EClinicalMedicine 17 (2019) 100226

Contents lists available at ScienceDirect

EClinicalMedicine

journal homepage: www.elsevier.com/locate/eclinm

Commentary

Time for the US food and drug administration approval of condoms for anal intercourse

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ARTICLE INFO

Article history:
Received 12 November 2019
Accepted 27 November 2019
Available online 12 December 2019

Research centering on men who have sex with men (MSM) commonly examines the role of anal intercourse in HIV transmission. However, anal intercourse is increasingly common and overlooked among heterosexual couples, possibly contributing to the rising rate of sexually transmitted infection (STI) in the United States (US). National surveys of heterosexually active women estimate recent and lifetime receipt of anal intercourse at 13.2% and 36.3%, respectively [1]. Similar surveys of men estimate proportions at 5.7% and 42.6% [2]. In the STI clinic setting, rates of heterosexual, unprotected anal intercourse have risen to approximately 18% [3]. As the probability of HIV transmission is greater with unprotected anal rather than vaginal intercourse, measures to prevent infections associated with anal intercourse are increasingly important, regardless of sexual orientation, and should neither be underemphasized nor stigmatized.

Despite the introduction of PreP and advances in microbicidal development, external and internal condoms remain the mainstay for STI prevention. However, currently available condoms are FDA-approved only for vaginal intercourse; usage for oral or anal intercourse is off-label. The complete lack of guidelines for use during anal intercourse for either the female condom [4] and limited guidelines for the male condom [5] perpetuate professional counseling based on anecdotal experience and limited evidence. The low utilization of condoms with anal sex among MSM, women with known HIV-infected partners, and commercial sex workers highlights the need for research on condoms for use in these setting.

Recognizing the importance of such information, Siegler et al. [6] conducted a rigorous, blinded, crossover randomized trial of latex condoms for anal and vaginal intercourse in Atlanta, Georgia, USA. They enrolled 252 MSM and 252 MSW and collected daily, electronic, self-reported diary data on condom failure (breakage/slippage), across 4884 sex acts. Standard, thin, and fitted condoms were provided as part of the crossover component, providing specific and valuable data on condom performance. They reported a lower clinical failure rate for condoms when used among MSM for anal intercourse versus MSW for vaginal intercourse (0.7% vs 1.9%; odds ratio 0.40, 95% confidence interval 0.21–0.75, $p < 0.001$), independent of condom thickness and fit.

It should be noted that while the investigators instructed participants to use water-soluble lubricant with each act of anal intercourse, this recommendation for the use of lubricant was not specifically given for vaginal acts. The use of condom-compatible lubricant may partially explain their observed failure rates with anal intercourse, which were well below rates reported in observational studies of condoms used for anal sex [7]. The statistically significant difference in condom failure between anal and vaginal intercourse reported in this study was mitigated in a sub-analysis accounting for the use of condom-compatible lubricant in both groups. This consideration should not diminish from recommendations to use latex condoms for anal intercourse, but rather embolden clinicians and public health officials to encourage their use with lubrication.

While randomized, controlled trial data suggest greater clinical failure rates with the use of polyurethane (8.5%) versus latex (1.6%) condoms during vaginal sex [8], the failure of polyurethane condoms, when used with lubricant, would not be expected to differ between acts of anal versus vaginal intercourse. Nevertheless, a separate trial of polyurethane, as well as other synthetic, non-latex condoms, is needed. Additionally, anal intercourse data from Siegler et al. came from MSM populations under the assumption that biological differences in condom failure would not differ based upon the receiving partner's gender. However, heterosexual MSW may engage in sexual practices that differ from MSM, which

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https://doi.org/10.1016/j.eclinm.2019.11.019

may entail transitions between vaginal and anal sex. Future studies may explore differences in condom failure with anal intercourse between MSW and MSM couples.

To obtain FDA approval, male condoms that are substantially similar in design to approved condoms, require data about clinical failure (breakage/slippage) based on 1000 uses of the product. These authors have met that standard by providing high-quality data from the largest sample of condom use with anal intercourse. That their reported rates of clinical failure during vaginal intercourse were similar to those from other randomized, controlled trials is reassuring [9] and supports the use of these data to provide an FDA label indication for anal intercourse. If there are any remaining questions, a smaller scale study (such as is being proposed to study female condoms) using post-coital tests for semen markers, such as PSA, from the rectum or the external surface of the condom could provide even more convincing data to support their use for STI protection with anal intercourse [10].

Declaration of competing interest

Dr. Nelson is a consultant for and receives grants from Agile Pharmaceutical, Bayer HealthCare, Merck, and Sebela Pharmaceutical. She is on the Speakers Bureau for Bayer HealthCare and Merck. She is also on the advisory board for AMAG. Dr. Nguyen has no relevant conflicts to disclose.

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