

Safety, acceptability, and tolerability of 3 topical microbicides among heterosexual Kenyan men.

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Abstract:

To compare the acceptability, tolerability, and safety of 3 topical microbicide formulations (62% ethyl alcohol in emollient gel and 0.1% and 0.4% benzalkonium chloride on a sanitary wipe) for use on male genitalia. This triple-randomized crossover study among men attending a sexually transmitted disease (STD) clinic in Nairobi, Kenya assigned individuals without clinical evidence of an STD to apply products to the penis in a predetermined random order, each for a 2-week period with a 1-week washout period between each product. Men recorded side effects and were examined for adverse events. Of 39 participants, 33 (84%) completed 6 clinic visits plus 3 home visits by community health workers. Participants reported use of 62% ethanol gel and 0.1% and 0.4% benzalkonium on 99%, 99%, and 96% of daily scheduled applications; 99%, 98%, and 97% of preintercourse applications, and 99%, 94%, and 98% of postintercourse applications. All participants said they would recommend all 3 products to a friend; 72% preferred the 62% ethanol gel, 17% the 0.1% benzalkonium, and 11% the 0.4% benzalkonium. One person developed objective signs of a genital ulcer after 14 days of 0.4% benzalkonium wipe use. Two of the 3 topical microbicides had minimal reported adverse effects, and no adverse effects were observed during use of the ethanol gel, which was preferred by most men.