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Use of a Prospective Sex diary to Study Anal Lubricant and Enema Use among High Risk MSM-Implications for HIV Prevention

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Abstract

Longitudinal data on episodes of receptive anal intercourse (RAI), lubricant, and enema use in 41 sexually active MSM were collected using a prospective sex diary. Data on 550 episodes of RAI showed that lubricants were used in 489/550 (88.9%) and enemas were used in 165/550 (30%) of RAI episodes.

Short Summary: This study showed feasibility of using a prospective sex diary to collect longitudinal data on lubricant and enema use among sexually active men who have sex with men.

Keywords

sex diary; online diary; MSM; lubricant; enema

BRIEF REPORT

In 2014, 67% of new HIV infections in the United States occurred among men who have sex with men (MSM) [1]. Most HIV transmissions among MSM occur during receptive anal intercourse (RAI) [2], which carries a per-act transmission risk of 1.38% [3]. Previous data have shown that use of products for RAI is common among MSM; 50-75% report using enemas or lubricants before, during or after RAI [4-7]. Some hyperosmolar and water-based lubricant and enema products have been shown to cause mucosal damage leading to the hypothesis that these products could increase HIV and sexually transmitted infection risk. [6-14]. Lubricants and enemas are both being considered as delivery vehicles for rectal microbicides [4-6, 15]; therefore, additional data about how MSM use these products are needed.

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Conflicts of Interest

There are no conflicts of interest or financial disclosures for any author.

Currently, little is known about the frequency and patterns of rectal enema and lubricant use among MSM over time, and this data could be useful to better understand rectal mucosal HIV transmission among MSM and to inform the design of rectal microbicides. Data on sexual practices can be challenging to collect due to its sensitive nature and potential for recall bias. Prospective sex diaries are considered a close approximation to a gold standard for measuring sexual behavior as they are associated with shorter recall periods and may be more accurate for frequent sex acts [16-20]. In this study, we used a prospective sex diary to examine the longitudinal use of enemas and lubricants during RAI among 41 HIV-negative, sexually active MSM.

From November 2013-June 2015, HIV negative MSM aged 18-45 years engaging in condomless receptive anal intercourse (CRAI) with an HIV negative partner were recruited from the Atlanta community for a study designed to understand the rectal mucosal effects of CRAI. Inclusion criteria included the ability for the sexual partner to come in for HIV testing at the study site, being in a monogamous relationship for 45 days and reporting a minimum of 4 episodes of CRAI in the last month. Key exclusion criteria included having a medical history precluding rectal biopsy procedures (e.g. bleeding disorder) and intent to use HIV pre-exposure prophylaxis during the study. Eligible men provided informed consent, underwent HIV testing, and peripheral blood and rectal biopsy sampling during study follow-up.

MSM engaging in CRAI were asked to keep an electronic or paper sex diary during the study that recorded each episode of RAI, whether a condom was used, type of lubricant used (if any), and type of enema used (if any). The electronic form of this diary used a mobile-enabled secure web application sponsored by REDCap (Research Electronic Data Capture) technologies to allow participants to fill out brief online surveys using a smartphone. Biweekly reminders to submit diary entries were sent to participants as needed. There was no specific compensation provided for diary entries however participants did receive compensation for study visit attendance.

For this report, descriptive statistics (proportions and medians with range) were calculated for participant demographics, frequency of RAI, and frequency and type of lubricant and enema use. RAI frequency rates were calculated by dividing the total number of RAI episodes recorded during the study by the number of weeks under observation or 'on study'. Per study protocol, participants were asked to abstain from sexual intercourse for a total of 17 days before and after rectal biopsy procedures; these days were subtracted from study follow-up time for this report since men were not expected to enter sex acts on those days. Spearman correlation co-efficients were used to determine the correlation between recalled RAI act frequency reported at the screening study visit and RAI act frequency recorded in the diary during prospective study follow-up. All study procedures were approved by the Institutional Review Board at Emory University.

Forty-one HIV-negative MSM engaging in CRAI were enrolled. Of these 41 men, 36 (87.8%) chose to keep an electronic sex diary whereas 5 (12.2%) men submitted paper diaries, which study staff subsequently entered into the electronic database. The median age of MSM participating in the study was 28 years (range 22-47 years) (Table 1). Information

about 550 unique episodes of RAI was collected over a median of 12 weeks on study (range 4-26 weeks). At the screening study visit prior to initiation of the sex diary, men reported a median of 60 episodes of CRAI in the past 12 months (range 4-480), 5 episodes in the last month (range 3-40), and 1 in the last week (range 0-10). The median RAI episodes per participant captured with the prospective sex diary was 11 (range 0-57) with a median of 3.9 sex acts monthly (range 0-30) and 0.9 sex acts weekly (range 0-7). Condoms were only used in 4/550 (0.73%) diary-recorded sex acts, reflective of our enrollment of MSM engaging in CRAI. CRAI frequency per month collected at the screening visit by study subject recall was not significantly correlated with CRAI frequency per month captured by the sex diary (Spearman $\rho=0.06$, $P=0.7$).

Personal lubricant use for RAI was common; lubricants were used during 489/550 (88.9%) of RAI episodes by 39/41 (95%) men. Among men who reported lubricant use, the median number of RAI episodes monthly with lubricant was 3.5 (range 0.3-28.9). Enemas were used during 165/550 (30%) of RAI episodes by 18/41 (43.9%) men. For the 18 men who reported enema use, the median number of RAI episodes monthly with enema use was 1.8 (range 0.3-11.3), and enemas were used during 165/274 (60%) of their RAI episodes. All men who reported enema use also used lubricants during the same RAI act.

