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# GENITAL HSV-2 SUPPRESSION IS NOT ASSOCIATED WITH ALTERATIONS IN THE VAGINAL MICROBIOME: A ONE-WAY, CROSS-OVER STUDY

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**Background** Women infected with herpes simplex virus type 2 (HSV-2) have increased risk of incident and refractory bacterial vaginosis (BV). We hypothesized that suppression of HSV-2 would be associated with decreased Nugent score and risk of BV.

**Methods** HSV-2 seropositive women with a self-reported history of BV self-collected daily vaginal and anogenital swabs for 28 days. Women then initiated valacyclovir 500 mg daily for a 2 week lead-in, followed by continued valacyclovir and self-collection of swabs for an additional 28 days. Anogenital swabs were tested for HSV DNA by PCR. Nugent score was performed on vaginal swabs (score  $\geq 7$  denoted BV). Quantitative PCR for three *Lactobacillus* species, *Gardnerella vaginalis*, *Megasphaera*, and BV-associated bacterium 2 was performed from DNA extracted from vaginal swabs. The primary outcome, per-participant median Nugent score at baseline compared to valacyclovir, was calculated using linear mixed models. We had 80% power to detect a 50% reduction in rate of BV on valacyclovir.

**Results** Forty-one women collected a median of 28 days of swabs during each study period. Thirty-three (80%) had a history of symptomatic genital HSV-2 infection, with a median of 2 self-reported recurrences in the past year (range 0–12). The genital HSV shedding rate decreased from 109 (9.7%) of 1126 days at baseline to 6 (0.05%) of 1125 days on valacyclovir (RR=0.06, 95% CI=0.02–0.13). Median Nugent score was 3.8 at baseline and 4.0 on valacyclovir (predicted change=0.26, 95% CI=-0.43–0.94). Women had BV on 343 (31.1%) of 1103 days at baseline and on 302 (27.7%) of 1091 days on valacyclovir (RR=0.90, 95% CI=0.68–1.20). Average log<sub>10</sub> concentrations of bacterial species did not change significantly during valacyclovir treatment.

**Conclusion** Use of short-term valacyclovir suppression among women with HSV-2 infection did not decrease the Nugent score or risk of BV and did not change concentrations of key vaginal bacteria.

**Disclosure** No significant relationships.

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# DETECTION OF Y-CHROMOSOMAL DNA CORRELATES WITH LAST UNSAFE SEXUAL EXPOSURE

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**Background** When *Chlamydia trachomatis* (CT) is detected after adequate treatment, this may reflect treatment failure or re-infection due to sexual re-exposure. For sexual exposure, researchers rely on self-reported data. Biomarkers such as Y-chromosomal DNA (Y-DNA) from vaginal and rectal samples may be used to support the validity of the self-reported sexual exposure data. The aim of this study was to validate detection of Y-DNA in a cohort of treated female CT patients, the Femcure study.

**Methods** Participants provided self-swabs for various days after treatment. For each swab, self-reported last unsafe (vaginal or rectal) sexual exposure (LUSE) was recorded in days (range t0-t14). Samples consisted of vaginal (n=120: 20 swabs at t=0,1,2,3,4; and 20 swabs at t=7,8) and rectal (n=43, 6 swabs at t0-1; 15 swabs at t2-5 and 22 swabs at t6-14) CT negative swabs in Roche COBAS PCR uniswab media (FemCure 2016–2017). CT negative human semen was used for spiking experiments. Quantitative detection of Y-DNA was performed using Quantifiler® Duo DNA Quantification Kit.

**Results** Samples with realistic spiked concentrations of ~0.5 ng/microliter Y-DNA remained stable and detectable until at least 35 days in the medium at 4°C. For vaginal swabs, detection of Y-DNA correlated inversely with LUSE: the Y-DNA detection percentage was 90%, 60%, 30%, 10%, 20% at t=0,1,2,3,4, and 5% at t7,8. In anal swabs, detection was 33% at t0-1 and 13% at t2-5 and t6-14.

**Conclusion** Y-DNA correlates strongly with LUSE in vaginal swabs, with high Y-DNA detection in the first 48 hours. Y-DNA detection data can be used to support self-reported sexual exposure data used in most research. The detection of Y-DNA in anal swabs has to be further validated as our study only included a limited number of anal samples at early time-points.

**Disclosure** No significant relationships.