Commentary

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

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\textbf{AR T I C L E  I N F O}

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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 microbicide 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 settings.

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/slipage), 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
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.

References

[1] Benson LS, Martins SL, Whitaker AK. Correlates of heterosexual anal intercourse among women in the 2006–2010 National Survey of Family Growth. J Sex Med 2015;12(8);1746–52. [Internet](cited 2019 Oct 5); Available from: http://www.ncbi.nlm.nih.gov/pubmed/26289541

[2] Herbenick D, Bongiovi J, Fu T-C (Jane), Dodge B, Guerra-Reyes L, Sanders S. Sexual diversity in the United States: results from a nationally representative probability sample of adult women and men. Xa J, editor. PLoS One 2017;12(7):e0181198. [cited 2019 Oct 6]; Available from: https://dx.plos.org/10.1371/journal.pone.0181198.

[3] Satterwhite CL, Kamb ML, Metcalf C, Douglas JM, Malotte CK, Paul S, et al. Changes in sexual behavior and STD prevalence among heterosexual STD clinic attendees: 1993–1995 versus 1999–2000. Sex Transm Dis 2007;34(10):815–19. [cited 2019 Oct 6]; [PAP]. Available from: https://insights.ovid.com/crossref?an=00002635-9000000000-95940

[4] Mantell JE, Kelvin EA, Exner TM, Hoffman S, Needham S, Stein ZA. Anal use of the female condom: does uncertainty justify provider inaction? AIDS Care 2009;21(9):1185–94. [cited 2019 Oct 10]; Available from: http://www.ncbi.nlm.nih.gov/pubmed/20024779.

[5] Brooks JT, Friedman A, Kachur RE, LaFlam M, Peters PJ, Jamieson DJ. Update: interim guidance for prevention of sexual transmission of zika virus — United States, July 2016. MMWR Morb Mortal Wkly Rep 2016;65(29):745–7. [cited 2019 Oct 10]; Available from: http://www.ncbi.nlm.nih.gov/pubmed/27466758

[6] Siegler AJ, Rosenthal EM, Sullivan PS, Christina Mehta C, Moore RH, Abshlager L, et al. Levels of clinical condom failure for anal sex: a randomized cross-over trial. EClinicalMedicine 2019;17[C]:100195.

[7] van Griesen GJ, de Vroome EM, Tielman RA, Coutinho RA. Failure rate of condoms during anogenital intercourse in homosexual men. Genitourin Med 1988;64(5):344–6. [cited 2019 Oct 6]; Available from: http://www.ncbi.nlm.nih.gov/pubmed/3203934.

[8] Frezieres RG, Walsh TL, Nelson AL, Clark VA, Coulson AH. Evaluation of the efficacy of a polyurethane condom: results from a randomized, controlled clinical trial. Fam Plann Perspect 1999;31(2):81–7. 1999/05/04. Available from: internal-pdf://177.255.1.10/1999-Frezieres-Evaluation-of-the-efficacy-of-a.pdf.

[9] Walsh TL, Frezieres RG, Peacock K, Nelson AL, Clark VA, Bernstein L, et al. Effectiveness of the male latex condom: combined results for three popular condom brands used as controls in randomized clinical trials. Contraception 2004;70(5):407–13. [cited 2019 Oct 6]; Available from: https://www.sciencedirect.com/Science/article/abs/pii/S000968130400157X.

[10] Walsh TL, Snead MC, St Claire BJ, Schwartz JL, Mauck CK, Frezieres RG, et al. Comparison of self-reported female condom failure and biomarker-confirmed semen exposure. Contraception 2019;100(3):406–12. [cited 2019 Nov 3]; Available from: http://www.ncbi.nlm.nih.gov/pubmed/31381878.