The 3 most common lubricant brands used included Swiss brand (106/489, 21.7%), WET (77/489, 15.7%) and AstroGlide (74/489, 15.1%), but these brands accounted for only 52.6% of all lubricant episodes. Silicone-based lubricants were used in 226/489 (46.2%) of RAI acts; while water based lubricants were used in 187/489 (38.2%). The most common types of enema used were shower douches (124/165, 75.2%) followed by fleet enemas (35/165, 21.2%). The most common type of enema fluid was tap water (124/165, 75.2%) followed by saline (32/165, 19.4%) with a very small percentage of sex acts (5/165, 3%) using sodium phosphate enemas.

Men were mostly consistent in the type and brand of product used; 20/39 (51%) men reported using the same type of lubricant for all RAI episodes. Thirteen men used two different brands of lubricant; however, in all instances, a second brand was only used during one sex act. Four men reported using 3 different lubricant brands, and 2 men used 4 different lubricant brands. All 39 men who reported lubricant use were consistent in use of water or silicone-based lubricant. There was similar consistency in the type of enema used with all men using either tap water or fleets enemas for all RAI episodes reported during the study.

Our results demonstrate that use of a prospective sex diary is feasible for longitudinal data collection to better understand product use during RAI among MSM. In our sample of MSM engaging in CRAI, lubricants were used in a large proportion of sex acts, 88.9%, and enemas were used in 30% of sex acts. Overall, men were consistent in the brand and type of product used and 43.9% of men reported using both enemas and lubricants during RAI.

This is the first study demonstrating use of a prospective sex diary to longitudinally collect information about lubricant and enema use among sexually active MSM. Prior studies examining product use during RAI have done so using retrospective data based on

participant recall which may be less accurate and subject to recall bias. In addition, few studies have collected data on product preferences and consistency of product use. Our data supports prior findings which report lubricant use during RAI in 50-93% of men [4-5] and enema use in 50-66% of men [6-7] demonstrating that use of these products is common among MSM and that many men use them together. Currently, very little is known about the mucosal effects of using these products together and future research should aim to understand the mucosal effects of this practice. Two previous studies on enema use collected information about product type and confirmed our findings of water-based enemas being the most commonly used enema type [6-7]. No prior study provided data on consistency of product use; however, prior studies reported that 77-92% of men were willing to use a topical microbicide [4-5]. Since rectal microbicides for HIV prevention are currently in development [15, 21-24], our data support the need for further research to understand the product preferences of MSM and how they are used.

Men used water-based lubricants and tap water enemas during 34% and 22.5% of RAI episodes respectively, however water-based products have been associated with greater epithelial denudation and potentially higher STI transmission risk compared to other product types (e.g. silicone-based lubricants) [6-14]. Given these potential harms, further investigation is ongoing to determine which product type would serve as the best drug delivery system while having the least harmful effect on the rectal mucosa [23-24].

Most men in our study utilized a mobile-enabled online sex diary to collect information on multiple RAI acts supporting the use of this method as a useful data collection tool. This “real-time” survey tool was administered in participant’s natural environment hence reducing potential for recall bias and allowing for more accurate and valid responses. There was a lower diary-reported sex act frequency compared to baseline reported sex act frequency. Possible reasons for this discrepancy include participant fatigue when recording frequent acts and the possibility of “reactivity”, the modification of a behavior as a result of recording it (i.e. as participants record the frequency of RAI, they are less likely to engage in the act) [16-17, 25].

This study is not generalizable to all MSM given that we enrolled MSM engaging in CRAI with a monogamous partner, our small sample size and limited racial diversity. However, we demonstrate the feasibility of prospective sex diary methods to justify pursuit of larger studies to explore product use and preferences among a more diverse sample of MSM. It is probable that not all RAI acts were recorded in the diary by participants during the study, and the observed estimates for product use may be underestimates of true usage. We also did not collect information about the timing of product use during sex (e.g. before or after sex), which may be important to fully understand rectal HIV transmission.

In conclusion, we show that MSM commonly use lubricants and enemas during RAI and are fairly consistent in the type and brand of product they use. A more detailed understanding of the product preferences of MSM will be important to inform the development of biomedical prevention tools that are appealing, safe, and efficacious for HIV prevention during RAI.

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Table 1

Characteristics and sex act information for study participants, N=41 men who have sex with men.

Characteristic	N (%)	Median (Range)
Median Age	N/A	28 (22-47)
<i>Race</i> White African American Latino	32/41 (78.1%) 7/41 (17.1%) 2/41 (4.9%)	N/A N/A N/A
<i>Baseline Reported Sex Acts</i> RAI per month	N/A	5 (3-40)
<i>Diary Reported Sex Acts</i> Median time on study (weeks) RAI per month. RAI acts with Lubricant RAI acts with Lubricant per month RAI acts with Enema RAI acts with Enema per month.	N/A N/A 489/550 (88.9%) N/A 165/550 (30%) N/A	12 (4-26) 3.9 (0-30) N/A 3.5 (0.3-28.9) N/A 1.8 (0.3-11.3)

Abbreviations. RAI, receptive anal intercourse