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Press Briefing: Tuesday, May 25, 1:15 p.m., ET
Use of Lubricants, Unprotected Anal Sex and the Risk of HIV

Study is first to evaluate safety of lubricants used in anal sex

A laboratory study that compared over-the-counter and mail-order lubricants commonly used with receptive anal intercourse found many of the products contain higher amounts of dissolved salts and sugars compared to what's normally found in a cell. As a result, the products had toxic effects on the cells and rectal tissue studied. Some of the lubricants caused significant portions of the epithelium – the layer of cells that serves as a protective barrier inside the rectum – to be stripped away. Conclusions cannot be made based on this study alone, though the results are compelling enough to wonder if these lubricants might have the same effect in people and thereby increase susceptibility to HIV, commented Charlene Dezzutti, Ph.D., from the University of Pittsburgh and Magee-Womens Research Institute, who led the study for the Microbicide Trials Network. The study, which was conducted in collaboration with International Rectal Microbicides Advocates (IRMA), was undertaken because little is known about the safety of lubricants even though they are frequently used during anal sex.

Six products were studied. Five (Astroglide, Elbow Grease, ID Glide, KY Jelly and Wet Platinum) were selected because they had been identified as those most commonly used by more than 6,300 respondents to an IRMA survey. The sixth product (PRÉ) was selected to serve as a control because it is isomolar. Osmolarity refers to the concentration of dissolved particles (salts and sugars) found inside a cell relative to the outside. A product that is isomolar has the same concentration of particles as inside the cell, whereas a product that is hyperosmolar has a higher concentration of salts and sugars relative to the cell. To correct this imbalance, a cell forces water out but then it becomes withered and dies. Most of the lubricants studied were water-based, except for Wet Platinum, which is a condom-compatible silicone-based product. The researchers characterized each product according to its osmolarity, pH and viscosity – or slipperiness. Studies then were conducted to determine the effect of each lubricant on different cell types, rectal and cervical tissue and on bacteria (microorganisms that are important to the health of the rectum). Based on the tests performed, PRÉ and Wet Platinum were shown to be safest, while Astroglide was the most toxic to cells and tissues and KY Jelly had the worst effect on the good bacteria, essentially wiping out an entire colony. PRÉ was the only water-based lubricant that was not hyperosmolar and did not disrupt the epithelium. None of the lubricants had measurable anti-HIV activity. In future studies, the researchers hope to determine the effect that different lubricants have on susceptibility to HIV infection in tissues.

Presentation: Tuesday, 10:30 a.m., May 25,., Ballroom
Session 38 – Oral Abstracts: Rectal Sex: Frequency and Impact (9:30 a.m.-11:00 a.m.)

(Abstract #347)
Safety and Anti-HIV Activity of Over-the-Counter Lubricant Gels

(see following page for full abstract)

Safety and Anti-HIV Activity of Over-the-Counter Lubricant Gels

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Background: Because lubricants may decrease trauma during coitus, it is hypothesized that they could aid in the prevention of HIV acquisition. However, the safety and anti-HIV activity is currently unknown for over-the-counter (OTC) lubricant gels.

Methods: Based on an International Rectal Microbicide Advocates survey, 6 OTC lubricant gels were tested: 5 aqueous-based (Astroglide, Elbow Grease, ID Glide, KY Jelly, and PRÉ) and 1 condom compatible silicone-based (Wet Platinum). Formulation characteristics (pH, osmolarity, and viscosity) were determined. Viability of *Lactobacillus* species and cells [Caco-2 (colorectal), HEC-1-A (uterine), and TZM-bl (cervical) epithelial cell lines and peripheral blood mononuclear cells (PBMCs)] exposed to the lubricants was evaluated. For cells, dilutions of each aqueous-based lubricant were made; Wet Platinum was used undilute. Transepithelial resistance of Caco-2 and HEC-1-A cell lines was measured to determine the impact of lubricants on epithelial cell monolayers. The anti-HIV activity was tested with the TZM-bl cell line. Colorectal and ectocervical safety was evaluated by the MTT assay and histology after apical application to polarized explant cultures.

Results: PRÉ was pH 7, isosmolar, with moderate viscosity. Elbow Grease, ID Glide, and KY Jelly were pH 4 to 5, 9 to 13-fold above isosmolar, with varying degrees of viscosity. Astroglide was pH 4, 21-fold above isosmolar, with low viscosity. KY Jelly which contains chlorhexidine had a complete loss of *Lactobacillus* viability, but the other lubricants had $< \log_{10}$ loss of bacteria and were considered safe. PRÉ was not toxic up to 1:10 dilution for the PBMCs and cell lines. Elbow Grease, ID Glide, and KY Jelly were not toxic up to 1:100 to 1:200 dilutions. Astroglide was not toxic up to 1:1500 dilution. Wet Platinum had no toxicity. PRÉ had no impact on the epithelial cell monolayers whereas the other aqueous-based lubricants disrupted the epithelial cell monolayers. All lubricants retained colorectal and ectocervical explant viability by MTT assay. Histology showed intact epithelium for PRÉ and Wet Platinum, while epithelial striping was observed for Astroglide, Elbow Grease, ID Glide, and KY Jelly. Lubricants had no measurable anti-HIV activity.

Conclusions: Our data suggests that PRÉ and Wet Platinum were safest. The hyperosmolar nature of the other lubricant gels was associated with cellular toxicity and may lead to increased risk of HIV infection.