



Mucosal Irritation Potential of Personal Lubricants Relates to Product Osmolality as Detected by the SMI (Slug Mucosal Irritation Assay).

Sexually Transmitted Diseases, 2008 May;35(5):512-516 Els ADRIAENS, PhD; Jean Paul REMON, PharmD. Laboratory of Pharmaceutical Technology, Ghent University, Harelbekestraat 72, 9000 Ghent, Belgium

Background

The slug mucosal irritation assay has recently been used as a sensitive measure of mucus membrane tolerance for vaginal microbicide products and carriers. In the current study, it was determined whether mucosal irritation potency of personal lubricants is related to varying product osmolalities.

Methods

Five commercial lubricants with an osmolality range were evaluated using the previously validated slug mucosal irritation assay. Specifically, *Arion lusitanicus* were treated with lubricants over 5 days to quantify mucus production and tissue damage, allowing assignment of each product into an irritation potency category (none, mild, moderate, or severe).

Result

The irritation potency (assessed by the mucus production) of the lubricants showed a significant, quadratic relationship with the product osmolality ($P = 0.001$; $R(2) = 0.99$). Femglide, a hypo-osmotic lubricant (32 mOsm/kg), caused a negative mucus production. Pré, an iso-osmotic lubricant (316 mOsm/kg), caused no changes. Two moderately hyperosmotic lubricants, Replens and K-Y jelly (2143 and 2463 mOsm/kg), induced mild and moderate irritation, respectively. The highly hyperosmotic lubricant Astroglide (5848 mOsm/kg) resulted in severe irritation and tissue damage.

Conclusion

Commonly used personal lubricants show a full range of mucosal irritation potential, which is related to product osmolality.