Among those with CD4 counts >350 cells/mm^3 at baseline ($n=100$), 20 (20%) were either on ART or were prescribed ART

Table 1. Demographic and Behavioral Characteristics for Racial/Ethnic Minority YMSM Enrolled in Clinical Cohort, Stratified by Baseline CD4 Count

	Baseline CD4 ≤350 cells/mm^3 (n=*55*) N *(%)*	*Baseline CD4 >350 cells/mm^3* (n=*100*) N *(%)*	*Chi-square test* p *value*
Site			$\chi^2=8.12$ $p=0.322$
Los Angeles County, CA	16 (29.1)	18 (18.0)	
Chapel Hill, NC	6 (10.9)	25 (25.0)	
Bronx, NY	8 (14.6)	20 (20.0)	
Detroit, MI	12 (21.8)	13 (13.0)	
Harris County, TX	6 (10.9)	13 (13.0)	
Chicago, IL	3 (5.5)	4 (4.0)	
Oakland, CA	3 (5.5)	5 (5.0)	
Rochester, NY	1 (1.8)	2 (2.0)	
Age			$\chi^2=4.78$ $p=0.092$
Less than 19	5 (9.1)	22 (22.0)	
19–22	41 (74.6)	68 (68.0)	
Older than 22	9 (16.4)	10 (10.0)	
Race/ethnicity			$\chi^2=2.34$ $p=0.311$
African-American	39 (70.9)	73 (73.0)	
Other	3 (5.5)	11 (11.0)	
Latino/Hispanic	13 (23.6)	16 (16.0)	
Sexual identity			$\chi^2=1.44$ $p=0.696$
Gay/homosexual/ queer/two spirited	35 (63.6)	63 (64.3)	
Bisexual	13 (23.6)	17 (17.4)	
Heterosexual	1 (1.8)	2 (2.0)	
Other	6 (10.9)	16 (16.3)	
Drug use (ever)			
Marijuana	29 (69.1)	67 (74.4)	$\chi^2=0.421$ $p=0.517$
Other drugs (excludes marijuana and alcohol)	20 (44.4)	40 (43.8)	$\chi^2=0.012$ $p=0.915$
Drank alcohol at least one day in last 14 days	27 (58.7)	59 (62.8)	$\chi^2=0.216$ $p=0.642$
Depressive symptomatology (CES-D score at baseline)			$\chi^2=116$ $p=0.733$
≥16	28 (57.1)	52 (54.2)	
<16	21 (42.9)	44 (45.8)	
New to Care	28 (50.9)	69 (69.0)	$\chi^2=4.96$ $p=0.026$
Education			$\chi^2=0.128$ $p=0.938$
Less than HS	14 (25.5)	26 (26.0)	
HS or GED	18 (32.7)	30 (30.0)	
Greater than HS	23 (41.8)	44 (44.0)	

that day and of those 18 (90%) had an undetectable viral load at their 6-month follow-up. Thirteen of these 100 clients had a CD4 count ≤350 cells/mm^3 at either or both of their 6- or 12-month follow-up appointments and of those two (15%) were started on ART.

Of subjects whose CD4 count was ≤350 cells/mm^3 at any point during the study ($n=67$), 48% ($n=32$) were either on or initiated ART (Table 2). Of the 35 subjects who did not initiate ART, 80% ($n=28$) had CD4 counts consistently ≤350 cells/mm^3 at throughout their follow-up. The mean CD4 count (Standard Deviation, SD) for those who did and did not initiate ART was 307.0 (SD=124.3) and 319.2 (SD=82.3), respectively. The only significant difference between those who started ART and those who did not, was that those who started were less likely to have consumed alcohol on at least 1 day in the 2 weeks prior to the study visit ($p=0.05$). Of those with at least one follow-up visit at 6- or 12-months after ART initiation ($n=47$), 35 (74%) had an undetectable viral load. There were no significant differences between those who did and did not achieve an undetectable viral load (data not shown).

Table 2. Baseline Demographic and Behavioral Characteristics for Racial/Ethnic Minority YMSM Who Had a CD4 Count ≤350 Any Time During the 12 Months of the Study

	Started ART (n=32) N *(%)*	*Did not start ART (n=35)* N *(%)*	*Chi-square test* p *value*
Site			$\chi^2=9.76$ $p=0.202$
Los Angeles County, CA	10 (31.3)	7 (20.0)	
Chapel Hill, NC	3 (9.4)	3 (8.6)	
Bronx, NY	3 (9.4)	11 (31.4)	
Detroit, MI	7 (21.9)	6 (17.1)	
Harris County, TX	5 (15.6)	3 (8.6)	
Chicago, IL	0	3 (8.6)	
Oakland, CA	3 (9.4)	2 (5.7)	
Rochester, NY	1 (3.1)	0	
Age			$\chi^2=1.27$ $p=0.530$
Less than 19	3 (9.4)	5 (14.3)	
19–22	25 (78.1)	23 (65.7)	
Older than 22	4 (12.5)	7 (20.0)	
Race/ethnicity			$\chi^2=0.016$ $p=0.992$
African-American	23 (71.9)	25 (71.4)	
Other	2 (6.3)	2 (5.7)	
Latino/Hispanic	7 (21.9)	8 (22.9)	
Sexual identity			$\chi^2=1.86$ p=0.394
Gay/homosexual/queer/two spirited	18 (56.3)	24 (70.6)	
Bisexual	8 (25.0)	7 (20.6)	
Heterosexual	0	0	
Other	6 (18.8)	3 (8.8)	
Drug use (ever)			
Marijuana	16 (64.0)	21 (77.8)	$\chi^2=1.20$ $p=0.273$
Other drugs (excludes marijuana and alcohol)	13 (50.0)	11 (35.5)	$\chi^2=0.122$ $p=0.269$
Drank alcohol at least one day in last 14 days	14 (51.9)	23 (76.7)	$\chi^2=3.84$ $p=0.0500$
Depressive symptomatology (CES-D score at baseline)			$\chi^2=0.134$ $p=0.714$
≥16	16 (59.3)	18 (54.6)	
<16	11 (40.7)	15 (45.5)	
New to Care	17 (53.1)	21 (60.0)	$\chi^2=0.321$ $p=0.571$
Education			$\chi^2=0.107$ $p=0.948$
Less than HS	8 (25.0)	9 (25.7)	
HS or GED	10 (31.3)	12 (34.3)	
Greater than HS	14 (43.8)	14 (40.0)	

