Use of Highly Active Antiretroviral Therapy in a Cohort of HIV-Seropositive Women

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Objectives. This study examined longitudinal trends in use of highly active antiretroviral therapy (HAART) among a cohort of HIV-positive participants in the Women's Interagency HIV Study.

Methods. Beginning in 1994, 1690 HIV-positive women reported detailed information about their use of antiretroviral therapy at 6-month study visits. Multivariate logistic and Cox regression analyses were used to estimate the likelihood of antiretroviral therapy and HAART use among women with study visits preceding and following HAART availability.

Results. Before the availability of HAART, the cohort's likelihood of any antiretroviral therapy use was associated with clinical indicators (CD4 count, viral load, symptom presence) as well as behavioral factors (abstaining from drug and alcohol use, participating in clinical trials). After HAART became commercially available, newly emerging predictors included college education, private insurance, absence of injection drug use history, and not being African American.

Conclusions. After the penetration of HAART into this cohort, additional differences emerged between HAART users and nonusers. These findings can inform public health efforts to enhance women's access to the most effective types of therapy. (*Am J Public Health.* 2002;92:82–87)

The use of highly active antiretroviral therapy (HAART) for the treatment of HIV/AIDS has prolonged life and revolutionized patient care.[1] However, questions remain about who does and does not have access to this latest and most potent antiretroviral therapy. Early studies showed that women were less likely than men to use zidovudine and initiated its use later in the course of their HIV disease.[2–5] More recent studies comparing men's and women's use of HAART confirmed these earlier findings.[6,7] Women also are underrepresented in HIV/AIDS clinical trials; they are less knowledgeable than HIV-positive men about the latest antiretroviral drug therapies, less aware of their eligibility to participate in such trials, and less likely to be recruited into such studies by their medical providers.[8–10]

Additional research has revealed significantly lower rates of use of zidovudine among members of racial and ethnic minorities, especially African Americans,[11,12] as well as less use of protease inhibitors and nonnucleoside reverse transcriptase inhibitors (NNRTIs).[1,6] Moreover, several studies have revealed disproportionately lower rates of antiretroviral therapy use among current or past drug or alcohol users,[2,4,9] especially those with a history of injection drug use.[13,14] Poverty and other resource constraints have been associated as well with a lower likelihood of use.[15,16]

Other factors appear to enhance rather than hinder access to antiretroviral therapy for HIV. Several studies have shown that having health insurance coverage (vs being uninsured) increases the likelihood of use of combination antiretroviral therapy.[1,6] In addition, having a college education appears to be positively associated with use of both earlier forms of antiretroviral therapy[17] and the latest multidrug regimens.[1] Finally, given guidelines recommending the use of HAART among individuals at certain CD4 and viral load levels,[18] it is not surprising that patients with CD4 cell counts below 500 are significantly more likely to be receiving combination antiretroviral therapy.[6,13]

The purpose of this study was to examine longitudinal trends of antiretroviral therapy use in a cohort of HIV-positive women enrolled in the Women's Interagency HIV Study, a multicenter investigation of the natural history of HIV disease in women. While previous studies have indicated that women, members of minority groups, and other populations of disadvantaged individuals are less likely to receive the most potent antiretroviral therapy, very little is known about which groups of women do and do not have access to these multidrug regimens. Also needed is a better understanding of how predictors such as education, ethnicity, and substance abuse influence access among HIV-positive women.

To explore these issues, this study addressed 4 major research questions: (1) What were the predictors of antiretroviral therapy use among a cohort of HIV-positive women in the pre-HAART era? (2) After the introduction of HAART, what proportions of the cohort members reported HAART use as well as any use of antiretroviral therapy? (3) What was the pattern of HAART penetration into the cohort over time as protease inhibitors and NNRTIs became available? and (4) What factors were significantly associated with HAART use, and were they different from those influencing the cohort's earlier use of antiretroviral therapy?

