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Performance of self-collected penile-meatal swabs compared to clinician-collected urethral swabs for the detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Mycoplasma genitalium* by Nucleic Acid Amplification Assays

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Abstract

Men were enrolled in a study to assess the performance and acceptability of self-collected penile meatal swabs as compared to clinician-collected urethral swabs for sexually transmitted infections (STIs). We expected penile-meatal swabs to perform favorably to urethral swabs for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG) detection by nucleic acid amplification assays (NAATs). Of 203 swab pairs tested; for CT, penile-meatal swab sensitivity was 96.8% and specificity was 98.8%. NG sensitivity and specificity were 100% and 98.9%, respectively. For TV, sensitivity was 85.0% and specificity was 96.7%. For MG sensitivity and specificity were 79.3% and 99.4%, respectively. No significant statistical differences between sample type accuracy (CT: p=0.625; NG: p=0.248; TV: p=0.344; and MG: p=0.070) existed. Most men, 90.1%, reported self-collection of penile-meatal swabs as “Very Easy” or “Easy”. Self-collected penile-meatal swabs appeared acceptable for NAAT STI detection and an acceptable collection method by men.

Keywords

Chlamydia trachomatis; *Neisseria gonorrhoeae*; *Trichomonas vaginalis*; *Mycoplasma genitalium*; self-collection; penile-meatal swabs; acceptability

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Introduction

Sexually transmitted infections (STIs) are a significant health burden in the United States which cost \$10–17 billion annually due to a prevalence of 110 million cases including 19 million new cases per year (Satterwhite 2013 and Owusu-Edusei 2013). *Chlamydia trachomatis* (CT) is the most prevalent of notifiable STIs with 1,401,906 cases reported to the Centers of Disease Control and Prevention (CDC), followed by *Neisseria gonorrhoeae* (NG) with 333,004 cases reported in 2013 (CDC 2014). *Trichomonas vaginalis* (TV) and *Mycoplasma genitalium* (MG) are STIs that also affect individuals in the United States, however, their exact prevalence is unknown because they are not reportable STIs to the CDC. Both TV and MG are a cause of urethritis in men and it is estimated that TV affects 7–8 million people in the United States and 180 million globally (*MMWR-STD Treatment Guidelines 2015*; Gaydos 2013). There is evidence that MG might have a role in increasing human immunodeficiency virus (HIV) infection risk and can also cause balanoposthitis and prostatitis (Daley 2014). STI testing recommendations by the CDC recommend yearly screening for chlamydia in sexually active women <25 years, but there are no current recommendations for yearly screening in heterosexual men; screening and subsequently treating men may greatly reduce the financial burden of STIs as well as decrease partner transmission. There are however recommendations for yearly screening of sexually active men who have sex with men (MSM) for chlamydia and gonorrhea (*MMWR-STD Treatment Guidelines 2015*). Current methods of screening men for STIs consist of either the collection of a urethral swab by a clinician for STI detection by culture or NAAT or the collection of first pass urine for testing by NAATs; however self-collected penile-meatal swabs could decrease wait times and expedite diagnosis and treatment in busy clinics (Potter 2014). Urethral swabs or urine sediment incubated in InPouch^{TM} TV and examined under a microscope for the presence of trichomonas is the current gold standard diagnostic for diagnosing men for TV. There are now also now 3 FDA cleared NAAT assays for the detection of TV (*MMWR-STD Treatment Guidelines 2015*). Self-collected penile swabs have been evaluated compared to urine using NAATs in research studies, but have not yet been compared to clinician-collected urethral swabs. Men are often hesitant to seek testing for STIs due to the pain associated with the collection of a urethral swab specimen; if men would self-collect their own penile swab specimen for STI testing, more men might seek testing and this approach could save valuable clinician time. We hypothesized that penile swabs would perform as well as urethral swabs for detection of STIs such as CT, NG, TV, and MG and that men would find the self-collected penile-meatal swab as an acceptable sample type for STI testing.

Materials and Methods

This study was approved by the Johns Hopkins School of Medicine Institutional Review Board and the Baltimore City Health Department and 203 enrolled male participants signed a written informed consent form.

