Demographics and Population Epidemiology of Mycoplasma genitalium infection: Correlation to Co-Infection and prior STI history

Josh Kostera, Ph.D., Jose Santiago, Ph.D.
Abbott Molecular, Des Plaines, IL

Background

Despite reports in the past few years that Americans are having less sex, the US Centers for Disease Control and Prevention (CDC) recently reported in 2019 that sexually transmitted infection (STI) cases are at an all-time high in the United States. The CDC report included statistics on confirmed cases of Chlamydia trachomatis and Neisseria gonorrhoeae, but did not include data for Trichomonas vaginalis and Mycoplasma genitalium.

Although Trichomonas vaginalis and Mycoplasma genitalium are generally recognized agents responsible for STI's, there is limited prevalence data in the United States. Worldwide, Trichomonas vaginalis is the single most prevalent non-viral STI and there is increasing evidence that Mycoplasma genitalium is independently associated with preterm birth and miscarriages, among other serious health issues. Mycoplasma genitalium infections are generally asymptomatic in both men and women that contributes to up to 35% of non-chlamydial non-gonococcal urethritis in men and linked to cervicitis and pelvic inflammatory disease in women. Treatment failures and antimicrobial resistant Mycoplasma genitalium has developed as a significant concern with rising incidence rates that has complicated the clinical management of this infection. Furthermore, current guidelines do not recommend routine screening for Mycoplasma genitalium, including women who are pregnant.

At present, neither Trichomonas vaginalis or Mycoplasma genitalium meet all the criteria for confirmed cases to be reported to the CDC. Left untreated or not accurately diagnosed, STIs can cause significant, serious long-term health consequences including sexual, reproductive, and psychological well-being that present an extensive challenge and burden to public health in the United States.

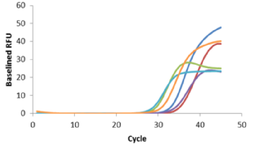
METHODS

Herein we present STI prevalence and socio-demographic epidemiological data associated with patients enrolled in a multicenter STI study using the automated multiplex qualitative CE marked assay, Alinity m STI. Symptomatic and asymptomatic patient samples included in the study originated from public STI clinics, primary care offices, and gynecology practices across the United States. The enrolled study population reflected a diverse number of participants that ranged in age from 17 to 74, with an approximately equal male to female ratio, prior STI history, single and married, education levels from primary to post-graduate, as well as different ethnicities.

Alinity m INSTRUMENT OVERVIEW

Nucleic acids from specimens are extracted using Alinity m Reagents. The Alinity m System employs magnetic microparticle technology to facilitate nucleic acid capture, wash and elution. The resulting purified nucleic acids are then combined with the liquid unit-dose activator reagent, lyophilized unit-dose Alinity m STI amplification/detection reagents and transferred into a reaction vessel. Alinity m Vapor Barrier Solution is then added to the reaction vessel which is then transferred to an amplification/detection unit for PCR amplification, and real-time fluorescence detection. The Alinity m STI assay is used for the detection and differentiation of urogenital disease pathogens, Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Trichomonas vaginalis (TV), and Mycoplasma genitalium (MG).

STI MULTIPLEX ASSAY

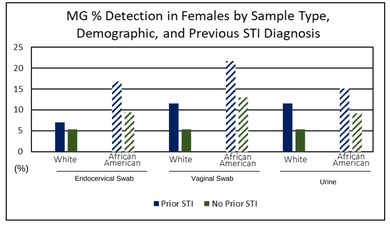


Picture is for illustrative purposes

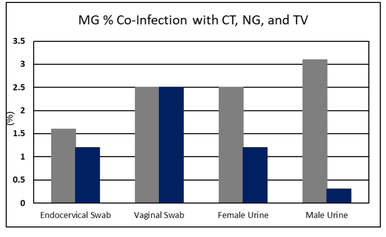
Pathogen	Target
C. trachomatis	Ribosomal (r) RNA
N. gonorrhoeae	OPA gene DNA
T. vaginalis	Ribosomal (r) RNA
M. genitalium	Ribosomal (r) RNA
Internal control	RNA target unrelated to target sequences
Cellular control	Beta Globin (BG)

DETECT AND DIFFERENTIATE 4 PATHOGENS IN ONE REACTION
< 115 MIN TO FIRST RESULT

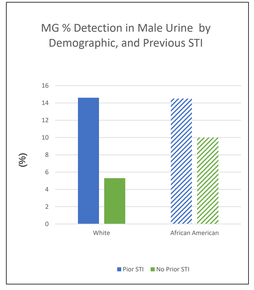
RESULTS



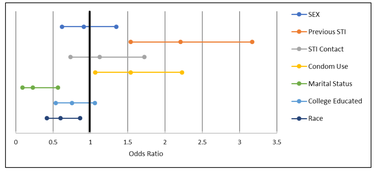
The chart above denotes Mycoplasma genitalium detection as a percentage in females enrolled in the study by sample type, ethnicity, and history of STI diagnosis. The column color/shade in the graph indicates study participants prior STI diagnosis status. The data collected from study participants in conjunction with MG detection in this cohort suggest that there is a potential relationship between having a prior STI diagnosis and increased probability of acquiring MG infection. Unlike males, in females, a history of prior STI's was found to be associated with a positive MG result and this association was statistically significant across all specimen types (individual specimen types and overall specimens p values ranged from 0.073 to <0.0001, respectively)



The chart above depicts Mycoplasma genitalium (MG) co-infection with Chlamydia trachomatis (CT) and or Neisseria gonorrhoeae (NG), and Trichomonas vaginalis (TV) as a percentage of individuals enrolled in the study. The grey columns in the graph indicate MG co-infection with CT and/or NG. The blue columns indicate MG co-infection with TV.

