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*Mycoplasma genitalium* in asymptomatic patients – implications for screening

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## Abstract

**Objectives:** *Mycoplasma genitalium* is well established as a cause of urethritis, and has also been associated with cervicitis, endometritis and pelvic infection. Low rates of infection suggest screening may be inappropriate in the general population but it remains unclear whether asymptomatic patients attending a sexual health clinic should be tested routinely. The objective of this study was to measure the positivity rate of *M. genitalium* infection in asymptomatic individuals presenting to a sexual health clinic to inform the need for screening in this population.

**Methods:** Asymptomatic patients were identified using a structured questionnaire and tested for *M. genitalium* from genital swabs or urine using two separate polymerase chain reaction (PCR) assays incorporating different primer sequences.

**Results:** 1304 patients were approached over a 6 month period. 743 (57%) patients were symptomatic and 168 (13%) refused consent leaving 394 (30%) patients who entered the study. Residual samples were available for 308 (79%) patients, 168 (54%) men and 140 (46%) women. 14/308 (4.5%, 95% CI 2.2%-6.9%) asymptomatic patients were infected with *M. genitalium*, and an additional 2 (0.6%, 95% CI 0.2%-2.3%) patients had discrepant PCR results. No significant associations were found between *M. genitalium* infection and age, gender, ethnicity or isolation site.

**Conclusion:** The positivity rate of *M. genitalium* infection in asymptomatic sexual health clinic attendees is comparable to that of gonorrhoea or chlamydia and, if evidence of pathogenicity continues to accumulate, a further assessment of the role of routine screening in this setting would be appropriate.

## Introduction

*Mycoplasma genitalium* is a small bacterium which is recognised as a cause of urethritis, cervicitis, and endometritis<sup>1,2</sup>. Upper genital tract involvement in women is also likely, with a reported association between *M. genitalium* and tubal factor infertility<sup>3</sup>, the isolation of the organism from endometrium and the fallopian tube<sup>4</sup>, and the inoculation of *M. genitalium* leading to salpingitis in non-human primates<sup>5</sup>. Measuring the positivity rate of asymptomatic infection with *M. genitalium* in patients attending sexual health clinics is needed to help determine whether testing for *M. genitalium* should be included within routine screening tests to exclude STIs in this setting.

The primary objective of this study was to measure the positivity rate of *M. genitalium* in asymptomatic men and women attending a sexual health clinic in the UK.

## Methods

A convenience sample of asymptomatic sexual health clinic attendees were approached to participate in the study. A paper based self administered questionnaire was used to determine whether patients had any genital tract related symptoms and asymptomatic individuals were approached to participate in the study.

Study participants were randomised to have either a physician/nurse taken genital swab (men – urethral swab, women – cervical swab) or a self taken specimen (men – urine, women – vulval swab). Male urine samples and female self taken vulval swabs were collected in Roche chlamydia polymerase chain reaction (PCR) media. Female cervical swabs and male urethral swabs were collected in Becton-Dickinson chlamydia strand displacement amplification (SDA) media.

More detailed description of the methodology is available in the web appendix.

## Results

1304 patients were approached over a six month period in 2006. 743 (57%) patients were symptomatic and 168 (13%) refused consent leaving 394 (30%) patients who entered the study. Residual samples were available for 308 (78%) patients. The patient characteristics, specimen distribution and history of STI for those entering the study are shown in the web appendix.

Fourteen (4.5%, 95% CI 2.2%-6.9%) patients were positive for *M. genitalium* on both the MgPa and Mg219 PCRs, 2 (0.6%, 95% CI 0.2%-2.3%) patients were positive only on the MgPa PCR and 292 (94.8%, 95% CI 92%-97%) patients were negative on both PCRs.

The associations between infection with *M. genitalium* and patient demographics, concurrent STI, type of specimen tested and past history of STI are shown in the Table. A significant association was found between *M. genitalium* infection and gonorrhoea. However, all 5 positive gonorrhoea samples were self taken vulval swabs tested using the Roche Amplicor PCR. Subsequent cervical specimens were taken for *N. gonorrhoeae* culture prior to treatment, of which 4 were negative and one was reported as positive. A non-significant trend towards higher rates of mycoplasma infection in women (9/138 – 6.5%, 95% CI 3.5%-11.9%) compared to men (5/168 – 3%, 95% CI 1.3%-6.8%) was also noted.