Collection

Men having clinician-collected urethral swabs for gonorrhea culture in the STD clinic in Baltimore, MD, were also asked to obtain a self-collected a penile-meatal swab after the urethral swab for detection of CT, NG, TV and MG by NAAT assays. The men that were having a urethral swab collected for culture had visited the STD clinic because they were either symptomatic or asymptomatic but reported to have an STI contact. The collection of samples was not randomized, the urethral swab was always taken first because the participants saw the clinician prior to being informed of the study. Men were given a \$10.00 gift card after completion of swab collection. After the culture/Gram stain was performed, the clinician-collected urethral swabs were placed into an APTIMA® Swab specimen Transport Tube (Hologic, San Diego, CA) to be delivered for NAAT testing to the Johns Hopkins University Sexually Transmitted Diseases Research Laboratory. Consented subjects were then given a kit including a set of written instructions with a diagram, in addition to verbal instructions with a visual aid to privately self-collect a penile-meatal swab using a dry Copan Ultrathin Flocked Swab (part no. 560C) (Copan, Brescia, Italy). After collection the swab was placed back in the plastic Copan transport tube and transported dry (Gaydos 2012) to the STD research laboratory. Penile-meatal swab specimens were placed in an APTIMA® Swab specimen Transport Tubes within 24 – 48 hours after arrival to the laboratory. Penile-meatal swabs and urethral swabs were assigned the same study number with either a U (urethral) or P (penile) prefix for pair identification.

Laboratory Testing

Testing for CT and NG was performed in real time as the samples arrived in the laboratory using the APTIMA Combo 2 (AC2) NAAT assay on the Panther platform (Hologic, San Diego, CA). All samples were then capped and frozen for retrospective TV and MG testing using a NAAT assay for TV, the APTIMA *Trichomonas vaginalis* (ATV) assay on the Panther platform (Hologic, San Diego, CA) and an APTIMA Analyte-specific reagents (ASR) NAAT assay for MG; a relative light unit (RLU) of 60,000 or greater was the cutoff used to determine positive specimens by the MG ASR. Penile-meatal swabs are not an FDA cleared sample type for the APTIMA Combo 2 assay while urethral swabs are. Neither the penile-meatal swab nor urethral swab is an FDA cleared sample type for the APTIMA *Trichomonas* or ASR MG assay. Pairs that had discordant results for either CT or GC were tested by another NAAT assay, the Cepheid Xpert CT/NG Assay (Sunnyvale, CA) (Gaydos 2013). Discordant pairs for TV and MG were tested by an in-house research PCR (Hardick A 2006 and Hardick J 2006).

Acceptability Survey

After participants had a urethral swab collected by the clinician and self-collected their penile-meatal swab they were given a short survey to gain information about sexual history, ease of use in self-collecting a penile-meatal swab specimen and willingness to pay for a potential Over-the-Counter (OTC) collection kit or having a diagnostic self-collection penile swab kit mailed to them.

Data Analysis

Data were summarized in percentages using descriptive data analysis. Sensitivity and specificity and the corresponding 95% confidence intervals of the self-collected penile swab NAAT to each STI were calculated using the clinician-collected urethral swab NAAT as the gold standard. The urethral swab was utilized as the gold standard sample type because it is the recommended sample type when performing culture for GC as well as being a FDA cleared sample type for the APTIMA AC2 assays. Kappa statistics were not calculated because the primary goal of comparing self-collected penile swabs to clinician-collected urethral swabs, which was used as the gold standard, was to determine accuracy of the assay with self-collected penile swabs rather than the inter-reliability between two technicians or two methods neither of which are the gold standard. The positive rates of two sets of the discrepant result samples confirmed by a second NAAT (urethral swab positive/penile swab negative versus urethral swab negative/penile swab positive) were compared using the Fisher's exact test. All statistical analyses were performed using SAS version 9.3 (SAS Institute Inc, Cary, NC).

Results

Demographics for the men surveyed: Ages of participants were, 17–20 yr. (8.4%), 21–30 yr. (48.3%), 31–40 yr. (16.2%), 41–50 yr. (9.3%), and 51 yr. and older (15.8%). Race included 93.6% black, 2.4% white, Asian/Pacific Islander accounted for 0.5%, and 1.5% were Hispanic. Previous STI infections were self-reported as: 38.4% of men had a previous CT infection, NG 28.6%, TV 7.4%, herpes 4.4%, and syphilis 6.4%. Previous history was also included in the survey of which 96% reported ever having been tested for HIV and condom use was reported as never (13.8%), sometimes (35.5%), most of the time (32.5%), and always (16.2%). Men surveyed also reported their number of sexual partners in the past 90 days to be: 0 partners (4.0%), 1 (50.2%), 2–4 (38.0%), 5–9 (3.4%), and more than 10 partners (2.0%). On the day of visit 62.5% reported symptoms (Table 1).

