# SEXUAL BEHAVIOURS AND PAST BACTERIAL VAGINOSIS (BV) CONTRIBUTE SIGNIFICANTLY TO BV RECURRENCE IN WOMEN RANDOMISED TO THE ORAL-CONTRACEPTIVE PILL

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#### Introduction:

Recommended therapy for bacterial vaginosis (BV) results in unacceptably high recurrence rates. Epidemiological evidence suggests that hormonal contraception use reduces the risk of BV recurrence. We conducted a pilot open-label randomised controlled trial (RCT) of combined (oestrogen-progesterone containing) oral contraceptive pill (COCP)-exposure to determine if it reduced BV recurrence following recommended antibiotic therapy over 6 months.

#### Methods:

Women attending the Melbourne Sexual Health Centre diagnosed with BV were prescribed first-line antibiotic therapy and assessed for eligibility. Participants were randomised 1:1 to either intervention (COCP) or control (current non-hormonal contraceptive practice) groups and followed monthly for 6 months or until BV recurrence, whichever occurred first. Modified intention-to-treat methods requiring either ≥1 clinical (primary/Amsel outcome) or ≥1 microbiological (secondary/Nugent outcome) assessment of recurrence were applied to determine cumulative recurrence rates. Secondary Cox regression analyses, adjusted for allocation, assessed factors associated with recurrence in all women, regardless of treatment group.

### **Results:**

Ninety-two of 95 women randomised provided baseline requirements: clinical cure (primary/Amsel outcome) was determined for 66 participants and microbiological cure (secondary/Nugent outcome) for 82 participants. BV-recurrence rates were similar in women randomised to the COCP (primary/Amsel outcome: 10/100 person-years, 95%CI:6,19/100PY) compared to controls (14/100PY, 95%CI:9,21/100PY, p=0.471). In secondary analyses, sex with an ongoing regular sexual partner (RSP; Amsel outcome: Adjusted Hazard Ratio[AHR]=3.09, 95%CI:1.40,6.87; Nugent outcome: AHR=2.97, 95%CI:1.49,5.83) and self-reported BV history (Amsel outcome: AHR=2.90, 95%CI:1.09,7.72; Nugent outcome: AHR=2.78, 95%CI:1.22,6.33) were associated with increased BV-recurrence.

#### Conclusion:

This pilot RCT of COCP-exposure did not improve BV cure but found sex with an ongoing RSP and a past history of BV were associated with recurrence. These data indicate reinfection and persistence are integral to the pathogenesis of recurrence may overwhelm possible beneficial effects of hormonal contraception on the vaginal microbiota.

## **Disclosure of Interest Statement:**

No conflict of interest for any listed authors.