HPTN 052

Sustained Treatment as Prevention: Continued Decreases in Unprotected Sex and Increases in Virological Suppression After HAART Initiation Among Participants in HPTN 052

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INTRODUCTION

HPTN 052 demonstrated a 96% reduction in HIV transmission in HIV serodiscordant couples where the HIV infected partner initiated ART between CD4 350–550 cells/mm^3 (early) vs. CD4 < 250 (delayed), at a median follow-up of 2 years. It also demonstrated an early treatment benefit to the HIV infected person. The study is still on-going in order to assess the durability of these effects.

METHODS

We enrolled 1763 serodiscordant couples (where one partner is HIV positive and the other is HIV negative) at 13 sites in nine countries; 54% of the participants were from Africa, and 50% of infected partners were men. HIV positive participants with CD4 counts between 350 and 550 cells/mm^3 were randomly assigned in a 1:1 ratio to receive antiretroviral therapy (ART) either immediately (early therapy) or when their CD4 cell count was ≤ 250 cells/mm^3 or had an AIDS-defining illness (delayed therapy). The primary prevention end point was linked HIV transmission in HIV negative partners. The primary clinical end point was the earliest occurrence of pulmonary tuberculosis, severe bacterial infection, a WHO stage 4 event, or death. Couples received counseling on risk reduction and the use of condoms, and treatment of sexually transmitted infections (STIs) and other medical conditions. HIV negative partners received HIV testing on a quarterly basis. An assessment of sexual behavior (via self-reported questionnaire) was conducted at each visit. The current analyses compared the sexual behavior of HIV-infected participants before and after they initiated HAART, and examined trends to evaluate whether risk taking changed over time by GEE models.

RESULTS

At enrollment, 4.0% of HIV-infected participants in the early treatment group (E) and 5.7% in the delayed arm (D) self-reported unprotected vaginal intercourse (UVI) with their primary partner within the past week.
At 3 months, 2.9% of E participants did, compared to 3.0% of D participants (p=0.9). Over 2 years, UVI decreased among all participants (β=-0.015, p=0.04), and the time trend was similar in both arms. Participants engaging in UVI were more likely to be female (AOR=1.6, 95% CI 1.1–2.4), from South America vs. Asia (AOR=16.0, 95% CI 8.2–31.3), from Africa vs. Asia (AOR=8.8, 95% CI 5.0–15.6), use substances (AOR=2.2, 95% CI 1.3–3.9), and have a lower viral load at enrollment (AOR=0.7, 95% CI 0.6–0.9).
After 2 years, 91% of E participants were virologically suppressed, compared with 22% of D participants.
Self-reported unprotected anal intercourse (UAI) was uncommon (<0.3% at baseline, and no change over time). Out of participants on HAART who engaged in UVI or UAI, 21% of them had detectable plasma viremia.

Table 1: Baseline Behavioral and Clinical Characteristics

CHARACTERISTICS	PARTNERS WHO WERE INFECTED WITH HIV-1		PARTNERS WHO WERE NOT INFECTED WITH HIV-1	
	Immediate (N=886)	Delayed (N=877)	Immediate (N=893)	Delayed (N=882)
DEMOGRAPHIC				
Female sex	432 (49%)	441 (50%)	441 (49%)	418 (47%)
Age (median)	33	32	32	32
SEXUAL ACTIVITY				
Any unprotected sex with any partner in last week	36 (4%)	51 (6%)	46 (5%)	52 (6%)
No. of sex partners in last 3 months				
0–1	831 (94%)	833 (95%)	863 (97%)	844 (96%)
2–4	48 (5%)	41 (5%)	29 (3%)	36 (4%)
>4	7 (1%)	2 (<1%)	1 (<1%)	1 (<1%)
No. of sex acts in last week				
0	246 (28%)	225 (26%)	253 (28%)	240 (27%)
1–2	430 (49%)	438 (50%)	410 (46%)	433 (49%)
3–4	156 (18%)	158 (18%)	180 (20%)	151 (17%)
4	54 (6%)	55(6%)	50 (6%)	57 (6%)
CLINICAL				
CD4 counts*	442 (373–522)	428 (357–522)	-	-
Plasma RNA (log10 scale)*	4.4 (3.8–4.9)	4.4 (3.9–4.9)	-	-

* Median, 25th percentile and 75th percentile are reported.