From 203 paired urethral/penile swabs that were tested for CT, NG, TV and MG; there were 32 penile swabs positive for CT (15.8%), 31 urethral positives for CT (15.3%); for CT, penile swabs had a sensitivity of 96.8% (30/31) and a specificity of 98.8% (170/172) as compared to test results from urethral swabs. Penile swabs tested for NG had a sensitivity and specificity of 100% (27/27) and 98.9% (174/176) respectively, with 29 penile positives for NG (14.3%) and 27 urethral positives for NG (13.3%). There were 23 penile positives for TV (11.3%) and 20 urethral positives for TV (9.8%); penile swabs for TV had a sensitivity of 85.0% (17/20) and specificity of 96.7% (177/183) as compared to urethral swabs. 24 penile swabs were positive for MG (11.8%) and 29 urethral swabs were positive for MG (14.3%). The sensitivity and specificity for penile swabs for MG was 79.3% (23/29) and 99.4% (173/174) respectively, as compared to urethral swabs. Results from most penile swabs and urethral swabs agreed. Discordant results included: 2 swab pairs that were penile +/-urethral- for CT, 1 was penile-/urethral + for CT; 2 pairs were penile+/urethral- for NG; 6 pairs were penile+/urethral- for TV and 3 were penile-/urethral+ for TV. Six pairs were penile-/urethral+ for MG and 1 pair was penile+/urethral- for MG. (Table 2) There were no statistically significant differences between results from self-collected penile-urethral swabs

and clinician-collected urethral swabs for NAATs ($p=0.248$ for NG; $p=0.625$ for CT; $p=0.344$ for TV; and $p=0.070$ for MG). Table 3 shows the results of the second NAAT assay on sample pairs that had discordant results. None of the 10 urethral swab positive but penile swab negative samples tested positive by a second NAAT while 64% (7/11) of urethral swab negative but penile swab positive samples did test positive by a second NAAT ($p=0.006$).

Of the 203 men in this study, 199 (98.0%) completed the survey. Results showed men rated ease of use in the following ways, 58.1% graded the penile swab “very easy” to use, 32% as “easy”, and 7.9% as “Okay”; no men selected “hard” or “very hard” to self-collect a swab. If an OTC self-collection and self-testing penile-meatal kit were offered, 69.4% of men would be willing to pay \$10, 15.7% would pay \$20, 6% would pay \$30, 1.5% would pay \$40, and 5.4% would pay \$50 or more. Similarly, if a self-collection penile-meatal swab and mail-in collection kit were to exist, 68% would pay \$10, 17.2% would pay \$20, 6.4% would pay \$30, 1% would pay \$40, and 5.4% would pay \$50 (Table 4).

Discussion

This study demonstrated that there was no statistical significance between the self-collected penile-meatal swab and the clinician-collected urethral swab for the detection of CT, NG, TV, or MG by NAAT assays and indicated that allowing men to self-collect a penile-meatal swab specimen may be adequate for STI screening for various sexual infections. Men are often hesitant to get tested for STIs due to the invasive nature and pain often experienced during the urethral swab collection procedure; this method requires the insertion of a swab approximately 2–3 cm into the male urethra for proper sample collection (MMWR Laboratory Guidelines, 2014). A penile-meatal swab is not as invasive as a urethral specimen and consists of placing the tip of the swab right at the urethral-meatal opening and rolling the swab around the opening in order to collect moisture to get an adequate sampling. Men also appear comfortable with the self-collection procedure of penile-meatal swabs with 90.1% of men reporting the penile-meatal swab be “very easy” or “easy” to collect.

