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Highly Active Antiretroviral Therapy versus Zidovudine for Prevention of Mother-to-Child Transmission in a Programmatic Setting, Botswana

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Abstract

Few studies have compared the programmatic effectiveness of the recommended strategies of antenatal highly-active antiretroviral therapy (HAART) and zidovudine for prevention of mother-to-child transmission (MTCT). We prospectively followed infants (93% formula-fed) whose mothers who took either HAART (258 infants) or zidovudine (170 infants) during pregnancy in the Botswana national program. Overall, 10 infants (2.5%) acquired HIV— 9 infants in the zidovudine group (5.5%, 95%CI 2.6-10.2%) and 1 infant in the HAART group (0.4%, 95%CI 0.0-2.2%). Maternal HAART was associated with decreased MTCT (P=0.001) and improved HIV-free survival (P=0.040) compared with zidovudine (with or without single-dose nevirapine) in a programmatic setting.

Introduction

The 2010 World Health Organization (WHO) guidelines for preventing mother-to-child transmission (MTCT) of HIV-1 recommend initiating highly-active antiretroviral therapy

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(HAART) early in pregnancy among women who need treatment for their own health (CD4+ cell count <350 cells/μL or WHO clinical stage 3 or 4). For pregnant women who do not yet need treatment for their own health, WHO recommends either maternal HAART or zidovudine with single-dose nevirapine (sdNVP, if duration of zidovudine <4 weeks), both followed by infant antiretroviral prophylaxis.[1] Some observational evidence[2-4] and lower MTCT rates reported from studies of HAART[5-8] than from studies of zidovudine,[9-11] suggest that maternal HAART may lead to greater reductions in MTCT at all CD4 strata. However, a recent randomized study of these strategies did not find a significant difference in MTCT risk for women with CD4+ cell counts >350 cells/μL.[12]

Few studies have compared the effectiveness of maternal HAART versus zidovudine in preventing MTCT in a resource-constrained, programmatic context. As governments and programs are deciding which strategy to implement for prevention of MTCT, we sought to compare rates of HIV infection between infants born to HIV-infected mothers taking either HAART or zidovudine in the Botswana national program.

Methods

We conducted a prospective observational study. Between February 2009 and April 2010, we approached HIV-infected mothers who delivered live-born infants on the maternity wards of a district referral hospital (Scottish Livingstone) and the largest national hospital (Princess Marina). Infants born to consenting Botswana citizens, at least 21 years old, and residing in the study catchment area were enrolled. Initially the cohort only included infants of women initiating HAART in pregnancy for a study of hematologic toxicity, but a protocol amendment (implemented after 10.6% of cohort had been recruited) expanded eligibility to HIV-exposed infants regardless of maternal antiretroviral treatment.

The Botswana national program provides free HIV treatment and prevention of MTCT interventions to Botswana citizens. In 2009, 32% of pregnant women were HIV-infected and 93% participated in the prevention of MTCT program.[13] According to national guidelines at the time of the study,[14] patients with CD4 cell count ≤ 250 cells/μL or WHO clinical stage 3 or 4 were eligible for HAART (zidovudine, lamivudine, and nevirapine for pregnant women). Pregnant women with CD4 cell count > 250 cells/μL were eligible for zidovudine (300 mg twice daily) from 28 weeks gestation through delivery. For women receiving < 4 weeks of zidovudine prior to delivery, sdNVP is recommended during labor. All infants are recommended to receive sdNVP (6 mg/kg) at birth and 4 weeks of zidovudine (4 mg/kg twice daily). The Botswana national program provides free infant formula.

Infants were followed in the study for health outcomes from birth to 6 months of age (antiretrovirals were administered by government clinics). Infant HIV testing was performed at 1 month (and repeated at 6 months for breastfed infants) by qualitative polymerase chain reaction (PCR) DNA assay using the Amplicor HIV-1 DNA PCR assay version 1.5 (Roche Diagnostic Systems, Branchburg, New Jersey). Positive results were confirmed by repeat testing. Infants who did not return for scheduled testing were traced in their homes. Infants with at least one positive HIV PCR were considered HIV-infected. Formula-fed infants with at least one negative HIV PCR after 4 weeks of age and breastfed infants with at least one negative HIV PCR at 6 months of age (or after last reported breastfeeding) were considered HIV-negative. Infants without an HIV PCR result after 4 weeks of age (or after last breastfeeding) were considered to have unknown HIV status.

Infants born to mothers taking combination antiretroviral therapy (at least 3 antiretrovirals) at the time of delivery were analyzed as part of the HAART group. Infants whose mothers took zidovudine, either alone or in combination with sdNVP, were analyzed as part of the

zidovudine group. Infants whose mothers took no antenatal antiretroviral therapy, or sdNVP only, were excluded from the analysis.

