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Male Circumcision and *Mycoplasma genitalium* Infection in Female Partners: a Randomized Trial in Rakai, Uganda

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Abstract

Objective—Previous randomized trial data have demonstrated that male circumcision reduces *Mycoplasma genitalium* prevalence in men. We assessed whether male circumcision also reduces *M. genitalium* infection in female partners of circumcised men.

Methods—HIV-negative men were enrolled and randomized to either male circumcision or control. Female partners of male trial participants from the intervention (n=437) and control (n=394) arms provided interview information and self-collected vaginal swabs that were tested for *M. genitalium* by APTIMA transcription-mediated-amplification-based assay. Prevalence risk ratios (PRR) and 95% confidence intervals (95%CI) of *M. genitalium* prevalence in intervention versus control group were estimated using Poisson regression. Analysis was by intention-to-treat. An as-treated analysis was conducted to account for study-group crossovers.

Results—Male and female partner enrollment sociodemographic characteristics, sexual behaviors, and symptoms of STIs were similar between study arms. Female *M. genitalium* prevalence at year-two was 3.2% (14/437) in intervention arm and 3.6% (14/394) in control arm (PRR=0.90, 95%CI 0.43–1.89, p=0.78). In an as-treated analysis, the prevalence of *M. genitalium*

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All authors contributed to the study design, data collection, data analysis, writing and reviewing the paper.

was 3.4% in female partners of circumcised men and 3.3% in female partners of uncircumcised men (PRR= 1.01, 95%CI 0.48–2.12, p=0.97).

Conclusions—Contrary to findings in men, male circumcision did not affect *Mycoplasma genitalium* infection in female partners.

Keywords

Male circumcision; mycoplasma genitalium; HIV; Uganda; sexually transmitted infections; transmission

Introduction

Mycoplasma genitalium is a sexually transmitted infection (STI), and growing evidence is demonstrating that it is associated with urethritis, cervicitis, salpingitis, and pelvic inflammatory disease [1]. The prevalence of *M. genitalium* among women in the general population is approximately 1–5% [1–4]. However, *M. genitalium* infection is substantially higher among HIV-positive women and female sex workers with the prevalence ranging from 10–26% [5–8]. *M. genitalium* infection has also been associated with an increased risk of acquiring HIV [9].

Three randomized trials in South Africa, Kenya and Uganda, demonstrated that male circumcision (MC) significantly decreases HIV acquisition in men [10–12]. In addition, these trials have shown that MC reduces herpes simplex virus type 2 (HSV-2) and human papillomavirus in men, and the Kenyan trial also demonstrated that MC decreases *M. genitalium* infection [13–16]. The Ugandan trial also showed that female partners of circumcised men have decreased prevalence of genital ulcer disease (GUD), *Trichomonas vaginalis*, bacterial vaginosis and human papillomavirus [17, 18].

We utilized data from a randomized controlled trial of MC in HIV-negative men in Rakai, Uganda, to assess the efficacy of MC for reducing female partner *M. genitalium* prevalence.

Materials and Methods

Participants, Study Design, and Randomization

The Rakai Health Sciences Program (RHSP), in Rakai, Uganda enrolled 5596 HIV-negative men in MC trials for HIV/STI prevention [10, 17]. Men were eligible for enrollment if they were uncircumcised, aged 15–49, had no medical indications or contraindications for MC, and provided written informed consent. Men were randomly assigned to receive immediate MC (intervention arm, n=2786) or MC delayed for 24 months (control arm, n=2810).

Consenting female partners of male trial participants who were married or in long term consensual relationships were invited to participate in a separate follow-up study [17]. All female participants provided written informed consent. The effects of MC on female STIs were secondary trial outcomes. As previously described, there were 648 women in the intervention arm and 597 women in the control arm, who were persistently HIV-negative, married, concurrently enrolled with their husband who participated in the trial and had a

swab collected at enrollment [17]. Of these women, 549 women in the intervention arm and 502 women in the control arm had swabs collected at year two [17]. However, swab samples from 220 randomly selected women (112 [20.4%] from the intervention arm and 108 [21.5%] from the control arm) were exhausted after being used for previous studies. Thus, the current study included the remaining 437 women from the intervention arm and 394 women from the control arm at year two. There were no differences in terms of age, marital status, religion, education, sexual partners, non-marital relationships, condom use, alcohol use, transactional sex, receipt of voluntary counseling and testing, HPV prevalence or self-reported symptoms of GUD, vaginal discharge or dysuria between this population and the primary trial population [17]. The primary objective of this analysis was to assess the efficacy of MC of HIV-negative men on female partner *M. genitalium* prevalence.