Sexual health awareness and responsibility for one’s own sexual health is rapidly becoming a widely accepted concept (Hesse 2014 and Gaydos 2016). Self-sampling can be beneficial for many reasons including screening asymptomatic persons and testing more people who are reluctant to visit a clinic due to inaccessibility, privacy concerns, discomfort, and time needed to attend a clinic (Paudyal 2015). Similarly to what was found in our study that 90.1% of men surveyed stated that self-collection was ‘very easy’ or ‘easy’ to use, there have been twenty-eight studies that looked at ease of use on various self-sampling methods and found on average that 88% of people found self-sampling to be ‘very easy’, or ‘easy’ to perform (Paudyal 2015). Not only did men find this sampling technique to be acceptable and easy to perform but 85.8% of men would pay \$10 – 20 for an over-the-counter (OTC) type of self-test kit in the future if one were to become available and 85.7% would pay for a self-collection mail-in type of kit. There are various programs now that utilize self-sampling techniques for both men and women for STI testing through mail-in collection kits as well as kits that can be dropped off after the participant collects their own sample (Owens 2010). Home collection provides a way for more persons to be screened for STIs and is often preferred over attendance to a clinic (Hesse 2014). Mailing of penile-meatal swabs can

greatly reducing leaking associated with mailing/shipping of urine specimens. Penile-meatal swabs can also be used as a collection method at non-traditional settings where bathroom facilities are limited, such as health fairs and community outreach. It has also been previously reported in a study of 634 matching self-collected penile-meatal (penile) swab/urine pairs that swabs identified more CT, NG and TV than urine samples by a NAAT assay (Chai 2010, Dize 2013). Although there are no current recommendations for routine screening of heterosexual men for CT and NG, screening and subsequently treating men in certain populations could help prevent costly sequelae in their female partners. There are recommendations for screening men who have sex with men (MSM) due to their increased risk for HIV and other STIs (MMWR Treatment Guidelines 2015). Utilizing self-collection swab techniques in men for STI detection could speed up clinic visits and screen more people in clinics that are offering “express visits” due to budget cuts (Dize 2015 and Golden 2010). Of the 32.5% of men who reported having no symptoms on the day of their clinic visit, 28.8% of those tested positive for having at least one infection. Express visits are often used for asymptomatic persons coming into an STD clinic, if these men are not seen by a clinician and screened for STIs during their visit, these infections can go undiagnosed and untreated. Self-collection of penile-meatal swab samples would be beneficial in these express visit scenarios.

As evident in Table 3, 64% (7/11) of penile swab positive samples also tested by positive by a second NAAT assay during discrepant testing while 0% of the urethral swab positives tested positive by a second NAAT, based on the data it is possible that participants may have been more thorough at collecting their specimens than the clinicians. This could be due to patients feeling responsible for their own sexual health and making sure to exhibit good sampling technique when collecting their specimen. The urethral swab was always collected first, this further indicates increased sensitivity of the penile swab. However, none of the assays utilized are FDA cleared for penile swab testing so we cannot definitively say if this was due to collection method, self vs. clinician, or sample type, penile vs. urethral. Factor that could also contribute to the absence of confirmation of urethral swab positives by a second NAAT include the urethral swabs being processed for culture and gram stain prior to NAAT testing, the nature of the processing could have reduced the number of organisms present on the urethral swab. Due to the APTIMA transport tubes being stored after CT/NG testing and having undergone a freeze thaw. Additional testing comparing urethral swabs and penile swabs should be performed with removal of the culture processing step to reduce bias between sample types.

There are limitations to this study. Since the men were seen at an STD clinic and were having urethral swabs obtained, most were symptomatic (62%) or were being tested as a STI contact, the willingness to self-collect may not be as high as if testing were performed in an asymptomatic group of men. Additionally, the results of the penile-meatal swab may be less accurate in an asymptomatic group of men; more research is needed in asymptomatic men. However, in our prior studies the self-collected penile-meatal swab performed well compared to urine samples in a group of men from whom, only 38% reported symptoms and self-collection for mail in of swabs appeared to be acceptable. (Chai 2010). A 2015 review done by Vodstrcil et al shows that there is a positive association between bacterial load and symptomatic infection (Vodstrcil 2015), however we do not know the bacterial load of

positive persons in this study and cannot infer if the organism load is higher in symptomatic men than asymptomatic men in this population. There are factors other than bacterial load that can affect clinical presentation of symptoms such as HIV status, age, and sex. Also, the penile-meatal swab is a flocked swab made out of nylon fibers which may have been better at collecting cells and organisms whereas the urethral swab is non-flocked and has a polyester tip applicator. To better assess how self-collected penile-meatal swabs perform as compared to clinician-collected urethral swabs further research studies should be performed with a randomization scheme as well as utilizing swabs of the same material and design to reduce bias.

