THE POTENTIAL HARMS OF PERSONAL LUBRICANTS

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INTRODUCTION

Over 100 years ago, the first personal lubricant became available when a surgical lubricant was re-formulated into a non-sterile, publicly available version, albeit by prescription[1]. The lubricant became commercially available in the 1980s, with most sales occurring in Brazil, Canada, and the United States (US). Currently in the US, personal lubricant use is common among women[2], men[3], and, specifically, gay and bisexual men[4], groups in which 66, 70, and 90% have ever used a lubricant, respectively. Water-based lubricants can be used alongside condoms during sexual activities, including vaginal-penile and penile-anal sex to ensure adequate lubrication[5] and comfort, to reduce condom breakage during anal sex[6], and to reduce friction.

In the US and Europe, personal lubricants are classified as class II or class IIa – "medical devices", respectively. In the US, new or modified lubricants must submit 510(k) clearance to the Food and Drug Administration (FDA), demonstrate safety and effectiveness, and show that they are reasonably equivalent to a legally marketed device. In both the US and Europe, the products are subjected to cytotoxicity, irritation, and sensitization testing, as well as acute toxicity testing (US only). In Canada, personal lubricants are classified as "cosmetics". Manufacturers must complete a Cosmetic Notification Form and provide details on ingredients (known, restricted, prohibited, unknown).

Regardless of the lubricant testing regulations, several studies have assessed lubricant safety since the late 1990s[7-14]. These evaluations demonstrated epithelial damage and irritation, raising concerns regarding safety, and leading to the release of an advisory note in 2012[15]. This advisory note recommended use of lubricants that are iso-osmolar, free of polyquaternium-15, and free of nonoxynol-9. Given the concerns regarding the safety of personal lubricants, we reviewed articles reporting on the safety of commercially available lubricants and the association between lubricant use and bacterial vaginosis (BV) and/or sexually transmitted infections (STIs).

NONOXYNOL-9

Cytotoxicity and epithelial damage have been reported after application of a nonoxynol-9 personal lubricant. In 2000, Phillips et al. tested two nonoxynol-9 containing lubricants in humans (n=4, 75% men); their application (namely K-Y®Plus and ForPlay®) caused extensive exfoliation of rectal epithelium[8]. Similarly, in 2004, Sudol and Phillips tested lubricants in a rectal mouse model[10]. Several lubricants tested caused epithelial sloughing, with K-Y®Plus (nonoxynol-9-containing) causing the most damage. K-Y®Plus also enhanced rectal herpes simplex virus 2 (HSV-2) infection. Nonoxynol-9 use is associated with genital lesions[16], and a randomized controlled trial consisting of female sex workers demonstrated that use of a nonoxynol-9 gel increased the risk of human immunodeficiency virus 1 (HIV-1) acquisition compared to the use of a placebo gel[9]. The risk was even higher among the most frequent users. Nonoxynol-9 use is not recommended[17]. Nevertheless, nonoxynol-9 containing products are still permitted by the FDA, as long as they adhere to specific labelling requirements[18].

OSMOLALITY

There is some evidence suggesting the osmolality of personal lubricants is associated with irritation and epithelial damage. In 2007, Fuchs et al. conducted a small study of 10 men who have sex with men (MSM), including men living with and without HIV[11]. The authors found that rectal application of hyperosmolar lubricant led to greater epithelial injury than an iso-osmolar lubricant. In 2008, Adriaens and Remon tested several lubricants on slugs[12]. The lubricants were found to cause mild, moderate, and severe irritation corresponding to the osmolality of lubricant used. However, in contrast to Adriaens and Remon's study in slugs[12], a study by Cunha et al. in cells showed no correlation between osmolality and cytotoxicity[19]. This study suggests the individual ingredients may be more important than the osmolality level itself.

In a human model of the vaginal epithelium, lubricants with an osmolality >1,500 mOsm/kg led to reductions in the epithelial barrier and damage to the structure of the vaginal model[20]. Similarly, in 2019, Wilkinson et al. tested the effect of lubricants with a range of osmolality values (270–10,300 mOsm/kg) in a human vaginal epithelial cell monolayer and a three-dimensional model[21]. The application of hyperosmolar lubricants was cytotoxic in both systems, and there was a correlation between osmolality and cytotoxicity. In addition, the hyperosmolar lubricants led to a reduction in cell viability and to changes in morphology, and some lubricants also altered inflammatory mediators[21]. The models to assess safety of lubricants are becoming increasingly sophisticated, which allow for testing of lubricant safety in more biologically relevant models.