METHODS

Study Background

The Women's Interagency HIV Study was designed to examine the course of HIV disease in women. Between October 1994 and November 1995, 2628 HIV-positive and HIV-seronegative women were enrolled in the study at 6 sites nationwide: Chicago, Los Angeles, San Francisco, Brooklyn, the Bronx, and Washington, DC. To be eligible, respondents had to be 13 years or older, had to be able to provide informed consent, had to be willing to undergo testing for HIV, and had to be able to travel to the clinic site, complete the baseline visit, and have blood drawn. Semiannually, participants return for a follow-up visit, at which time information on use of antiretroviral therapy is collected, extensive interviews are administered, physical and obstetric-gynecologic examinations are performed, and blood is collected. Further details of the study and characteristics of the cohort have been reported elsewhere.[19]

The point at which the first protease inhibitor became commercially available, April 1996, represented the inauguration of the HAART era in this study. Data were derived from 1690 Women's Interagency HIV Study participants who met the inclusion criteria of being HIV seropositive; completing one or more study visits between April 1, 1996, and September 30, 1998 (82% of all HIV-positive women enrolled did so); and having no history of HAART use before protease inhibitors became commercially available (26 women were eliminated from the sample owing to their participation in early drug trials). Study attrition among the HIV-positive women was due to 319 deaths and 52 discontinued enrollments.[20]

Procedures

At each interview, women reported the names of all antiretroviral medications they were currently taking and had taken since the time of their last study visit. All drugs were later coded and classified into protease inhibitors, nucleoside reverse transcriptase inhibitors, NNRTIs, and other HIV-related drug therapies (e.g., hydroxyurea). Women were shown pictures of different drugs to help them identify specific medications.

Studies of patient recall in reporting complex pharmaceutical regimens[21–23] have shown that accuracy rates are greater when, as in this study, questions are medication specific and refer to frequently taken and recently used drugs. Other variables that affect recall accuracy (education, age) were controlled for in the analysis. Women were not asked about the dates they initiated drug regimens. Thus, this analysis focuses on the dates and predictors of women's first reports of HAART use since their last study visit rather than on onset of use.

Measures

Dependent variables. In accordance with the 1998 National Institutes of Health (NIH) guidelines,[18] we defined HAART as 2 or more nucleoside reverse transcriptase inhibitors in combination with a protease inhibitor (e.g., indinavir, saquinavir, ritonavir, nelfinavir) or an NNRTI (e.g., nevirapine, delavirdine). Women reporting use of one protease inhibitor combined with zidovudine and stavudine were not classified as HAART users because that combination is antagonistic, and NIH guidelines recommend against its use. However, women reporting use of 2 or more protease inhibitors were classified as HAART users, as were women using hydroxyurea in combination with certain antiretroviral therapies.

In the analysis, non-HAART combination antiretroviral therapy, monotherapy, and no therapy were considered non-HAART. In analyses of pre-HAART use of antiretroviral therapy, reports of the use of any such therapy were classified as antiretroviral therapy use. Reports at each study visit were coded as including use of either any antiretroviral therapy or HAART.

Independent variables. CD4 counts were measured by immunofluorescence, via flow cytometry, at laboratories participating in the AIDS clinical trials quality assurance program. Plasma HIV RNA levels were measured via a nucleic acid sequence–based amplification technique (Organon Teknica, Durham, NC). Dichotomous variables were constructed to assess high vs low viral load (greater than vs less than or equal to 20 000 copies/mL) and CD4 cell counts (less than vs greater than or equal to 500 cells/mL). Four groups were then created: low CD4/high viral load, low CD4/low viral load, high CD4/high viral load, and high CD4/low viral load.

Ethnicity was assessed through dichotomous variables representing African American, Latina/Hispanic, and White women. Age was measured in decades, per 10-year increase. Health insurance coverage was coded into 3 dichotomous variables (public, private, or none).

History of injection drug use, current street drug or alcohol use (including marijuana, hashish, crack/cocaine, heroin, and amphetamines), any education above the high school level, living in poverty (using US Department of Labor federal poverty-level criteria for the year in which income was measured), presence of one or more HIV/AIDS-related clinical symptoms (including fever, diarrhea, memory problems, numbness, weight loss, confusion, and night sweats), and previous experience in clinical trials (other than studies of HAART) were coded as dichotomous measures. Finally, site was coded via indicator variables; the Chicago center was the arbitrary reference category.