The maternal and infant characteristics and MTCT rate of the HAART and zidovudine groups were compared using Fisher's exact test and Wilcoxon signed rank test. Rates of MTCT for each group were estimated using infants with known HIV status as the denominator and exact methods were used to calculate 95% confidence intervals (95% CI). Statistical analyses were performed with SAS, version 9.2 (SAS Institute, Cary, NC). All tests were two-tailed and P-values of less than 0.05 were considered statistically significant.

The study was reviewed and approved by the Botswana Health Research Development Committee and the Institutional Review Board of the Harvard School of Public Health. Participating mothers provided written informed consent.

Results

Study participants

A total of 811 potentially eligible mothers were identified, however 157 were discharged prior to being approached (typically weekend deliveries) and 59 were referred for participation in another study (first HIV-exposed infant identified daily for 2 months of the study). Of 595 mothers approached, 439 (73.7%) agreed to participate. Four hundred and forty-four infants (including 5 sets of twins) were enrolled. Sixteen (3.6%) were excluded from the analysis because their mothers did not take zidovudine or HAART. Of the remaining 428 infants, 258 (60.3%) were born to mothers taking antenatal HAART and 170 (39.7%) to mothers taking antenatal zidovudine (with 18 also receiving sdNVP).

Reflecting Botswana treatment guidelines, mothers receiving HAART had lower CD4 cell counts than mothers in the zidovudine group (Table 1). Most mothers in both groups opted to formula-feed. Among women not on HAART at conception, the duration of antenatal treatment prior to delivery was longer in the HAART group (HAART 12.0 weeks, zidovudine 10.4 weeks) due to the more than half of mothers starting HAART in the first and second trimesters. The proportion initiating antiretrovirals after 30 weeks gestation did not differ between groups (HAART 32.5%, zidovudine 26.2%).

Mother-to-Child Transmission

Final HIV status could be determined for 415 infants (97.0%). Maternal verbal report alone was used to determine status for 4 HIV-negative infants (3 HAART and 1 zidovudine). HIV status could not be determined for 9 infants (5 HAART and 4 zidovudine) who died prior to HIV testing and an additional 4 infants who were lost-to-follow-up (1 HAART and 3 zidovudine).

Overall, 10 infants (2.5%) became HIV-infected during follow-up— 9 (5.5%, 95%CI 2.6-10.2%) in the zidovudine group and 1 (0.4%, 95%CI 0-2.2%) in the HAART group. MTCT was significantly more likely in the zidovudine group (relative risk 13.9, 95%CI 1.8-108, P=0.001). Findings were similar if the zidovudine group was restricted, as suggested by current WHO recommendations, to mothers with CD4 cell counts ≥ 350 cells/μL (relative risk 13.3, 95%CI 1.6-112, P=0.007). Five (55.6%) of the 9 of the infant infections in the zidovudine group occurred among women with CD4 cell counts greater than 350 cells/μL. A non-significant trend towards greater effectiveness of HAART was also observed among the sub-set of 68 mothers who initiated antiretroviral therapy after 30 weeks gestation (HAART 2.9%, zidovudine 12.5%, *P*=0.209).

As shown in Table 2, all HIV infections occurred in formula-feeding infants who received single-dose nevirapine and twice-daily zidovudine for 4 weeks. Three transmitting mothers took zidovudine for less than 4 weeks prior to delivery, however none received sdNVP as recommended (overall, 5 of 16 women who received less than 4 weeks of zidovudine received sdNVP).

Compared with non-transmitters, mothers in the zidovudine group who transmitted HIV had lower CD4 cell counts (median 368 versus 434 cells/μL, P=0.046), shorter duration of zidovudine (median 6.9 versus 10.5 weeks, P =0.009), and decreased gestational age at delivery (37.3 versus 39.1 weeks, P=0.016). However, we did not observe a difference in the timing of zidovudine initiation between transmitters and non-transmitters (30.4 versus 28.4 weeks gestation, P=0.215).

Survival

Twenty (4.8%) infants died from birth to 6 months of age, including 3 infants with known HIV-infection (2 HIV-infected infants died prior to receipt of HIV test result and one died shortly after initiating HAART). The proportion of infants surviving to 6 months did not differ between the HAART and zidovudine groups, 96.1% and 94.1%, respectively (P=0.357). The proportion of infants surviving free of HIV through 6 months of age was greater for the HAART group (95.7%) than for the zidovudine group (90.4%, P=0.040).

Discussion

In a resource-constrained, programmatic setting, we found that maternal HAART was associated with a substantial decrease in the rate of mother-to-child transmission compared with zidovudine. Mothers who took antenatal HAART had considerably lower CD4 cell counts, a factor strongly associated with MTCT,[15] but were still less likely to transmit HIV. Infants born to mothers receiving HAART experienced greater HIV-free survival than infants whose mothers took zidovudine.