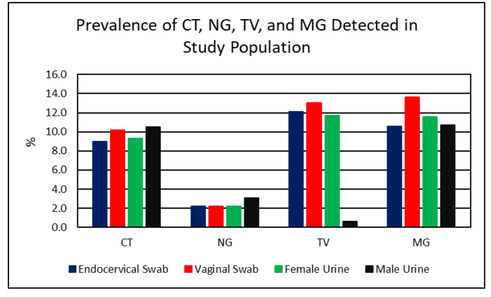


Mycoplasma genitalium detection in urine as a percentage in males enrolled in the study by demographic and history of STI diagnosis. The columns in the graph indicate race and those with a history of prior STI diagnosis (in blue). The solid column represents individuals who identified themselves as white and the dashed columns represents individuals who identified themselves as African American. The green bars denotes individuals who have not been previously diagnosed with an STI.



The odds ratio with 95% confidence intervals was calculated for predictor variables to assess the probability of MG infection. Data shown above. In this study cohort previous STI diagnosis and acknowledged condom use had the most impact on MG infection detection.

Study Demographics		
Sex	Male	51.91%
	Female	48.09%
Median Age (Range)	Male	28 (17, 74)
	Female	28 (17, 66)
Race	White	47.80%
	African American	52.20%
Ethnicity	Hispanic/Latino	35.63%
	Non-Hispanic/Latino	62.61%
Prior STI Infection	Yes	49.27%
	No	50.73%
STI Contact	Yes	19.65%
	No	80.35%
Condom Use	Yes	64.22%
	No	35.48%
Marital Status	Single	81.82%
	Married	12.76%
	Separated	1.61%
	Divorced	3.23%
	Widowed	0.29%
	Unknown	0.29%
Education Level	Primary	8.21%
	Secondary	36.66%
	College	47.65%
	Post-Graduate	6.89%



The graph above shows the overall STI prevalence detection in the study population across sample type. Notably, TV and MG were detected at slightly higher percentages than CT.

CONCLUSIONS

The enrolled study population (n=634) reflected a diverse number of participants that ranged in age from 17 to 74, an approximately equal male to female ratio, prior STI history, marital status, education level, and ethnicity. Demographic data collected from study participants is presented in Table 1. Participants in this cohort who have previously been diagnosed with an STI had an overall Mycoplasma genitalium prevalence rate that was approximately double those who have not been previously diagnosed with an STI. The p-value results from the null hypothesis significance test showed that for all female specimen types and overall (male female) specimens are statistically significantly different between individuals that were previously diagnosed with a STI versus those who have not been previously diagnosed with a STI, regardless of ethnicity. In male urine, however, a similar relation of MG detection was evaluated and found to not be statistically significant different. Suggesting that for females, prior STI history may be a potential predictive indicator of increased risk of Mycoplasma genitalium infection/transmission.

The clinically relevant cohort of data presented in this study underscore the need to better understand the prevalence and co-infection rate of lesser known, but equally relevant STI pathogens, which may be often overlooked, especially in non-white populations. As more STI prevalence data is collected and analyzed, consideration should be applied to expanding testing algorithms to better comprehend the prevalence of these pathogens in the general population.

REFERENCES

1.Twenge, JM; Sherman, RA; Wells, BE. Declines in Sexual Frequency among American Adults, 1989–2014. Archives of Sexual Behavior 2017; 46:2389-2401.
2.Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2018. U.S. Department of Health and Human Services; 2019.
3.Cleveland Clinic Journal of Medicine. 2019 November;86(11):733-740.
4.Field N, et al. Sex Transm Infect 2018;94:226–229
5.Donders GG, Ruban K, Bellen G, Petricevic L. Mycoplasma/ureaplasma infection in pregnancy: to screen or not to screen. J Perinat Med 2017; 45(5):505–515.
6.Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep 2015; 64(RR-03): 1–137
7.Wangu, Z, Burstein, G R. Adolescent Sexuality: Updates to the Sexually Transmitted Infection Guidelines. Pediatric Clinics of North America 2017; 64:389-411.
8.Anagrius C, Lore B, Jensen JS. Mycoplasma genitalium: prevalence, clinical significance, and transmission. Sex Transm Infect. 2005;81(6):458-62.

ACKNOWLEDGEMENTS

The authors would like to acknowledgethe Abbott Molecular Clinical Affairs team and Statistical support group for their assistance in organizing the data and statistical analysis.