Statistical Analysis

Patterns of antiretroviral therapy use were examined over a period beginning with the first study visit in October 1994 and ending in September 1998. Logistic regression analysis was used to assess predictors of exposure to antiretroviral therapy immediately before HAART availability. HAART-use relative risks after April 1, 1996, were calculated through Cox regression analyses with the dependent variable right-censored. Predictor variables (fixed covariates) were CD4 and HIV RNA (at the most recent visit occurring before April 1, 1996), along with history of injection drug use, recent drug or alcohol use, education, age, health insurance coverage, income, study site, clinical symptoms, and previous exposure to clinical trials (all assessed at the first visit after April 1, 1996).

RESULTS

The 1690 women meeting the inclusion criteria closely resembled the HIV-seropositive Women's Interagency HIV Study cohort in regard to demographic characteristics.[18] Participants ranged in age from 17 to 73 years, with a mean of 36.4 years (median = 36). The majority were African American (57%); 24% were Hispanic/Latina, and 19% were White. Approximately half (48%) lived in poverty. More than a third of the women (37%) had not completed high school, another third (32%) had a high school diploma, and the final third (31%) had completed some college. While 41% of the women reported a history of injection drug use at their initial study visit, only 11% reported current injection drug use. However, 42% reported using some kind of street drug or alcohol in the previous 6 months.

Almost three quarters of the women (74%) reported some type of public health insurance coverage (Medicaid, Medicare, CHAMPUS [Civilian Health and Medical Program of the Uniformed Services], AIDS Drug Assistance

Program), 12% reported private health insurance coverage, and 14% reported no coverage. Just over half (53%) reported clinical symptoms related to HIV/AIDS. Thirty percent of the women had CD4 cell counts below 200, 43% had CD4 counts between 200 and 500, and 27% had CD4 counts above 500. Forty percent of the women had HIV RNA levels at or below 4000 copies/mL, 15% had levels between 4000 and 20 001 copies/mL, and 45% had levels above 20 000 copies/mL. Only a small percentage (7%) had participated in an HIV/AIDS clinical study.

To answer the study's first research question, we identified factors associated with pre-HAART use of antiretroviral therapy among these 1690 women at their study visit immediately preceding the point at which protease inhibitors became commercially available. As shown in Table 1, women with low CD4/high viral load levels and low CD4/low viral load levels were significantly more likely to report use of antiretroviral therapy, while those reporting drug or alcohol use in the previous 6 months and those from the San Francisco site were significantly less likely to report use of such therapy. Moreover, women with HIV/AIDS-related clinical symptoms were significantly more likely to report use of antiretroviral therapy, as were those who had previously participated in clinical trials. Ethnicity, educational attainment, age, health insurance status, poverty, and history of injection drug use were not associated with likelihood of antiretroviral therapy use in the pre-HAART period.

The next research question concerned patterns of HAART use reported after protease inhibitors had become commercially available. Table 2 shows that half (51%) of the women reported HAART use at one or more study visits after April 1, 1996; 38% of the women reported HAART use at every visit occurring after April 1996, and 13% reported starting and then discontinuing use of HAART. Many of the women in the non-HAART group were receiving some other type of combination antiretroviral therapy (24% of all women), and 6% were receiving monotherapy; 19% of all women reported no use of antiretroviral therapy at any study visit after April 1, 1996.

Analyses restricted to those women reporting HAART use indicated the relatively slow pace of HAART adoption by the cohort. In the first 6 months of HAART availability (April–September 1996), only 14% of all eventual users reported beginning HAART regimens since their most recent study visit; a third (33%) reported that their first HAART use occurred in the next 6 months (October 1996–March 1997). Thus, fewer than half (47%) of all eventual HAART users had reported these regimens within a year after widespread HAART availability. They were joined by another 28% at the end of the next 6 months and another 19% at 18 to 24 months, with 6% of all users first reporting HAART use more than 2 years after it became available.