At each annual study visit, women were interviewed to ascertain sociodemographic characteristics, sexual risk behaviors, and health status. During the mid-point trial study visit (year one), women presenting with either discharge (n=148, 17.8%) or dysuria (n=46, 5.5%) were treated with metronidazole and azithromycin to cover vaginal and cervical infections. Women presenting with genital ulcers (n=16, 1.9%) were treated with azithromycin and acyclovir. Women were also asked to provide blood samples and self-administered vaginal swabs. They were instructed to squat, insert a 20-cm Dacron or cotton-tipped swab and to rotate the swab high in the vaginal vault. After collection, the women handed the swab to a field worker who placed the swab in 1 ml of AMPLICOR specimen transport medium (Roche Diagnostics, Indianapolis, IN). This approach to specimen collection was well accepted, with compliance rates over 90% at study visits. The specimens were maintained at 4–10 °C for less than 6 hours until they were frozen at −80 °C.

The trials were approved by the Uganda National Council for Science and Technology, the Science and Ethics Committee of the Uganda Virus Research Institute (Entebbe, Uganda), the Committee for Human Research at Johns Hopkins University Bloomberg School of Public Health (Baltimore, MD, USA), and the Western Institutional Review Board (Olympia, WA, USA) [10, 17, 18]. The trials were overseen by independent Data and Safety Monitoring Boards. The trials were registered with ClinicalTrials.gov, NCT00425984 and NCT00124878.

M. genitalium, HPV, and HIV Detection

M. genitalium infection was detected using the APTIMA transcription-mediated amplification (TMA)-based Research Use Only (RUG) assay (Gen-Probe, San Diego, CA), as previously described [19].

HPV Linear Array (Roche Diagnostics, Indianapolis, IN) was utilized to detect 37 HPV genotypes [14]. HIV status was determined using two separate ELISAs, and discordant results were confirmed by HIV-1 Western Blot [10].

Statistical Analysis

Enrollment and follow-up characteristics, sexual risk behaviors and STI symptoms in men and their female partners were tabulated by study arm and differences assessed by chi-square tests. All p-values were 2-sided.

The primary assessment of MC efficacy for reduced female *M. genitalium* prevalence used an intention-to-treat analysis. An as-treated analysis was also carried out, in which intervention arm women were classified as crossover exposures if their male partner remained uncircumcised at the annual follow up visit, and partners of control arm men were classified as crossover exposures if the male partner underwent MC from other sources during the follow-up interval in which the procedure was performed.

Prevalence risk ratios (PRR) and 95% confidence intervals (95%CI) of *M. genitalium* prevalence in intervention versus control group were estimated using Poisson regression. Multivariate Poisson regression was used to estimate adjusted PRRs (adjPRRs) after adjusting for enrollment covariates that differed significantly between the arms at $p < 0.15$ and known risk factors for *M. genitalium* infection, which included enrollment age, treatment for vaginal discharge, dysuria, or genital ulcers at the mid-point trial visit, and the year two follow-up number of sex partners (1 vs. >1), condom use, non-marital relationships, and transactional sexual intercourse.

Analyses were performed using STATA 11.2 (StataCorp LP, College Station, TX).

Results

Male baseline sociodemographic characteristics, sexual behaviors, and symptoms of STIs were similar between study arms, except more men in the control arm reported drinking alcohol prior to sexual intercourse (p=0.01) (Table 1). The female enrollment characteristics were similar between trial arms (Table 1). In addition, human papillomavirus (HPV) prevalence was similar at enrollment for the female partners between the two trial arms.

The overall prevalence of *M. genitalium* at year two was 3.4% (28 cases of 831 women). In the intention-to-treat analysis, *M. genitalium* infection was detected in 14 female partners of men in the intervention group and in 14 female partners of men in the control group at the two year follow-up visit. Female partner prevalence at year two was 3.2% in the intervention arm and 3.6% in the control arm (PRR=0.90, 95%CI 0.43–1.89, p=0.78) (Table 2). After adjustment, the PRR (adjPRR) of *M. genitalium* infection in female partners of intervention relative to control arm men was 0.93 (95%CI 0.43–2.03, p=0.86).

In an as-treated analysis, the prevalence of *M. genitalium* was 3.4% in female partners of circumcised men and 3.3% in female partners of uncircumcised men (PRR= 1.01, 95%CI 0.48–2.12, p=0.97).

Self-reported rates of female partners' sexual behaviors and STI symptoms were assessed by the male partner's trial arm and follow up interval. There were no differences at year two among the female partners between study arms in self-reported number of sexual partners, GUD, vaginal discharge, or dysuria (Table 3). There were also no differences in the report

of non-marital relationships (2.3% [10/435] of women in the intervention arm and 3.4% [13/388] of women in the control arm, p=0.36). However, there were more women in the control arm who reported differences in condom use (22.7% [88/388]) compared to intervention arm women (13.1% [57/435], p=0.001).