Discussion

Overall, there was a low rate of ART use in this population of racial/ethnic minority YMSM, with one-half of the sample requiring therapy based on the 2006 DHHS guidelines that recommended treatment for asymptomatic patients with CD4 counts ≤350 cells/mm^3 and only about one-half of those subjects with an indication for ART receiving it.[18] While this number is low, it is consistent with 2003 data from the Center for Disease Control and Prevention's National HIV Surveillance System project that estimated only 55% of all Americans ages 15–49 living with HIV/AIDS who were eligible for treatment at a threshold of CD4 count ≤350 cells/mm^3 were receiving ART.[19]

The only predictor we found associated with lack of ART use was alcohol use in the 2 weeks prior to the study visit. Physicians are less likely to prescribe ART to patients who report heavy alcohol use.[20] A clear negative effect of alcohol use on adherence has been previously reported.[21–24] A recent meta-analysis found that those who used alcohol were 50–60% as likely to be adherent compared to those who abstained.[24] These results suggest that more interventions that target adolescents' alcohol use in the context of ART are warranted.

As the pendulum shifts towards earlier initiation of ART,[17,25,26] achieving and maintaining a high degree of adherence is crucial. Incomplete suppression associated with the

selection of drug-resistance is clinically important, as virologic failure increases the risk of subsequent failures due to a decreasing number of treatment options. Of those youth who were started on ART, the majority (74%) did achieve undetectable viral loads. A review of trials using combination therapy in ART-naïve patients found levels of virologic success ranging from 51% to 79% for currently utilized NNRTI, or boosted PI regimens in adult cohorts.[27] Thus, despite prior studies documenting poor adherence among adolescents, we found high levels of virologic suppression in this cohort. Our success was likely related to the youth-focused interventions (*e.g.*, case management, peer counseling, support groups, drop-in clinics) specifically targeting racial/ethnic minority YMSM at each site.

Prior studies have documented significant differences between race and virologic efficacy with significantly lower odds of obtaining virologic suppression in African Americans compared to Whites.[28,29] While our sample was small and consisted of only young gay and bisexual men of color, we did not detect any differences in demographic features between those who achieved virologic suppression and those who did not.

In addition to the clear health benefits to individuals themselves from improved adherence, improvements in adherence are also fundamental to an emerging paradigm called "test and treat." This paradigm suggests that if all members of a community who are HIV positive are identified, linked to care, treated with ART, and achieve viral suppression, the rate of HIV transmission would be dramatically reduced.[30] Thus, the timely use of ART has important implications for both the individual and also for public health. Only 44% of our sample reported using a condom at last episode of anal intercourse. Moreover, of the 12 YMSM on ART who were not suppressed, only four (33%) reported using a condom at their last episode of anal sex. From a public health perspective, nonadherent and viremic patients likely play a large role in the transmission of HIV, including drug-resistant HIV strains.[31–34]

Our study should be considered in light of several limitations. Despite including racial/ethnic minority YMSM from multiple, geographically diverse locations, the overall sample size was small and the findings cannot be generalized to the entire population of racial/ethnic minority YMSM or to other populations of HIV-infected adolescents such as women and injection drug users. Moreover, almost one-third of the cohort did not have clinical data available and were not included in this analysis. Measurement of retention in care should be based not just on completion of surveys or attendance at study visits, but should include appropriate documentation of provision of clinical care, which consists of having CD4 counts and viral loads measured every 3–4 months.[17] We are unable to determine whether this lack of data represents a failure of participants to attend medical visits, a failure of providers to appropriately order the tests, or a failure of the SPNS demonstration sites to abstract participant clinical data, though great efforts were undertaken to obtain complete data. It is possible that those with missing clinical data are subjects either out of care or inconsistent in attending medical visits, thereby underestimating the severity of disease for this population.

Based on cumulative observational cohort data demonstrating the benefits of antiretroviral therapy in reducing AIDS- and non-AIDS-associated morbidity and mortality, the DHHS panel now recommends antiretroviral therapy for adults and adolescents with CD4 counts between 350 and 500 cells/mm^3.[17] Thus, the number of patients eligible for earlier initiation of therapy has increased, but the benefits of early treatment cannot be realized if those who need the medications are not receiving them. Given the continued increase in cases of HIV infection among racial/ethnic minority YMSM, efforts to increase both the provision of ART to this population and support services that encourage adherence are warranted.

Author Disclosure Statement

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