

(14%) of women diagnosed as having VVC alone. Of the 471 women diagnosed as having co-BV/VVC based on clinical criteria, only 191 (41%) had culture confirmation of yeast plus a Nugent score of ≥ 7 . Of the remaining women, 105 (22%) had BV alone, 126 (27%) had yeast alone, and 49 (10%) had neither BV nor yeast. Intermediate Nugent scores of 4-6 were noted in 109 (23%) of women diagnosed with co-BV/VVC.

CONCLUSION: In this large multicenter study employing standard clinical diagnostic algorithms for BV, VVC, and co-BV/VVC, possible mixed infection occurred in 14-20% of women diagnosed as having a single condition, while clinical diagnosis of co-BV/VVC was lab confirmed in fewer than half. Reliance on clinical criteria for diagnosis of BV and/or VVC can lead to misdiagnosis.

LEARNING OBJECTIVES: Describe the limitations of clinical criteria for diagnosis of bacterial vaginosis and vulvovaginal candidiasis, especially when present as co-infections.

16 Elevated risk of bacterial vaginosis among copper intrauterine device users: a prospective cohort analysis



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OBJECTIVES: To evaluate the association between copper IUD (Cu-IUD) use and bacterial vaginosis (BV) incidence among women enrolled in the MTN-020/ASPIRE trial.

METHODS: This secondary analysis includes 2,614 HIV-negative women ages 18-45 from Malawi, South Africa, Uganda and Zimbabwe. Women reported use of Cu-IUD, injectable contraceptives (DMPA, NET-EN), oral contraceptives (OC), implants containing etonogestrel or levonorgestrel, or none/other non-hormonal contraception at monthly visits. BV was evaluated by Nugent score at 6-monthly intervals. We used Andersen-Gill proportional hazards models to evaluate the association between contraceptive method and BV. Among new Cu-IUD users, we used generalized estimating equations to test changes in incidence following initiation and subsequent discontinuation of Cu-IUD. All models were adjusted for potential confounders, including number of sexual partners, condom use, partner circumcision status, intravaginal practices, and study site.

RESULTS: Throughout follow-up, DMPA was the most commonly used contraceptive (47%), followed by implant (32%), Cu-IUD (24%), OC (21%), NET-EN (19%), and none/other non-hormonal contraception (15%). Relative to women using none/other non-hormonal contraception, women using Cu-IUD had higher BV incidence (138 cases per 100 person-years [95% CI: 130, 147] vs. 112 [95% CI: 98, 127]; HR: 1.27, 95% CI: 1.10, 1.46). Results were

similar when comparing BV incidence among Cu-IUD users to OC and implant users. Among 304 women who initiated Cu-IUD during follow-up, BV incidence increased nearly two-fold in the 6 months following initiation relative to the 6 months prior to initiation (RR: 1.91, 95% CI: 1.46, 2.50). Seventy-four (24%) women subsequently discontinued Cu-IUD use; BV incidence remained elevated in the 6 months following discontinuation (RR: 1.58, 95% CI: 1.10, 2.27), then was similar to pre-initiation rates within one year (RR: 1.13, 95% CI: 0.71, 1.81).

CONCLUSION: These data add to the growing body of evidence that Cu-IUD users have an elevated risk of BV, and further suggests that Cu-IUD discontinuation is associated with decreased risk within a year. Women and their providers may wish to consider BV risk when discussing contraceptive options. Future research should investigate the mechanism(s) by which Cu-IUD use increases BV risk, as well as a potential mediating role of BV in increasing HIV risk among Cu-IUD users in settings with high HIV incidence.

LEARNING OBJECTIVES: Learners will be able to describe the association between Cu-IUD use and incident bacterial vaginosis.

17 Results of a phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of astodrimer gel for prevention of recurrent bacterial vaginosis



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OBJECTIVES: To determine the efficacy and safety of Astodrimmer Gel in reducing recurrent BV in women with a history of recurrent BV.

METHODS: A total of 864 women aged 18-45 were enrolled at 67 centers in the US, Canada, Mexico and Puerto Rico. The target population was women with a history of recurrent BV (episodes in the past year), and a current diagnosis of BV by 3/4 Amsel criteria and Nugent score (NS) 4. Women received a 7-day course of oral metronidazole (500mg BID) for their BV. Subjects successfully treated (no symptoms, Amsel criteria for discharge, whiff test and clue cells all negative) were randomized 1:1 to receive 5g of Astodrimmer 1% Gel (N=295) or placebo (N=291), vaginally, QOD for 16 weeks. Women were evaluated every 4 weeks for BV recurrence. Those who remained recurrence-free through 16 weeks were followed for up to 12-weeks off-therapy. The primary efficacy endpoint was BV recurrence, defined as 3 Amsel criteria, at or by Week 16 in the mITT population. Secondary analyses included time to recurrence, and recurrence of symptoms, individual Amsel criteria and NS 7-10.

RESULTS: Astodrimmer Gel was superior to placebo for the primary and most secondary efficacy measures. BV recurrence rate at or by Week 16 was 44.2% (130/294) vs 54.3% (158/291); P=.015. The time to BV recurrence, as assessed by difference in survival curves, was significantly longer for Astodrimmer Gel vs placebo; P=.007. Recurrence of BV symptoms (vaginal odor and/or discharge) at or by Week 16 was less frequent in the Astodrimmer group (27.9%; P=.002) vs placebo (40.6%). The rate of recurrence of individual Amsel criteria, except pH, was also lower in the Astodrimmer group. The recurrence of BV defined as NS 7-10 or by composite of NS