Figure 1 illustrates penetration of HAART into the entire cohort by showing the reports of use (since the last study visit) of 3 types of antiretroviral therapy: monotherapy, non-HAART combination antiretroviral therapy, and HAART. Calendar times are shown as the midpoints of 6-month interview windows (e.g., percentages for July 1997 refer to study visits from April 1997 through September 1997). Reports of monotherapy declined substantially (from 28% at study visits occurring in the January 1995 window to 4.3% in July of 1997) and remained low throughout the period (5.6% at interviews occurring in the July 1998 window), while use of HAART increased substantially, from 1.2% at interviews taking place in the January 1996 window to

TABLE 1—Logistic Regression Predicting HIV-Positive Women's Antiretroviral Therapy Use at Most Recent Study Visit Occurring Before April 1, 1996

	Odds Ratio	95% Confidence Interval	*P*
CD4/viral load (VL)			
High CD4/low VL	1.00		. . .
Low CD4/high VL	5.19	3.78, 7.13	<.001
Low CD4/low VL	4.20	3.07, 5.74	<.001
High CD4/high VL	0.85	0.53, 1.39	NS
Race			
White	1.00		. . .
African American	0.79	0.55, 1.12	NS
Hispanic/Latina	0.83	0.55, 1.26	NS
History of injection drug use	1.10	0.83, 1.45	NS
Recent drug or alcohol use	0.61	0.48, 0.79	<.01
Some college	0.99	0.75, 1.31	NS
Age (per 10-year increase)	1.05	0.89, 1.24	NS
Health insurance coverage			
None	1.00		. . .
Public	1.13	0.83, 1.54	NS
Private	0.86	0.58, 1.29	NS
Living in poverty	1.00	0.78, 1.30	NS
1 or more clinical symptoms	1.38	1.08, 1.78	<.05
Clinical trial participation	2.31	1.26, 4.23	<.05
Center			
Chicago	1.00		. . .
Bronx	0.71	0.46, 1.09	NS
Brooklyn	0.85	0.54, 1.34	NS
Washington, DC	1.12	0.70, 1.80	NS
Los Angeles	1.28	0.80, 2.03	NS
San Francisco	0.44	0.29, 0.67	<.001

Note. Data were collected before widespread commercial availability of protease inhibitors.

TABLE 2—HIV-Positive Women's Antiretroviral Therapy Use Over All Completed Study Visits: April 1, 1996–September 1, 1998

Antiretroviral Therapy Status	Women With 1 or More Study Visits After April 1, 1996, % (No.)
Ever on HAART post–April 1996	51 (860)
On HAART/then off	13 (213)
On HAART/never off	38 (647)
Never on HAART post–April 1996	49 (830)
On non-HAART combination therapy	24 (405)
On monotherapy solely	6 (103)
No therapy	19 (322)
Total	100 (1690)

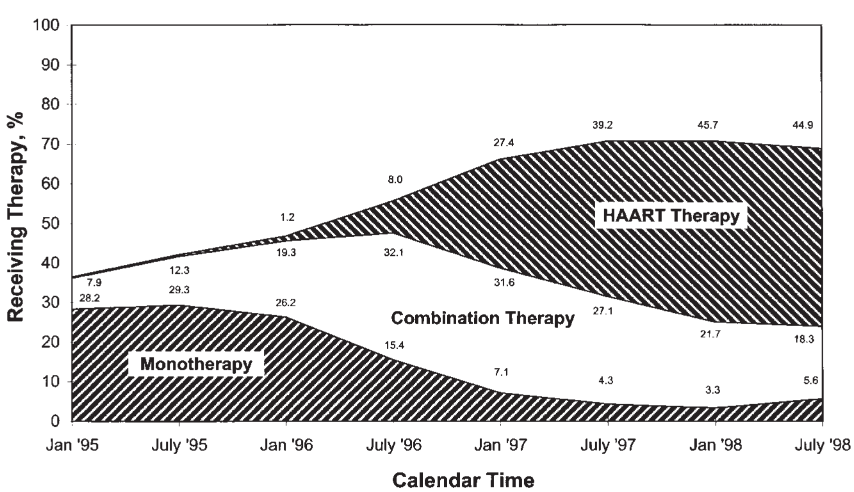
Note. HAART = highly active antiretroviral therapy. Data were collected following the commercial availability of protease inhibitors.