BACTERIAL VAGINOSIS

Several cross-sectional and cohort studies in women have evaluated the association between lubricant use/type and bacterial vaginosis (BV), a common vaginal infection. A 2007 cross-sectional study reported an association between petroleum jelly use and BV, as well as saliva use and BV[22]; however, in a cohort study of the same population, petroleum jelly and saliva were not found to be independent predictors of BV[23]. The authors did not assess commercialother lubricants use. An additional cross-sectional study from

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2010 reported an association between vaginal lubricant use in the last three months and BV[24]. This was confirmed in a small cohort study (n=29) by Brotman et al. in 2010. The authors found lubricant use in the last 24 hours to be associated with BV[25]. However, a larger cohort study by Brown et al. (n=141) did not find an association between commercial lubricant or oil use and BV[26]. This study did find, however, an increased risk of BV among petroleum jelly users compared to non-users. Altogether, it is unclear the level of risk of BV associated with different lubricant use (commercial lubricants, oil, saliva, petroleum jelly, etc.). Clarifying the association between lubricant use with BV is needed, as BV may increase the risk of gonorrhea and chlamydia[27], herpes[28], trichomonas[29], and HIV[30].

HERPES SIMPLEX VIRUS 2

The association between lubricants and HSV-2 susceptibility was assessed in three studies. Two studies in 1998[7] and 2004[10], respectively, used a rectal mouse model to test the effect of personal lubricants. Another study in 2010 assessed the effect of personal lubricants in a vaginal mouse model[13]. Phillips and Zacharopoulos tested the effect of nonoxynol-9-containing personal lubricants, which showed enhancement of rectal HSV-2 infection[7]. As mentioned previously, Sudol and Phillips's 2004 study tested lubricants in a rectal mouse model[10]. Two hyperosmolar lubricants, K-Y Plus® (nonoxynol-9-containing) and Astroglide®, caused significantly and non-significantly enhanced rectal HSV-2 infection, respectively. A later evaluation in 2010 assessed different topical products, including a personal lubricant (K-Y® Warming Jelly), effect on vaginal HSV-2 susceptibility, demonstrating enhanced susceptibility to infection after K-Y® Warming Jelly application[13]. As mentioned previously, the spermicide nonoxynol-9 is no longer recommended[17]; however, K-Y® Warming Jelly is still commercially available.

GONORRHEA,CHLAMYDIA,ANDSYPHILIS

In 2012, Gorbach et al. evaluated the association between lubricant use and prevalent rectal STIs (chlamydia and/or gonorrhea) among men and women practicing receptive anal intercourse (n=348)[31]. The authors found lubricant use is associated with prevalence of rectal STI (odds ratio=2.98, 95%CI 1.09–8.15). Additionally, more rectal STIs were detected among exclusive water-based lubricant users compared to other users (6.1% versus 2.7%). In contrast to the Gorbach et al. (2012) study, a smaller study (n=146) by Maierhofer et al. in 2016 found consistent lubricant use was not associated with prevalence of rectal STI (chlamydia and/or gonorrhea) among MSM, prevalence ratio=0.78 (95%CI 0.50–1.22)[32]. A limitation of the study is that while the authors identified the brand name of the lubricant used, they did not reveal the type of lubricant used (i.e. water-, oil-, or silicone-based). Some of the brand-name lubricants were associated with rectal STI, although this could be due to multiple testing. While the studies by Gorbach et al.[31] and Maierhofer et al.[32] have differing results, a cohort study assessing STIs acquired over time provides additional evidence for the association between lubricant use and STIs[33]. In 2020, Blair et al. reported cross-sectional data from a longitudinal cohort study (n=313) evaluating the association between lubricant use and laboratory-confirmed STI (gonorrhea, chlamydia, and/or syphilis) among MSM living with and without HIV[33]. The authors found an association between consistent lubricant use and STI diagnosis (adjusted odds ratio=1.81; 95%CI 1.11–2.96). These findings suggest lubricants may increase the risk of rectal STI, which is especially relevant as some STIs may be associated with an increased risk of HIV acquisition[34-36].

