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# Clinical and sexual risk correlates of *Mycoplasma genitalium* in urban pregnant and non-pregnant young women: cross-sectional outcomes using the baseline data from the Women's BioHealth Study

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## Abstract

**Objective—**Research exploring the clinical and sexual risk correlates is essential to define universal standards for screening and management for *Mycoplasmagenitalium* (MG). The objective of this study is to determine the baseline prevalence of MG and associated clinical risks using cross-sectional data.

**Methods—**Adolescent and young adult women 13–29 years were recruited during clinical visits during which biological specimens were collected for *Neisseriagonorrhoeae* (NG) and *Chlamydia trachomatis* (CT) testing to provide vaginal specimens for MG and *Trichomonasvaginalis* (TV) testing. Demographic, clinical and sexual risk data were collected after obtaining written consent. MG was tested using the hologicGenprobe transcription-mediated amplification–MG



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analytespecific reagent assay and TV by the Aptima TV assay. Bivariate analyses were used to evaluate differences in MG prevalence based on pregnancy status, demographic factors, clinical symptoms, concurrent STI and sexual risk behaviour quiz score (maximum score=10).

**Results—**483 patients with a mean age of 22.4 years (SD 3.6) were enrolled. Most participants were pregnant (66%) and asymptomatic (59%). MG was the most common STI (MG 16%, TV 9%, Ct 8%, NG 1%). Neither pregnancy nor symptoms were predictive of STI positivity. thirty-five per cent of non-pregnant and 45% of pregnant adolescents ≤19 years were positive for any STI. participants with MG were 3.4 times more likely to be co-infected with other STIs compared with those with other STIs (or 3.4, 95% CI 1.17 to 10.3, p=0.021). Mean risk quiz scores for STI positive women were six points higher than those who were STI negative (β=0.63, 95% CI 0.36 to 0.90, p<0.001). there were no differences in risk scores for MG-positive participants compared with other STI positivity.

**Conclusion—**MG infection was common, associated with STI co-infection and often asymptomatic, and pregnancy status did not confer protection.

## INTRODUCTION

Lower genital infection with *Mycoplasma genitalium* (MG) has been associated with adverse clinical outcomes in women,[1–3] and antibiotic resistance may undermine the effectiveness of standard treatments posing a major threat to reproductive health.[4,5] Given the public health goals for infertility prevention[6] and the anticipated availability of commercial MG testing, research exploring the clinical and sexual risk correlates in women is essential to better define national recommendations for screening and management. These data are particularly relevant in large academic centres situated in communities with documented disparities in STIs for which public health control programmes may be contextualised to meet the needs of the population. While MG has been described in urban young women, often the samples emerge from high-risk clinical settings such as public health clinics The purpose of this research was to determine the prevalence of MG among a cohort of young urban women seeking routine gynaecological care in a large urban academic centre and the associated clinical risks among affected patients.

## STUDY METHODS

Pregnant and non-pregnant women aged 13–29 years were recruited during gynaecological and prenatal visits, during which vaginal and/or endocervical specimens were collected for *Neisseria gonorrhoeae* (NG) and *Chlamydia trachomatis* (CT), to also provide specimens for MG and *Trichomonas vaginalis* (TV) testing between 1 September 2015 and 30 November 2016. Participants were patients being seen in Adolescent/Young Adult Medicine and Obstetrics and Gynaecology clinics within a large academic centre on the east coast of the United States for which STIs represent a major area of health disparity facing the general population.[7]

Patients provided basic demographic, clinical symptomatology (vaginal discharge, bleeding, vaginal irritation, dysuria, dyspareunia and abdominal pain) and sexual risk data using an established risk quiz tool found to be highly predictive of risk for STI positivity in women.[8]

The maximum risk score of 10 indicates the highest STI risk level on an additive scale of 0–10. MG testing was performed using the Hologic/Gen-Probe transcription-mediated amplification–*Mycoplasma genitalium* (MG) analyte-specific assay and TV by the Aptima TV assay in an academic research laboratory.[89] NG and CT Aptima Combo2 results were abstracted from the patient's electronic health record as reported by the hospital laboratory. No remuneration was provided for data (demographics, sexual risk and symptoms on requisition form) or specimen collection. However, patients with positive results were notified and offered treatment through the institutional Adolescent/Young Adult Title X programme and/or through the collaborating obstetrics/gynaecology practice and offered re-screening at 3 months. The Johns Hopkins Medicine institutional review board approved the study (IRB00068584).

Descriptive analyses were performed to assess patients' demographic data, clinical presentations (symptoms, pregnancy status) and STI screening results for all patients. Sample size and timeline for data collection were based on clinical volume in recruitment sites, number of subgroup analyses to be performed, existing positive STI screening rates in each site and preliminary data from our current PID trial. Chi-square analyses were used to compare screening results based on pregnancy status at the time of screening (pregnant vs non-pregnant). Student's t-test was used to compare the age and risk score by pregnancy status. We also examined whether having symptoms at the time of screening was related to screening results, and whether women with positive MG screen were more likely to have co-infections with other infection, using $\chi^2$ statistics. Linear regression was used to estimate the average difference in risk score for women with at least one positive STI screen and those who were not positive and to compare the average risk score for women with MG-positive screens to those of women with the other positive STI screening results.

