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Improvement in healing and reduction on HIV shedding following addition of episodic Acyclovir therapy to the syndromic management of genital ulceration; a randomized controlled trial

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Background: It is uncertain if herpes episodic treatment will have clinical benefit if delivered at primary care settings, where there is delay in treatment initiation.

Methods: A double-blind randomized placebo-controlled trial of a 5-day course of Acyclovir 400mg 3-times/day was conducted among men with GUD at three clinics in South Africa. At baseline, participants received syndromic management and were screened for HIV and HSV2 serology and ulcer etiology by PCR. Participants were followed for a month, to evaluate healing of ulcers, and collect blood and ulcer specimens to test for HIV-1. Ulcer specimens were tested with HIV-1 Amplicor 1.5 Ultra Sensitive Assay (Roche, Branchburg, NJ) with a lower threshold of 50 copies/ml. The main outcomes were ulcer duration and lesion HIV-1 RNA among HIV-1 sero-positive participants with a herpetic ulcer, assessed at day-7.

Results: 615 men were enrolled: 309 received Acyclovir and 306 placebo. The median age was 29 years, 63% were HIV-1-positive and 70.6% were HSV2 sero-positive. Median HIV-1 plasma viral load and CD4 count were 87,100 copies/ml and 282 cells/mm3, respectively. There were 298 HIV-1-positive men with a herpetic ulcer; information on ulcer healing by day-7 was available for 275 (92%). Acyclovir improved ulcer healing; with 59% on Acyclovir healing by day 7 compared to 41% receiving placebo (p=0.003), median time to healing was reduced by Acyclovir by three days [6 (95% CI: 5- 7) and 9 days (95% CI: 7-10), respectively (p=0.001)]. Acyclovir also reduced HIV-1 ulcer shedding at day-7 with 25% with detectable HIV-1 on Acyclovir and 38% on placebo (p=0.05). Mean ulcer HIV-1 RNA loads at day 7 were 0.44 log10 copies/ml (95% CI: -0.17-1.06) and 1.19 log10 copies/ml (95% CI: 0.71-1.68), respectively (p=0.04).

Conclusions: The addition of Acyclovir to the syndromic management of GUD will be beneficial for patient symptom relief and can potentially reduce HIV transmission by reducing genital HIV-1 shedding.

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