*M. genitalium* isolation rates between clinical specimens were: male urine 2/84 (14%), male urethral swab 3/84 (21%), female vulval swab 6/59 (43%), female cervical swab 3/79 (22%).

## **Conclusions**

A positivity rate of *M. genitalium* of 4.5% (95% CI 2.2%-6.9%) was found in asymptomatic patients attending a sexual health clinic, with a non-significant trend towards higher rates of infection in women

Genitourinary medicine clinics in the UK perform over 1.5 million tests for STIs per year and do not currently screen routinely for *M. genitalium*. The largest previous study of STI clinic attendees examined 353 men

without urethritis and reported a prevalence of 0.8%, although symptoms or signs other than those associated with urethritis were not reported.<sup>6</sup> A total of 81 patients from 3 additional studies detected only 6 infections in asymptomatic clinic attendees.<sup>7,8,9</sup> Our positivity estimate may provide a more accurate measure reflecting a large sample size, inclusion of male and female patients, use of a well validated assay, confirmatory testing and a systematic approach to screening for asymptomatic infection prior to testing.

In the same clinic population, and over the same time period, the positivity rate of gonorrhoea was 264/7820 (3.4%) and for chlamydia 766/7820 (9.8%), and screening for both these infections is recommended in asymptomatic attendees at UK sexual health clinics.<sup>10</sup> Before making a clear recommendation on screening for mycoplasma, a further assessment of the risk and consequences of pelvic infection in untreated women is required. In addition, a commercially available, validated and reasonably priced test for *M. genitalium* is a prerequisite to wider implementation of screening or testing. As more information on the pathogenesis of the infection becomes available, this study supports the need to review the role of screening for *M. genitalium* infection in asymptomatic sexual health clinic attendees.

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Table Associations with *Mycoplasma genitalium* infection in asymptomatic genitourinary medicine clinic attendees

|                            |                           | M.<br>genitalium<br>negative<br>(n=292) | M.<br>genitalium<br>positive<br>(confirmed<br>on both<br>PCRs)<br>(n=14) | p value<br>(chi<br>square) |
|----------------------------|---------------------------|---|--|----------------------------|
| age group                  | 15-20                     | 67 (93%)                                | 5 (7%)   |                            |
|                            | 21-25                     | 104 (94%)                               | 6 (6%)   |                            |
|                            | 26-30                     | 53 (100%)                               | 0  |                            |
|                            | over 30                   | 68 (96%)                                | 3 (4%)   | 0.3                        |
| gender                     | male                      | 163 (97%)                               | 5 (3%)   |                            |
|                            | female                    | 129 (94%)                               | 9 (6%)   | 0.14                       |
| ethnic group               | White                     | 195 (96%)                               | 9 (4%)   |                            |
|                            | Black Caribbean           | 59 (94%)                                | 4 (6%)   |                            |
|                            | Black African/Black other | 10 (91%)                                | 1 (9%)   |                            |
|                            | other                     | 28 (100%)                               | 0  | 0.51                       |
| isolation site             | urine                     | 82 (98%)                                | 2 (2%)   |                            |
|                            | urethral swab             | 81 (96%)                                | 3 (4%)   |                            |
|                            | vulval swab               | 53 (88%)                                | 6 (12%)  |                            |
|                            | cervical swab             | 76 (95%)                                | 3 (5%)   | 0.14                       |
| history of<br>gonorrhoea*  | Yes                       | 5 (100%)                                | 0  |                            |
|                            | No                        | 285 (96%)                               | 13 (4%)  | 0.63                       |
| history of<br>chlamydia*   | Yes                       | 59 (92%)                                | 2 (8%)   |                            |
|                            | No                        | 231 (96%)                               | 11 (4%)  | 0.66                       |
| concurrent<br>gonorrhoea** | Yes                       | 3 (60%)                                 | 2 (40%)  |                            |
|                            | No                        | 279 (96%)                               | 10 (4%)  | <0.001                     |
| concurrent<br>chlamydia*** | Yes                       | 23 (97%)                                | 2 (3%)   |                            |
|                            | No                        | 262 (96%)                               | 11 (4%)  | 0.35                       |

\* data unavailable for 3 patients

\*\* data unavailable for 16 patients

\*\*\* data unavailable for 12 patients

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Contribution of authors:

JR – study concept, design, supervision, manuscript preparation

LB – study design, data collection, supervision, manuscript review

PM – laboratory testing, manuscript review

SA - laboratory testing, manuscript preparation, manuscript review