HUMAN IMMUNODEFICIENCY VIRUS

In 2011, Begay et al. tested 41 personal lubricants[14]. In vitro testing demonstrated that 4 of the 41 commercially available lubricants tested enhanced HIV-1 infection. Most of these lubricants were hyperosmolar and 3 contained polyquaternium-15, indicating a potential risk for these products. A year later, Dezzutti et al. reported results of a study testing the safety and anti-HIV-1 activity of water-based lubricants in cell lines and explant cultures of the colorectum and ectocervix[37]. Of the 10 water-based lubricants tested, 6 were hyperosmolar and exhibited damage to cervical and colorectal explant tissues. Astroglide®, a highly hyperosmolar lubricant containing polyquaternium-32, was not found to enhance HIV-1 replication in the tissues. While another hyperosmolar lubricant, K-Y Jelly®, demonstrated a reduction in HIV-1 replication, the authors attributed this to a reduction in tissue viability. In 2015, Vishwanathan et al. demonstrated that while rectal application of a highly hyperosmolar lubricant (containing polyquaternium-15) leads to epithelial sloughing, this lubricant does not increase risk of simian-human immunodeficiency virus in macaque[38]. In 2019, Rao et al. reported on correlates of water-based lubricants among MSM living with and without HIV[39]. The authors did not find an association between water-based lubricant use and HIV diagnosis. To summarize these findings: while an early study from 2011 showed enhancement of HIV-1 infection in cells[14], an ex vivo[37], animal[38] and observational study in humans[39] did not demonstrate an association between lubricant use and HIV susceptibility and/or infection.

PUBLIC HEALTH POLICY IMPLICATIONS

In 2012, the World Health Organization (WHO) issued an advisory note for personal lubricant procurement[15]. The report suggested an ideal osmolality of below 380 mOsm/kg, but on an interim basis, 1,200 mOsm/kg would suffice. The report also recommended avoiding polyquaternium-15; however, four years later, in a report from the November 2016 "Global consultation on personal lubricants" meeting, the organization no longer restricted use of polyquaternium-15 based on the lack of evidence of harm[40], highlighting the challenge in determining which ingredient in the lubricant actually causes damage, irritation, and/or increased risk of STIs. For osmolality, the original statement was retained: 380 mOsm/kg would be the ideal osmolality for personal lubricants, but the use of lubricants up to 1,200 mOsm/kg for procurement agencies was still supported. Hyperosmolar lubricants tend to be more harmful to the epithelium than their iso-osmolar counterparts. Nevertheless, the WHO/United Nations Population Fund (UNFPA) issued in July 2019 a draft report on "Specifications for plain lubricants", in which it states that the osmolality cut-off of 1200 mOsm/kg is under revision[41].

There does appear to be some level of risk associated with personal lubricant use. Some earlier recommendations have been either

reverted (polyquaternium-15) or are under revision (osmolality limit). This indicates the evolving and changing recommendations and the current lack of concrete evidence showing safety and/or harm. It is clear that additional epidemiologic and clinical studies are needed, especially longitudinal studies that evaluate the association between the use of different water-based (and silicone-based) lubricants and the safety and/or risk of BV, STIs, and HIV, especially in at-risk populations such as people living with HIV, MSM, and sex workers. There is also a need to assess personal lubricant safety and risk of STIs for vaginal use, as the majority of studies published thus far have been for rectal use. Iso-osmolar lubricants without nonoxynol-9 may be the best lubricant choice. Until more definitive evidence is available, in the interim it is advisable to lower STI risk by using condoms and condom-compatible lubricants, as well as practicing monogamy and testing for STIs.

Participation of each author

Cassandra Laurie performed the search and drafted the manuscript. Cassandra Laurie and Eduardo Franco critically reviewed the manuscript and approved the final version.

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Conflict of interests

The authors do not have any conflicts of interest related to this work. ELF served as an occasional advisor for companies involved with HPV vaccines (Merck, GSK) and HPV diagnostics (Roche Diagnostics) and as a Steering Committee Member for a publicly funded study in Finland that received support from GSK. ELF holds a patent related to the discovery "DNA methylation markers for early detection of cervical cancer", registered at the Office of Innovation and Partnerships, McGill University, Montreal, Quebec, Canada (October 2018). A provisional utility patent application before the United States Patent & Trademark Office was also filed (November 2018).

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