Discussion

We found that MC of HIV-negative men did not affect female partner *M. genitalium* prevalence. The lack of MC efficacy for prevention of *M. genitalium* infection in female partners of HIV-negative men is likely due to multiple factors. *M. genitalium* infection from outside relationships could have diluted the potential efficacy of MC. The study may have lacked the power to detect an effect of MC on female partners' *M. genitalium* infections. The three MC trials have shown consistently that MC reduces viral STIs among men [20, 21]. More recent evidence has shown that MC modifies and reduces the penile microbiome [22], but has limited to no impact on bacterial STIs for men, specifically syphilis, *Neisseria gonorrhoeae, Chlamydia trachomatis, and Trichomonas vaginalis* [14, 23–25]. These pathogens are usually found in urethral cells and not in the foreskin. While *M. genitalium* is a urethral pathogen, the foreskin may also be a reservoir for *M. genitalium* [26]. Consequently, it may be biologically plausible that MC has no effect on *M. genitalium* infection in female partners since the impact of MC on bacterial STIs among men is limited. Further research is needed in this area to understand the role of the foreskin, bacterial pathogens, and HIV risk.

There are limitations with this study. The women were all in stable partnerships with HIV-negative men, and may represent a self-selected population of more compliant lower risk participants in both arms. Although the MC trial in Kenya showed the circumcised men had lower *M. genitalium* prevalence [15], we unfortunately did not have urine or urethral swabs to evaluate the men in this trial. The risk behaviors and symptoms of STIs are self-reported and the data were potentially vulnerable to recall and reporting bias. We do not know the prevalence of *M. genitalium* at enrollment. However, female partner participants of the two trial arms were likely similar since there was no difference in the demographics, sexual behaviors or HPV prevalence at enrollment. We were unable to assess the impact of MC on *M. genitalium* acquisition and a portion of the year two *M. genitalium* prevalence could represent chronic infection from enrollment.

Despite the benefits for female partners of circumcised men, such as reduced rates of high-risk HPV transmission, genital ulcer disease, trichomoniasis, and bacterial vaginosis [17, 18], MC did not affect the prevalence of *M. genitalium* infection to their female partners in this study.

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Key Messages

- Previous randomized trial data have demonstrated that male circumcision reduces *Mycoplasma genitalium* prevalence in men and there are derivate benefits for female partners.
- It is not known whether male circumcision also reduces *M. genitalium* infection in female partners of circumcised men.
- This study demonstrated that contrary to findings in men, male circumcision does not affect *Mycoplasma genitalium* infection in female partners.

Table 1

Baseline characteristics, risk behaviors, and symptoms of sexually transmitted infections of men and their female partners by study arm.

	Men			Female Partners		
	Intervention group (n=407)	**Control group (n=370)**	**p-value**	**Intervention group (n=437)**	**Control group (n=394)**	**p-value**
Age (years)			0.75			0.88
15–19	5 (1.2%)	5 (1.4%)		50 (11.4%)	45 (11.4%)	
20–24	75 (18.4%)	78 (21.1%)		138 (31.6%)	131 (33.2%)	
25–29	118 (29.0%)	115 (31.1%)		122 (27.9%)	115 (29.2%)	
30–34	108 (26.5%)	88 (23.8%)		78 (17.8%)	60 (15.2%)	
35–49	101 (24.8%)	84 (22.7%)		49 (11.2%)	43 (10.9%)	
Marital Status			0.47			0.54
Not married	1 (0.2%)	0 (0.0%)		1 (0.2%)	0 (0.0%)	
Monogamous	349 (85.7%)	325 (87.8%)		353 (80.8%)	325 (82.5%)	
Polygynous	57 (14.0%)	45 (12.2%)		83 (19.0%)	69 (17.5%)	
Religion			0.62			0.28
Catholic	256 (62.9%)	260 (70.3%)		269 (61.6%)	245 (62.2%)	
Protestant	120 (29.5%)	86 (23.2%)		122 (27.9%)	101 (25.6%)	
Saved/Pentecostal/other	28 (6.9%)	22 (5.9%)		40 (9.2%)	35 (8.9%)	
Muslim	3 (0.7%)	2 (0.5%)		6 (1.4%)	13 (3.3%)	
Education			0.32			0.57
No education	29 (7.1%)	36 (9.7%)		71 (16.2%)	54 (13.7%)	
Primary	304 (74.7%)	276 (74.6%)		317 (72.5%)	292 (74.1%)	
Secondary or higher	74 (18.2%)	58 (15.7%)		49 (11.2%)	48 (12.2%)	
Number of sexual partners past year^			0.21			0.20
0	0 (0.0%)	0 (0.0%)		1 (0.2%)	0 (0.0%)	
1	235 (57.7%)	197 (53.2%)		428 (97.9%)	380 (96.4%)	
2+	172 (42.3%)	173 (46.8%)		8 (1.8%)	14 (3.6%)	
Non-marital relationships in past year			0.77			0.07
No	340 (83.5%)	312 (84.3%)		435 (99.5%)	387 (98.2%)	
Yes	67 (16.5%)	58 (15.7%)		2 (0.5%)	7 (1.8%)	

