

Oral Abstract Session: Female Initiated HIV Prevention Technology

TUAC102 - Diaphragm and gel adherence in a safety trial in Harare, Zimbabwe

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Objectives: Product adherence is central to assessing safety and effectiveness of prevention methods. We measured adherence over six months in a placebo-controlled safety trial of the diaphragm and microbicide Cellulose Sulfate (CS).

Methods: 117 Zimbabwean women were randomized into 2 diaphragm/gel (CS or KY Jelly) groups (n= 77) or to CS gel alone (n= 40). All were given condoms and asked to use them for every sex act. Adherence was assessed monthly by ACASI, by asking how often products were used since last visit (always, sometimes, never). Adherence was defined as always inserting an applicator of gel in the vagina before sex (gel group), or always inserting the diaphragm with gel in the dome, and always inserting another applicator of gel directly in the vagina (diaphragm/gel groups). We examined sociodemographic, behavioral, acceptability and partner-related predictors and used generalized estimating equation models to predict the probability of product adherence during the follow-up period.

Results: Mean age was 29 (range 18-48), 97% were married, 76% had one lifetime partner and 90% used their assigned product (s) at follow-up. Median weekly sexual frequency (4) was consistent over time and across groups. Average product adherence at follow-up was 48% (visit range: 41%-62%) and did not differ by group. Consistent male condom use was similar between groups (50%) and was the only significant predictor of product adherence. However, this was significantly stronger in the gel group (OR = 24.2; 95%CI: 9.9-59.1) than in the diaphragm/gel group (OR = 11.1; 95%CI: 5.3-23.2) (p=0.05).

Conclusions: Product adherence was similar between groups even though a diaphragm/gel combination may seem more complex to use. Adherence to both condoms and products was strongly associated. This may bias effectiveness results in future trials of female controlled methods (FCM), as it will be difficult to extricate the effect of the FCM from that of condoms.

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