## RESULTS

Four hundred and eighty-three patients with a mean age of 22.4 years (SD 3.6) were enrolled in the study and provided vaginal test samples. A total of 166 (34%) patients were pregnant. Most (79%) patients were African American, with a secondary education or higher. Forty per cent were married or in a committed relationship. Fifty-nine per cent of women were asymptomatic at the time of data collection. MG was the most common infection among the women in this general clinical sample of women with the following infection prevalence outcomes (MG 16%, TV 9%, CT 8%, NG 1%) (table 1). Pregnant women had higher levels of education (P=0.001) and were more often in committed relationships (P=0.016) than non-pregnant women; however, there were no significant differences in prevalence based on pregnancy status. Overall, 28% (n=135) of patients had any STI and 30% (n=49) of pregnant patients had at least one STI (table 1). Adolescents, defined as patients ≤19 years, were 25% (n=123) of the overall sample and 35.8% (n=44) of adolescents were pregnant. Thirty-five per cent of adolescents had any STI and 45% of pregnant adolescents had at least one STI.

Neither pregnancy (OR 1.13, 95% CI 0.74 to 1.70, P=0.583) nor symptoms (any symptoms vs none, OR 1.14, 95% CI 0.77 to 1.72, P=0.575) were predictive of any STI positivity. Women with MG were 3.4 times more likely to have co-infections compared with those with other STIs (OR 3.4, CI 1.17 to 10.3, P=0.021). Mean risk quiz scores for STI positive (any

STI) women were six points higher than those who were STI negative (β=0.63, 95% CI 0.36 to 0.90, P<0.001). There were no differences in risk scores for MG-positive women compared with other STI positivity (β=0.09, 95% CI −0.34 to 0.52, P=0.679 for difference in average risk score).

## CONCLUSION

MG infection is a common infectious agent with emerging significance among pregnant and non-pregnant women seeking care in routine practice. While symptomatic patients were significantly more likely to have MG infection and to be co-infected with other organisms, the prevalence of infections among asymptomatic patients was significant and higher than CT prevalence for which there are active public health control programmes and primary and prevention plans in the United States.[10] Further, pregnancy status does not confer protection for young women. This may reflect various factors such as relationship instability, partner separation and/or concurrency given the low rates of marriage/committed relationships among pregnant participants. It may also reflect ongoing untreated infection in the context of stable relationships, as routine MG screening is not recommended by the Centres for Disease Control and Prevention Sexually Transmitted Disease Treatment guidelines.[10] Unfortunately, there are no FDA-cleared commercial assays currently available and commercial laboratories only offer research MG tests.

Our work supports prior research by other teams both in the international contextw[12] as well as in the United States[1w13w14] demonstrating that MG has recently become a common STI, but does not yet have a strategy for public health control, but that has the potential to influence the reproductive health and morbidity outcomes in young women. We add to the literature by examining MG rates among this population with significant STI disparities.[w15w16] We also include both adolescent and young adult women, assess the disease prevalence by pregnancy status and further clarify that like CT, many patients with MG will present with asymptomatic infections.

The study findings must be considered in light of several general limitations. This was a cross-sectional analysis of data from a convenience sample of women being seen within a single institution and city for routine acute or primary gynaecological and/or obstetrical care. Findings may not be generalisable to the larger population in the city and/or to other dissimilar populations. However, our institution is a major regional care provider, so the outcomes are relevant. The increasing availability of data indicates that MG infection is prevalent within pregnant and non-pregnant women seeking care in routine practice. The findings are consistent with prior MG research from this setting.[3]

Longitudinal clinical outcomes after MG infection based on treatment status are needed to better define a public health control strategy for MG for pregnant and non-pregnant women. In the interim, it is critically important that providers consider MG infection for young women care with persistent symptoms despite negative testing for NG and CT.

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**Table 1:**

Symptoms, risk score and STI result

| | Overall (n=483) | Pregnant (n=166) | Not Pregnant (n=317) | Or* (95% CI) | P Value |
|---|---|---|---|---|---|
| Symptoms; N (%) | | | | | 0.002† |
| None | 287 (59%) | 115 (69%) | 172 (54%) | (reference) | |
| 1–2 | 149 (31%) | 43 (26%) | 106 (33%) | 1.65 (1.08 to 2.52) | |
| 3+ | 47 (10%) | 8 (5%) | 39 (12%) | 3.26 (1.47 to 7.23) | |
| Risk score (0–10); mean (SD) | 4.0 (1.4) | 4.0 (1.0) | 4.0 (1.6) | | 0.779‡ |
| STI positivity; N (%) | | | | | |
| *Mycoplasma genitalium* | 75 (16%) | 28 (17%) | 47 (15%) | 0.87 (0.52 to 1.45) | 0.602† |
| *Trichomonas vaginalis* | 43 (9%) | 14 (9%) | 29 (9%) | 1.09 (0.56 to 2.13) | 0.790† |
| *Chlamydia trachomatis* | 39 (8%) | 15 (9%) | 24 (8%) | 0.83 (0.42 to 1.62) | 0.592† |
| *Neisseria gonorrhoeae* | 7 (1%) | 2 (1%) | 5 (2%) | 1.35 (0.22 to 14.32) | 0.710§ |
| Any STI | 135 (28%) | 49 (30%) | 86 (27%) | 0.89 (0.59 to 1.35)¶ | 0.583† |
| More than one STI | 23 (5%) | 7 (4%) 47 (15%) | 16 (5%) | 1.21 (0.49 to 3.00)** | 0.677† |

*For women who are not pregnant relative to those who are pregnant.

†Significance determined by $\chi 2$ test.

‡Significance determined by Student's t-test.

§Significance determined by Fisher's exact test.

¶Reference no STI.

**Reference no or single STI.