Figure 1:
Percent of Heterosexual Participants Who Reported Unprotected Sex with Any Partner

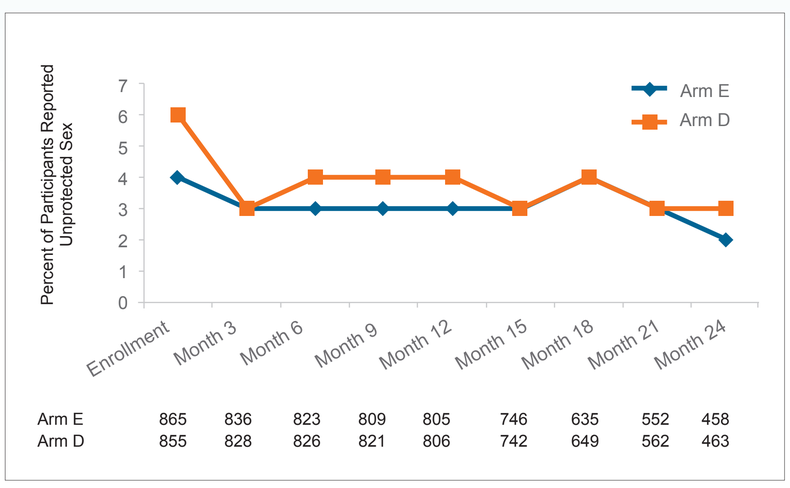


Figure 2:
Percent of Heterosexual Participants Who Had Detectable VL and Reported Unprotected Sex

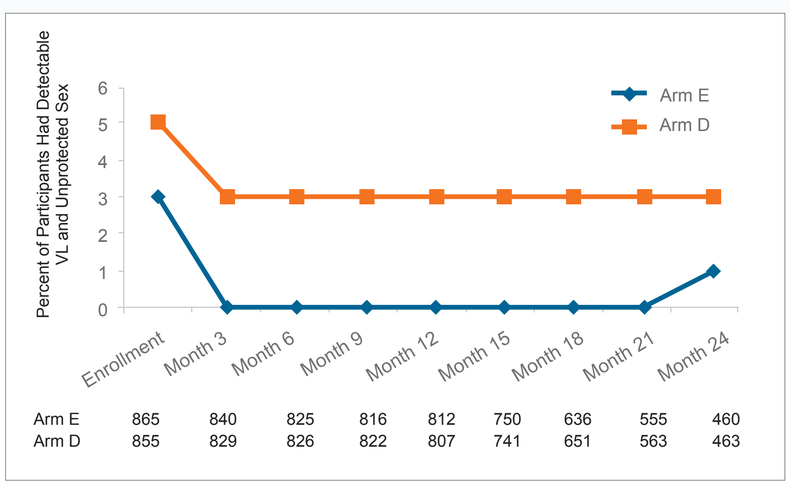
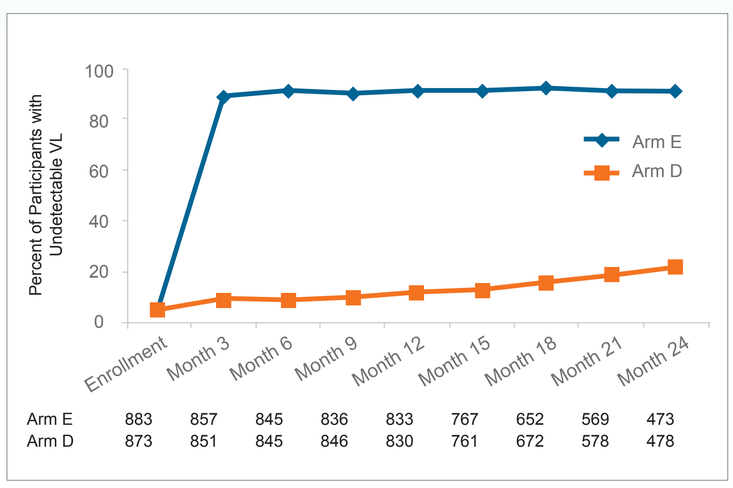


Figure 3:
Percent of Participants with Undetectable VL



CONCLUSIONS

Participants randomized to early HAART and those who subsequently initiated HAART did not increase risk taking behavior over several years. The decrease in sexual risk taking, coupled with effective virologic suppression, suggest that earlier initiation of HAART could have sustained effects in decreasing HIV transmission.

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