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RECTAL MICROBICIDE ACCEPTABILITY: RESULTS OF A VOLUME ESCALATION TRIAL

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INTRODUCTION: The volume of a microbicidal gel required to prevent HIV transmission during anal intercourse may far exceed volumes customarily used in vaginal trials. As much as 50 ml may be required given the large mucosal surface area involved. Using a placebo gel, we conducted an escalation trial to determine the maximum volume that men would be willing to use during receptive anal intercourse (RAI).

METHODS: 20 HIV-uninfected men of diverse ethnic backgrounds with a history of recent unprotected RAI with a serodiscordant partner or one of unknown status were recruited at Fenway Community Health, in Boston, MA, the largest gay health center in New England. Participants agreed to self administer increasing volumes (5, 20, 35, and 50 ml) of a placebo gel rectally on different days and to rate volume acceptability. Once each individual reached the maximum volume acceptable to him, he was asked to use that volume in three condom-protected RAI occasions and rate volume acceptability under those circumstances. In-depth qualitative interviews followed, and data about participants' experience with the gel were analyzed.

RESULTS: Two participants were lost to follow up. Among the remaining 18, the maximal acceptable dose was reported as 50 ml for 9 participants, 35 ml for 6, and 20 ml for 3. At the time of this writing, only 12 participants had used their maximum acceptable volumes during sex, 10 accepting the same level individually established, one reducing it from 50 to 20 ml, and another from 35 to 20 ml.

CONCLUSIONS: Among men who engage in high risk RAI, 15 out of 18 would use 35 ml of a microbicidal gel. Use during sex may lead to reductions in the acceptable volume. Rectal microbicides can be an important prevention tool for men who do not use condoms consistently.

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