SHIV Infection Risk after Rectal Application of a Highly Osmolar Personal Lubricant

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Abstract

Background: Personal lubricant use is common for anal sex. Some water-based products with high osmolality and low pH damage rectal tissues. Additionally, the preservation polyquaternium 22 (PQ22) in Lubricin® (Microcosm Health) damages rectal tissue in vitro. The lubricant CTL-580 (CTL) and benzoic acid (BA) protect rectal tissue from injury caused by PQ22. We had previously observed rectal tissue cytotoxicity in such an environment. Use and procurement of additional lubricants for male and female condoms: the WHO issued an interim advisory note on lubricants. C.S. Dezzutti, E.R. Brown, B. Moncla, J. Russo, M. Cost, L. Wang, K. Uranker, R.P. Wolitski, Charles Rose, Michael Hendry, Richard Wolitski, Dr. Ellen Kersh.

Objective: To determine susceptibility to infection, we compared virus doses needed for infection in 144 macaques and 1,808 (728, 4495) in controls. The estimated AID50 was 1,721 (414, 7165) in controls (Fig. 5, Table 2); the AID50 ratio was not significantly different (p=0.6467).

Conclusions

Although we observed acute cytotoxicity in rectal tissues, the test lubricant did not increase susceptibility to infection.

The lubricant did not exacerbate infection risk in this model.

This study constitutes an important first step in the in vivo evaluation of lubricants with regards to HIV transmission.

Study limitations

Only one product was evaluated.

Applications were not traumatic.

Since sex was not modeled, beneficial effects of lubrication not observed.

This macaque model might not be sensitive enough to assess increased risk of HIV infection.

Design and Rationale

To determine susceptibility to infection, we compared virus doses needed for infection in 21 lubricant- or buffer-treated cymomolgous macaques.

We had observed rectal tissue cytotoxicity in such an animal model (Fig. 1-3, 5), high osmolality and low pH damage rectal tissues.

In the challenge studies, the macaques received six rectal infusions of lubricant/buffer during 3 weeks (Fig. 4), followed by rectal virus exposures at varying doses (1.25-25,000 tissue culture infectious doses (TCID50) of SHIV162p3) 30 minutes after lubricant/buffer application.

Uninfected macaques were rest for at least 6 weeks, and then re-exposed to higher doses until 51 exposures (controls=7, lubricant=8) had occurred. We calculated and compared animal infectious doses (AID50) for rectal tissue injury and infection.

We compared animal infectious doses (AID50) by modeling HIV infection as a function of the log10 TCID50 by using logistic regression.

Results

Recal cytokynes, including pro-inflammatory ones, peaked at acute time points post-lubricant application (Fig. 18, Table 1).

We observed epithelial peeling and associated blood (Fig. 28BC); rectal pH and microflora remained unchanged (data not shown).

Recal biopises (30 minutes post-lubricant application) showed mild inflammation (Fig. 3).

The estimated AID50 and 95% CI for TCID50 were 146,336 (1.0, 4.5) in lubricant-treated macaques; and 1,721 (414, 7165) in controls (Fig. 5, Table 2); the AID50 ratio was not significantly different (p=0.6467).

Also not significant in the two study arms were the differences in plasma viremia and rectal virus shedding (Fig 6).

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