Women in this study initiated antiretroviral therapy under routine programmatic conditions without expanded access to viral load testing, specialist care, or adherence support present in many clinical trials. However, the observed MTCT rate in the HAART group is among the lowest reported in the literature[3, 5-8, 16], supporting the effectiveness of HAART for the prevention of MTCT outside the context of a clinical trial.

Our findings do not support the equivalence of zidovudine and HAART for prevention of MTCT. More than half of all infant HIV infections in the zidovudine group came from women with CD4 cell counts ≥ 350 cells/μL. The MTCT rate in this group was significantly higher than in the group of women with much lower CD4 cell counts, and consequently at greater risk,[15] who received antenatal HAART. While shorter duration of antenatal antiretroviral treatment for women on zidovudine may have contributed to increased risk compared with HAART, this effect is unlikely to be substantial. Late antiretroviral initiation was associated with increased risk of MTCT, but was similarly common in both groups. In addition, extending zidovudine monotherapy beyond 4-6 weeks does not appear to lead to further reductions in HIV viral load[17, 18] or the proportion of women with an undetectable viral load at delivery,[12] important predictors of MTCT risk.[2, 3]

This cohort provides insight to some implementation challenges. While we noted possible programmatic improvements from a prior study,[19] delays in CD4 testing and HAART initiation contributed to 9 women (8.3%) eligible for HAART not starting prior to delivery, including one who transmitted HIV to her infant. Of women not on HAART at conception, 44 (15.5%) were not CD4 tested in the 6 months prior to delivery. We also observed the

difficulty of delivering sdNVP to the relatively small group of mothers receiving < 4 weeks of zidovudine— only 5 (22.7%) eligible women received sdNVP. Prematurity, rather than delayed initiation, was the principal reason in both groups for decreased duration of antenatal antiretroviral therapy. Finally, nearly one-third of neonates in this cohort were premature or low birth weight, emphasizing the importance of improving access to neonatal services in parallel with programs to prevent MTCT.

In contrast with prior studies of programmatic effectiveness that have relied on the results on the subset of infants presenting for testing,[4, 20-22] the prospective determination of HIV status in this study should reduce the possibility of bias. However, the analysis is subject to several limitations. We were unable to determine the HIV status for 13 infants (3.0%), including 9 who died prior to testing (none of an apparent AIDS illness), and consequently may have missed some infant HIV infections. Few women elected to breastfeed, so we cannot assess the effectiveness of HAART for prevention of breast milk transmission. With only one transmission in the HAART group, we were unable to construct a reliable multivariate model to adjust for baseline differences in maternal and infant characteristics. While many of these differences would be expected to decrease the apparent effectiveness of HAART, the non-randomized design and earlier initiation of HAART limits a conclusive assessment of HAART versus zidovudine.

In summary, we have shown that HAART initiated in a programmatic setting without frequent viral load monitoring or specialized care is highly effective at preventing MTCT. Use of antenatal HAART was associated with substantial decreased risk of MTCT compared with zidovudine (with or without sdNVP). The findings of this study indicate that a strategy to provide HAART for all HIV-infected women, as is currently being piloted in Botswana, could nearly eliminate infant HIV infection.

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Table 1

Participant and delivery characteristics for the study cohort.

	Maternal Antenatal Treatment		
	HAART (N = 258)	**Zidovudine (N = 170)**	***P*-value[a]**
Maternal Characteristics			
Enrollment site, no. (%)			1.0
Gaborone (city)	143 (55.4)	94 (55.3)	
Molepolole (village)	115 (44.6)	76 (44.7)	
Monthly personal income, no. (%)			0.742
None	87 (33.9)	52 (30.6)	
≤ $100	52 (20.2)	34 (20.0)	
> $100	118 (45.9)	84 (49.4)	
Electricity in household, no. (%)	125 (48.5)	76 (44.7)	0.489
Age at delivery (years), median (IQR)	31.1 (27-35)	28.8 (25-32)	< 0.001
Recent CD4+ cell count (cells/μL), median (IQR)[b]	263 (195-424)	430 (344-602)	< 0.001
Nadir CD4+ cell count (cells/μL), median (IQR)	188 (126-230)	—	—
Antiretroviral regimen at delivery, no (%)			—
ZDV/3TC/NVP[c]	208 (80.6)	0	
TDF/FTC/NVP	12 (4.7)	0	
D4T/3TC/NVP	10 (3.9)	0	
ZDV/3TC/LPV/r[d]	28 (10.9)	0	
ZDV monotherapy	0	152 (89.4)	
ZDV with single-dose NVP	0	18 (10.6)	
HAART prior to conception, no (%)	144 (55.8)	0 (0)	—
Duration of HAART prior to conception (months), median (IQR)	28.7 (15-51)	—	—
Duration of antenatal antiretroviral treatment (weeks), median (IQR)[e]	12.0 (7-18)	10.4 (8-12)	< 0.001
Gestational age at antiretroviral treatment initiation (weeks), median (IQR)[e]	26.9 (21-31)	28.5 (28-30)	0.004
Initiated antiretroviral treatment after 30 weeks gestation, no (%)[e]	37 (32.5)	43 (26.2)	0.283
Delivery Characteristics			
Gestational age at delivery (weeks), Median (IQR)	38.9 (37-40)	39.1 (38-40)	0.150
Caesarian delivery, no (%)[f]	31 (12.3)	11 (6.5)	0.067
Spontaneous membrane rupture, no (%)	187 (72.5)	116 (68.2)	0.385
Infant Characteristics			
Male sex, no (%)	132 (51.2)	84 (49.4)	0.767

