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### Title

Menstrual Cup Use and Intrauterine Device Expulsion in a Copper Intrauterine Device Contraceptive Efficacy Trial

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**OBSTETRICS**

**FIRST PLACE**

**Preterm Delivery Prediction Using Phosphorylated Insulin-Like Growth Factor in Rural Kenya**

[OP01-1A]

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Lisa Gilligan, MBA, and Thomas K'Ouma Matete, MD

**INTRODUCTION:** To evaluate the feasibility and accuracy of a test analyzing for the presence of phosphorylated insulin-like growth factor binding protein-1 (pIGFBP-1), in predicting preterm delivery in asymptomatic women in the rural Kenya.

**METHODS:** This was a prospective cohort study conducted by Saving Mothers from 2013-2019. Asymptomatic women presenting for routine prenatal care in West Pokot, Kenya were enrolled. Pregnant women were recruited prior to 24 weeks and offered the opportunity to return at 28-32 weeks gestation to obtain the phosphorylated insulin-like growth factor binding protein-1 (pIGFBP-1) assay. Dating was established by last menstrual period and confirmed by ultrasound. Patients who tested positive received betamethasone, and were referred to the maternity waiting home. Outcome data was collected after delivery and sensitivity, specificity, positive and negative predictive values were reported for the test.

**RESULTS:** 669 women were recruited. 469 returned for the second visit to receive the test, and presently 370 have complete data for analysis. 180 tested positive for preterm birth risk, 143 of whom delivered prior to 37 weeks gestation (Positive Predictive Value = 79.4%). 190 tested negative, 176 of whom delivered after 37 weeks (Negative Predictive Value = 92.6%). Sensitivity for the test was 91.0%. Specificity was 82.6%.

**CONCLUSION:** The pIGFBP-1 point of care test is effective in predicting risk for preterm birth in asymptomatic women in rural Kenya. This allows for risk-stratification in low resource settings. Proper intervention may optimize utilization of scarce resources and improve maternal and child health.

**Financial Disclosure:** The authors did not report any potential conflicts of interest.

**CONTRACEPTION/FAMILY PLANNING**

**SECOND PLACE**

**Menstrual Cup Use and Intrauterine Device Expulsion in a Copper Intrauterine Device Contraceptive Efficacy Trial [OP01-1B]**

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and Diana Bliithe, PhD

**INTRODUCTION:** Menstrual cup use for menstrual hygiene is increasingly popular. We evaluated relationship of menstrual cup use and intrauterine device (IUD) expulsion in a prospective trial of two copper IUDs.

**METHODS:** An ongoing 3-year contraceptive efficacy trial randomized women to one of two copper IUDs, with successful placement in 1,092 women. Institutional Review Board approval was obtained, and all subjects provided informed consent. Follow-up visits in the first year occurred at 6 weeks, and then 3, 6, and 12 months after insertion. At nine months after initiating enrollment, we modified the protocol to advise subjects against concurrent menstrual cup use with the IUD. We evaluated the association of menstrual cup use and expulsion risk over the first 24 months of study conduct.

**RESULTS:** Overall, 266 (24.4%) women reported menstrual cup use. At 24 months after initiating enrollment, 46 (17.3%) cup users and 43 (5.2%) non-users experienced expulsion (odds ratio 3.81 [95% CI 2.45-5.92]). Fourteen (30.4%) menstrual cup users with expulsion reported

the event occurred during menstrual cup removal. At Year 1 of the study, expulsion rates among menstrual cup users and non-users were 14.3% and 4.7%, respectively (P<.001). By the end of Year 2, these rates were 23.2% and 6.5% (P<.001).

**CONCLUSION:** We found higher than expected IUD expulsion rates in menstrual cup users amongst participants in a prospective trial of two copper IUDs. Copper IUD users should be cautioned that concurrent menstrual cup use increases the risk of IUD expulsion and expulsion risk continues with ongoing menstrual cup use.

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**OBSTETRICS**

**THIRD PLACE**

**Vaginal Cleansing and Azithromycin at Cesarean Delivery; A Quality Improvement Study [OP01-1C]**

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**INTRODUCTION:** The objective was to assess the stepwise implementation of pre-operative vaginal cleansing and intravenous (IV) azithromycin on the rate of surgical site infection (SSI) for women who undergo cesarean delivery (CD) intrapartum or after rupture of membranes.

**METHODS:** This was a quality improvement study comparing 3 groups: 1). 12 months of pre-intervention; 2). 14 months of vaginal cleansing as infection prophylaxis; 3). 16 months of both vaginal cleansing and azithromycin IV as infection prophylaxis. The primary outcome, which was analyzed by control charts, was the rate of SSI as defined by the Center for Disease Control and Prevention (CDC). This study was IRB approved.

**RESULTS:** There were 1,033 patients included from the 3 study periods. The total rate of SSI rate decreased from 22% to 12.5% after implementing vaginal cleansing. Special cause variation was seen with an 8-point shift starting 4 months after implementation of vaginal cleansing. This decrease was sustained during the following 26 months. Adding azithromycin IV did not significantly further lower the rate of SSI. When examined separately, deep SSI (P=.009) and endometritis (P=.001) significantly decreased in the post-intervention periods. Pre-operative vaginal cleansing compliance rose to 74%, and then further increased to 85% 1 year after implementation. Azithromycin IV compliance rose to 75%.

**CONCLUSION:** In this quality improvement study, implementation of vaginal cleansing decreased the SSI rate by 43%, from 22% prior to either intervention to 12.5% after addition of vaginal cleansing. The addition of azithromycin IV did not result in any further change in SSI rate.

**Financial Disclosure:** The authors did not report any potential conflicts of interest.