44.9% at the end of the study period. Use of non-HAART combination therapy increased and then declined, starting at 7.9% at interviews in the January 1995 window, rising to 32.1% at interviews in the July 1996 window, and falling to 18.3% at the end of the period.

The final research question concerned predictors of HAART use and whether these predictors were different from variables predicting the cohort's earlier antiretroviral therapy use (i.e., before HAART availability). HAART use relative risks at all study visits occurring after April 1996 were calculated with the same model used to predict pre-HAART use of antiretroviral therapy. As shown in Table 3, women with low CD4/high viral loads were 4 times as likely as those with high CD4/low viral loads to report HAART use. Those with low CD4/low viral loads were 2.9 times as likely to report HAART regimens, and those with high CD4/high viral loads were 2.4 times as likely to do so.

African American women were significantly less likely to report HAART use (odds ratio [OR]=0.80, 95% confidence interval [CI]=0.64, 0.99) at any study visit after April 1996. Women with a history of injection drug use (OR=0.79, 95% CI=0.66, 0.94) and those reporting recent drug or alcohol use (OR=0.82, 95% CI=0.69, 0.97) were also significantly less likely to report use of HAART. On the other hand, women with some college education were significantly more likely to report HAART use (OR=1.19, 95% CI=1.00, 1.42), as were those with private health insurance (OR=1.29, 95% CI=1.00, 1.66) and those who had previously participated in clinical drug studies (OR=1.34, 95% CI=1.02, 1.76).

Finally, in comparison with the Chicago site, women at the Los Angeles site were significantly more likely to report HAART use, while those from the San Francisco site were significantly less likely to report use of HAART; the remaining 3 sites did not differ significantly from Chicago. Additional variables that were found to be nonsignificant in this model included number of study visits, use of individual street drugs, occurrence of pregnancy, number of children in the home, number of adults in the home, dichotomous measures of study visit intervals (above or below median number of days between visits), and individual interaction terms between site and CD4, viral load, and drug or alcohol use.



Note. HAART = highly active antiretroviral therapy.

FIGURE 1—Reports of antiretroviral therapy use in the past 6 months among seropositive Women's Interagency HIV Study participants, 1995–1998.

DISCUSSION

This analysis has identified a number of factors associated with the likelihood of reports of HAART use after adjustment for the clinical laboratory markers CD4 and viral load. African American women were less likely to report taking HAART regimens, suggesting potential benefits from special outreach and medical education efforts directed toward this group. Women with histories of injection drug use also were less likely to report HAART regimens, as were those with recent use of alcohol and street drugs. Such women may be less likely to be offered these therapies because of physicians' perceptions that they are poor risks for adherence, even though they may have discontinued injection drug use or their current alcohol and street drug use may not preclude medication compliance. Alternatively, these women may have

TABLE 3—Estimated Risk (Cox Regression) of Highly Active Antiretroviral Therapy Use: April 1, 1996–September 1, 1998

