Rectal Lube May Need to Be Supercharged Before It's Feasible

Early studies of dapivirine lubricant for anal sex indicate how far the field has come—and how far it still has to go.

February 17, 2021 By Heather Boerner

Early human trials of a lubricant formulated specifically for anal sex and infused with the HIV prevention drug dapivirine showed higher drug concentrations in blood plasma than previous models. But those levels were still 35% lower than when people used the gel with an applicator, and the drug didn't show up in rectal tissue at all.

"This does open the door for the possibility of rectal microbicides serving as a sexual lubricant," said Ken Ho, MD, of the University of Pittsburgh, who presented the data at the HIV Research for Prevention (HIVR4P) conference. "Changes to the formulation to increase the dose of drug delivered could be promising and would probably be needed to continue the rectal microbicide agenda."

The presentation was part of a larger move to create on-demand and topical HIV prevention approaches that don't impact the entire body. A vaginal ring loaded with dapivirine has already been found to be roughly 50% effective in preventing vaginal HIV acquisition of HIV in open-label trials.

But fewer products have been aimed at people who have anal sex. The dapivirine gel developed for vaginal use, for instance, was not tested or designed to be effective in the rectum. So researchers have spent the last few years working on anal-sex-specific topical formulations that include gels, douches and lubes.

Studies on gels and lubes presented at HIVR4P this week use a variety of medications, including the investigational MIV-150/zinc acetate gel and OB-002, an experimental CCR5 agonist.

Protection Through Lube

In the MTN-033 study, researchers randomized 16 HIV-negative cisgender men, 10 of whom were white. Half of participants were instructed to apply a 0.05% dapivirine gel with a rectal applicator. The other half were assigned to apply the medicated lubricant with a "coital simulation device"—that is, a dildo.

Ten days after enrollment, participants applied one dose of the gel. Blood samples were taken within 24 yours, and rectal fluid and tissue samples were taken at one, four and 24 hours. After two to four weeks, participants were asked to apply the gel or lubricant again. Researchers used the same timeline to sample blood plasma, tissue and rectal fluid.

No study-related adverse events with either application method were reported.

Then they looked at the samples.

“You can see that the dapivirine gets in and is absorbed into the bloodstream in small amounts,” said Ho. “Comparatively, we saw more with the applicator and less with the [as-]lubricant.”

Overall, dapivirine concentrations in plasma resulting from lubricant use were 35% of what they were for people using the applicator. In rectal fluid, dapivirine levels were higher among lubricant users at one hour but fell precipitously at four hours. People who used the applicator saw a drop from one to four hours, also, but it was less significant.

When the researchers exposed the rectal tissue samples to HIV, they didn’t find that much difference in infectivity in either group from baseline to one hour—which makes sense, since they detected the drug only in one sample of rectal tissue, from a person in the applicator arm. There was no evidence of dapivirine in rectal tissue of people who used the drug as a lubricant.

Still, Ho called the evidence of dapivirine in tissue in the applicator arm a “signal” that indicates that a reformulated gel that lasts longer and contains a higher concentration of dapivirine might be protective.

Click here to read the full MTN-026 abstract.

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