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PREGNANCY AND PREGNANCY OUTCOME AMONG WOMEN IN THE DART TRIAL

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BACKGROUND: DART is a randomized trial of ART-monitoring strategies among adults with symptomatic HIV infection and CD4 <200 cells/mm³ initiating ART in Kampala and Entebbe (Uganda) and Harare (Zimbabwe). Of 3316 enrolled participants, 1867 are women of child-bearing age.

METHODS: Reported pregnancies are confirmed by testing, and information is collected 2 weeks' post-partum on outcome, mother and infant ART, breast-feeding, and congenital abnormalities.

RESULTS: After a median 2.4-year follow-up, 197 pregnancies have been reported in 182 (9.7%) women <45 years at enrolment (4.6/100 person-years, 95% CI 4.0 to 5.3); 15 had 2 pregnancies. Median (IQR) baseline CD4 was 115 (53 to 161) cells/mm³ in women who became pregnant vs 88 (31 to 140) in those who did not ($p < 0.001$); 18% vs 25% were WHO stage 4 at baseline ($p = 0.06$). Pregnancy rate increased with time on ART (3.8, 4.2, and 5.0/100 person-years 0 to 6, 7 to 12, >12 months from ART initiation respectively). Proportions of women becoming pregnant in Entebbe, Kampala, and Harare were 14%, 8%, and 8%, respectively (26%, 14%, and 16% women aged 18 to 30). All women took ART in pregnancy: combivir with tenofovir (TDF; 70%), nevirapine (NVP; 15%), or abacavir (ABC; 5%), stavudine-containing regimens (d4T; 8%), other (2%). All except 1 continued through delivery; 31 (16%) pregnancies are ongoing and 7 (4%) with gestation >40 weeks have outcome currently unknown. Among 159 with known outcome, 82 (52%) were live births, 12 (8%) stillbirths, and 65 (41%) terminations (13 second trimester; 35 reported as induced, varying by clinical site). Of the 94 births, 16 (17%) were delivered by cesarean (8 emergency, 8 elective), 17 (18%) had gestation <37 weeks (8 live births [4 <33 weeks], 9 stillbirths [8 <33 weeks]), and 2 (2%) had congenital abnormalities (1 club foot,

1 hydrocephalus [which died]). Of the women, 2 died (1 following post-partum hemorrhage, 1 of unknown cause). Of 82 infants, 63 (77%) received ART (single-dose NVP 43%, 7 days' ZDV 15%, single-dose NVP+ZDV 17%, other 2%). There have been 5 neonatal deaths, 3 within 24 hours (1 <37 weeks); 21 (29%) of 73 infants known to be alive at 2 weeks were breast-fed. No infant has been diagnosed as HIV infected.

CONCLUSIONS: Pregnancy rates increased over time and fetal loss varied by site. This is the largest dataset on *in utero* exposure to 3 NRTI; so far, congenital abnormality rates appear similar to other studies. Despite taking HAART, a minority of women choose to breastfeed. Follow-up of infants to ascertain infection status and monitor effects of intrauterine ART is ongoing.

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