	Maternal Antenatal Treatment		
	HAART (N = 258)	**Zidovudine (N = 170)**	***P*-value[a]**
Low birth weight (< 2.5 kg), no (%)	57 (22.1)	23 (13.5)	0.031
Small for gestational age, no (%)[g]	54 (20.9)	23 (13.5)	0.055
Premature (< 37 weeks), no (%)	59 (22.9)	32 (18.8)	0.336
Received infant prophylaxis, no (%)[h]	246 (95.4)	165 (97.1)	0.455
Breastfed, no (%)	20 (7.8)	8 (4.7)	0.237
Unknown infant HIV status, no (%)	6 (2.3)	7 (4.1)	0.389
Infant death by 6 months of age, no (%)	10 (3.9)	10 (5.9)	0.357

Note. HAART, highly-active antiretroviral therapy; ZDV, zidovudine; IQR, interquartile range; 3TC, lamivudine; NVP, nevirapine; FTC, emtricitabine; D4T, stavudine; LPV/r, ritonavir-boosted lopinavir;

[a] Fisher's exact test or Wilcoxon rank sum test.

[b] Most recent CD4 prior to delivery. Measured within 6 months of delivery for 75% of mothers on HAART and 91% of mothers on zidovudine. CD4 drawn 6 months post-partum used for one mother.

[c] Includes one mother taking ZDV, 3TC, and efavirenz.

[d] Includes two mothers taking 3TC, abacavir, and LPV/r, two mothers taking D4T, 3TC, and LPV/r and one mother taking TDF, FTC, and LPV/r.

[e] Includes only mothers beginning HAART or ZDV during pregnancy. Mothers taking HAART at conception are excluded from these calculations.

[f] 78.5% of Caesarian deliveries were emergent.

[g] < 10 percentile on Botswana normative table (unpublished data, Botswana Harvard AIDS Institute)

[h] Received both infant single-dose NVP and 4 week supply of infant ZDV.

Table 2

Characteristics of mother-to-child transmission pairs.

	Maternal Treatment	CD4 (cells/μL)	Gestational Age at Treatment Initiation (weeks)	Gestational Age at Delivery (weeks)	Duration of Antenatal ART (days)	Mode of Delivery	Infant Prophylaxis	Feeding Method from Birth
1	ZDV	306	32.1	33.7	12	Vaginal	sdNPV+ZDV	Formula
2	ZDV	253	27.3	32.0	34	Cesarean	sdNPV+ZDV	Formula
3	ZDV+sdNVP	611	30.9	41.6	76	Vaginal	sdNPV+ZDV	Formula
4	ZDV	438	28.7	32.1	25	Vaginal	sdNPV+ZDV	Formula
5	ZDV	153[a]	37.6	37.6	1	Vaginal	sdNPV+ZDV	Formula
6	ZDV	454	26.3	39.1	91	Vaginal	sdNPV+ZDV	Formula
7	ZDV+sdNVP	368[b]	30.4	37.3	49	Vaginal	sdNPV+ZDV	Formula
8	ZDV	250[c]	28.3	35.0	48	Vaginal	sdNPV+ZDV	Formula
9	ZDV	383	31.7	39.0	52	Vaginal	sdNPV+ZDV	Formula
10	ZDV/3TC/NVP	145	30.3	37.3	50	Vaginal	sdNPV+ZDV	Formula

Note. HAART, highly-active antiretroviral therapy; ZDV, zidovudine; 3TC, lamivudine; NVP, nevirapine; sdNVP, single-dose nevirapine.

[a] Antenatal clinic documentation indicates that initiation of zidovudine was delayed awaiting outcome of a referral for HAART. Labor commenced prior to scheduled visit for HAART initiation.

[b] Drawn 6 months post-partum. No antenatal CD4 measurement performed.

[c] Antenatal clinic staff incorrectly understood that women with CD4 of 250 did not qualify for HAART.