In summary, self-collected penile swabs appeared to be an acceptable sample type for the detection of CT, NG, TV, and MG by NAAT assays in the group of mostly symptomatic men and were an acceptable and easy to use sample type according to the men in this study. This self-collection process could expedite express visits in a busy STD clinic and identify more infections than if these men were not screened. Penile swabs also show promise as a method of utilizing one sample type for multiple STIs and allowing men to feel more responsible for taking charge of their own sexual health.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- We show that penile-meatal swabs appear to be an acceptable sample type.
- Compared to urethral swabs, penile-meatal swabs performed well.
- Men are willing to collect their own swab sample and find it easy to perform.

Table 1

Demographic information of 203 male participants who self-collected a penile-meatal swab and had a clinician-collected urethral swab.

Characteristics	Category	Number (%) N=203*
Age (years)	17–20	17 (8.4)
	21–30	98 (48.3)
	31–40	33 (16.2)
	41–50	19 (9.3)
	51+	32 (15.8)
Race	Black	190 (93.6)
	White	5 (2.4)
	Asian/Pacific Islander	1 (0.5)
	Hispanic	3 (1.5)
Previous STI Infection	CT	78 (38.4)
	GC	58 (28.6)
	TV	15 (7.4)
	HSV	9 (4.4)
	Syphilis	13 (6.4)
Condom Use	Never	28 (13.8)
	Sometimes	72 (35.5)
	Most of the Time	66 (32.5)
	Always	33 (16.2)
# of Partners in the Past 90 days	0	8 (4)
	1	102 (50.2)
	2–4	78 (38)
	5–9	7 (3.4)
	10	4 (2)
Day of Visit Symptoms	Yes	127 (62.5)
	No	66 (32.5)
	Not Reported	6 (3)

* Missing survey results for 4 (2%) participants.

Table 2

Comparison of self-collected penile swabs to clinician collected urethral swabs tested by NAATs for the detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Mycoplasma genitalium*.

STI	Number of Paired Specimens Tested	Number of Specimens with Results				% Sensitivity (CI ^b)	% Specificity (CI ^b)
		U+/P+ ^a	U-/P-	U+/P-	U-/P+		
<i>Chlamydia trachomatis</i>	203	30	170	1	2	96.8 (81.4 – 99.8)	98.8 (95.4 – 99.7)
<i>Neisseria gonorrhoeae</i>	203	27	174	0	2	100 (84.4 – 100)	98.9 (95.5 – 99.8)
<i>Trichomonas vaginalis</i>	203	17	177	3	6	85.0 (61.1 – 96.0)	96.7 (92.6 – 98.6)
<i>Mycoplasma genitalium</i>	203	23	173	6	1	79.3 (59.7 – 91.2)	99.4 (96.3 – 99.9)

^a“U” is the reference method result (urethral swab), and “P” is the comparative method result (penile-meatal swab). “+” is a positive result, and “-” is a negative result.

^b 95% confidence intervals for overall agreement of the reference method and the comparative method.

TABLE 3

Discordant analysis of self-collected penile-meatal/clinician-collected urethral swab pairs by a second NAAT test.

STI	Number of Discordant Pairs	Discordant Results		Positive by a second NAAT	
		U+/P ^a –	P+/U–	U+	P+
<i>Chlamydia trachomatis</i>	3	1	2	0	1
<i>Neisseria gonorrhoeae</i>	2	0	2	0	2
<i>Trichomonas vaginalis</i>	9	3	6	0	3
<i>Mycoplasma genitalium</i>	7	6	1	0	1

^aU– is the reference (urethral swab) method result, and P+ is the comparative (penile-meatal swab) method result, and “–”, “+” is a positive result, and “–” is a negative result.

TABLE 4

Acceptability of the self-collected penile-meatal swab type assessed by male participants in this study.

Questions	Response	Number (%) N=203*
Ease of Collection	Very Easy	118 (58.1)
	Easy	65 (32)
	Ok	16 (7.9)
	Hard	-
	Very Hard	-
Willingness to pay for Over the Counter kit	\$10	141 (69.4)
	\$20	32 (15.7)
	\$30	12 (6)
	\$40	3 (1.5)
	\$50+	11 (5.4)
Willingness to pay for home mail-in kit	\$10	138 (68)
	\$20	35 (17.2)
	\$30	13 (6.4)
	\$40	2 (1)
	\$50+	11 (5.4)

* Missing survey results for 4 (2%) participants.