	Men			Female Partners		
	Intervention group (n=407)	**Control group (n=370)**	**p-value**	**Intervention group (n=437)**	**Control group (n=394)**	**p-value**
Condom use in past year[&]			0.74			0.06
None	277 (68.1%)	242 (65.4%)		382 (88.0%)	323 (82.6%)	
Inconsistent use	126 (31.0%)	124 (33.5%)		52 (12.0%)	67 (17.1%)	
Consistent condom use	4 (1.0%)	4 (1.1%)		0 (0.0%)	1 (0.3%)	
Alcohol use with sex in past year	211 (51.8%)	225 (60.8%)	0.01	153 (35.0%)	128 (32.5%)	0.44
Transactional sexual intercourse in past year[*]	2 (0.5%)	2 (0.5%)	0.92	2 (0.5%)	2 (0.5%)	0.92
Prior receipt of voluntary counseling and testing	79 (19.4%)	53 (14.3%)	0.06	87 (19.9%)	68 (17.3%)	0.58
Self-reported symptoms of STDs in past year						
Genital ulcer disease	37 (9.1%)	35 (9.5%)	0.86	64 (14.6%)	50 (12.7%)	0.41
Urethral or vaginal discharge	15 (3.7%)	21 (5.7%)	0.19	211 (48.3%)	181 (45.9%)	0.50
Dysuria	22 (5.4%)	33 (8.9%)	0.06	92 (21.1%)	90 (22.8%)	0.53
Human papillmoavirus (HPV) prevalence[#]	-----	-----	-----	222 (50.8%)	218 (55.3%)	0.19

Data are n (%). The number of men is less than the number of female partners enrolled due to polygynous unions.

[^]Number of sexual partners during past year includes long-term partner.

[&]Condom use data was not available for three female partners from both the intervention arm and control arm.

[*]Transactional sexual intercourse was defined as sexual intercourse in exchange for money or gifts.

[#]Male HPV prevalence was not evaluated for all men.

Table 2

Female Mycoplasma genitalium prevalence at year two by trial arm (intention-to-treat analysis) and circumcision status (as-treated analysis).

Intervention group		Control group		PRR (95% CI)	adjPRR (95% CI)*
MG positive/ N*	Percent (%)	MG positive/ N*	Percent (%)		
Intention-to-treat					
14 / 437	3.2%	14 / 394	3.6%	0.90 (0.43–1.89)	0.93 (0.43–2.03)
As-treated					
14 / 413	3.4%	14 / 418	3.3%	1.01 (0.48–2.12)	1.00 (0.46–2.18)

*Adjusted for age, treatment for vaginal discharge, dysuria, or genital ulcers at the mid-point trial visit (year one), and the year two follow-up number of sex partners (1 vs. >1), condom use, non-marital relationships, and transactional sexual intercourse.

Table 3

Sexual risk behavior of female partners at year two.

	Female Partners		
	Intervention group (n=435)#	**Control group (n=388)#**	**p-value**
Number of sexual partners past year^			0.29
0	0 (0.0%)	0 (0.0%)	
1	422 (97.0%)	371 (95.6%)	
2+	13 (3.0%)	17 (4.4%)	
Non-marital relationships in past year			0.36
No	425 (97.7%)	375 (96.6%)	
Yes	10 (2.3%)	13 (3.4%)	
Condom use in past year			0.001
None	375 (86.2%)	299 (77.1%)	
Inconsistent use	57 (13.1%)	88 (22.7%)	
Consistent condom use	3 (0.7%)	1 (0.3%)	
Transactional sexual intercourse in past year*	2 (0.5%)	1 (0.3%)	0.89
Self-reported symptoms of STDs in past year			
Genital ulcer disease	60 (13.8%)	69 (17.8%)	0.11
Urethral or vaginal discharge	162 (37.2%)	143 (36.9%)	0.63
Dysuria	62 (14.3%)	70 (18.0%)	0.14

Data are n (%).

Demographic data were not available for two women in the intervention arm and six women in the control arm.

* Transactional sexual intercourse was defined as sexual intercourse in exchange for money or gifts.