	Relative Risk	95% Confidence Interval	*P*
CD4/viral load (VL)			
High CD4/low VL	1.00		. . .
Low CD4/high VL	4.04	3.14, 5.21	<.001
Low CD4/low VL	2.87	2.22, 3.71	<.001
High CD4/high VL	2.39	1.64, 3.49	<.001
Race			
White	1.00		. . .
African American	0.80	0.64, 0.99	<.05
Latina/Hispanic	1.09	0.85, 1.40	NS
History of injection drug use	0.79	0.66, 0.94	<.01
Recent drug or alcohol use	0.82	0.69, 0.97	<.05
Some college	1.19	1.00, 1.42	<.05
Age (per 10-year increase)	1.05	0.95, 1.16	NS
Health insurance coverage			
None	1.00		. . .
Public	1.16	0.96, 1.40	NS
Private	1.29	1.00, 1.66	<.05
Living in poverty	1.01	0.86, 1.20	NS
1 or more clinical symptoms	1.09	0.93, 1.28	NS
Clinical trial participation	1.34	1.02, 1.76	<.05
Center			
Chicago	1.00		. . .
Bronx	1.13	0.86, 1.48	NS
Brooklyn	0.90	0.67, 1.21	NS
Washington, DC	0.79	0.79, 1.58	NS
Los Angeles	1.38	1.05, 1.82	<.05
San Francisco	0.69	0.51, 0.93	<.05

Note. Data were collected following the commercial availability of protease inhibitors.

decided against taking HAART when it was offered; our data do not allow us to identify those women who were offered HAART but declined its use. Also, some women may have been less likely to be offered HAART owing to their less frequent use of health services in general.

Study participants with private health insurance were significantly more likely to report HAART use, suggesting that women without private health insurance coverage may have reduced access to the most effective treatments for HIV. Women with previous experience participating in clinical trials also were more likely to report use of HAART. It may be that such participation indicates a predisposition to try new treatment approaches, thus influencing a woman's likelihood of deciding to use potent combination antiretroviral therapies. Or it may be that participation in clinical trials is simply a marker for access to treatment or higher quality care.

Participants reported significantly different rates of HAART use depending on geographic location. Although the reasons for this disparity are not entirely clear, some of the variance may be due to differences in care availability, such as access to medical providers with more experience in the area of HIV, among women at different locations. Each individual site represented a consortium of study venues, with participants who received care from a variety of providers and who were recruited from settings as diverse as private physicians' offices, public hospital outpatient clinics, and street outreach. Further exploration of these site differences is currently under way among Women's Interagency HIV Study investigators.

In the period immediately before the availability of protease inhibitors, fewer factors distinguished between users and nonusers of antiretroviral therapy in our cohort. In this pre-HAART era, aside from the clinical indicators CD4, viral load, and HIV-related symptoms, use was predicted by a woman's current drug or alcohol use and her previous experience in clinical trials. After penetration of HAART into the cohort, additional differences emerged between users and nonusers of this more effective and fundamentally different type of antiretroviral therapy. Given the complexity of these regimens, their expense, and their reliance on near-perfect adherence for efficacy, perhaps it is not surprising that new variables emerged to influence rates of use, including education, private insurance coverage, absence of drug or alcohol use, and non–African American racial/ethnic status.

The challenge residing in this knowledge is that of ensuring that use of HAART is not restricted to women from certain racial/ethnic groups or educational backgrounds or to those with certain types of health insurance coverage or drug use histories. Efforts are clearly called for to educate physicians about the vulnerability of disadvantaged groups of women in regard to receiving less effective HIV therapies. This includes increasing physicians' sensitivity to patients' differing cultural beliefs about Western medicine[24] and their previous antiretroviral therapy experiences,[25] as well as the need to involve women's families and significant others in education about HAART.[26]

Similarly, intensive and sensitive efforts to educate women about available therapies can help them make informed decisions about whether and when to initiate HAART regimens. This should include efforts that address the concerns of patients who are skeptical about the value of HAART[27] and focus on accommodating treatment preferences, especially those of African Americans, who according to previous research[28] are less likely to express their treatment preferences to physicians.

Efforts to treat patients with the latest multidrug antiretroviral therapy may have inadvertently enhanced some disadvantages and barriers typically encountered by low-income, culturally diverse women in their efforts to obtain health care. However, awareness of these factors points to needed supports and services that can increase our potential to provide the latest, highest-quality antiretroviral therapy to the largest numbers of eligible HIV-positive women. This knowledge, it is hoped, can be applied to empower women's medical decision making in collaboration with their health care providers and thus improve their clinical outcomes and quality of life. ■

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