Performance of Self-collected penile swabs for the detection of Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, and Mycoplasma genitalium

Charlotte A. Gaydos, MS, MPH, DrPH
Professor
Division of Infectious Diseases
Johns Hopkins University
Baltimore, Maryland, USA

Disclosures

• I have received funding for research grants and have been a lecturer for Becton Dickinson, Gen-Probe/Hologic, Abbott Molecular Diagnostics, Siemens Health Care Diagnostics, Sekisui, and Cepheid

Background

• Clinician-collected urethral swabs are used for culture of gonorrhea (NG) in males and for detection of chlamydia (CT) and NG by NAATs

• We hypothesized self-collected penile-meatal swabs would perform as well as urethral swabs for detection of CT, NG, trichomonas (TV) and mycoplasma (MG) and that they would be acceptable to males

Methods

• Men having urethral swabs obtained for NG culture in the STD clinic volunteered to collect penile-meatal swabs

• Urethral swabs and paired penile-meatal swabs were placed into separate transport media for testing by NAATS

• NAATs were performed for CT, NG, TV, and MG for urethral and penile-meatal swab pairs

• Acceptability questionnaires were given

• Gram Stain & culture results for GC determined

Results

Of 203 paired urethral/penile-meatal swabs:

- CT: 32 penile positive (15.8%)
  31 urethral positive (15.3%)
- NG: 29 penile positives (14.3%)
  27 urethral positives (13.3%)
- TV: 23 penile positives (11.3%)
  20 urethral positives (9.9%)
- MG: 24 penile were positive (11.8%)
  29 urethral were positive (14.3%)

Race: 93.6% Black
Symptoms: 62.5% Symptomatic
Age (years)
- 17-20: 8.4%
- 21-30: 48.8%
- 31-40: 16.2%
- 41-50: 9.3%
- >50: 15.8%
PN last 90 days
- 1: 50%
- 2-4: 38%
- 5-9: 3.4%
Condom Use: Never: 13%
Results

Table 1. *Chlamydia trachomatis*

<table>
<thead>
<tr>
<th></th>
<th>Urethral Positive</th>
<th>Urethral Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penile Positive</td>
<td>30</td>
<td>2</td>
</tr>
<tr>
<td>Penile Negative</td>
<td>1</td>
<td>170</td>
</tr>
</tbody>
</table>

Sensitivity: 96.8%
Specificity: 98.8%
PPV: 93.8%
NPV: 99.4%

Table 2. *Neisseria gonorrhoeae*

<table>
<thead>
<tr>
<th></th>
<th>Urethral Positive</th>
<th>Urethral Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penile Positive</td>
<td>27</td>
<td>2</td>
</tr>
<tr>
<td>Penile Negative</td>
<td>0</td>
<td>174</td>
</tr>
</tbody>
</table>

Sensitivity: 100%
Specificity: 98.9%
PPV: 93.1%
NPV: 100%

Of the 29 urethral/penile NG NAAT positives, 25 were positive by Gram Stain and 21 were positive by culture.

Table 3. *Trichomonas vaginalis*

<table>
<thead>
<tr>
<th></th>
<th>Urethral Positive</th>
<th>Urethral Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penile Positive</td>
<td>17</td>
<td>6</td>
</tr>
<tr>
<td>Penile Negative</td>
<td>3</td>
<td>177</td>
</tr>
</tbody>
</table>

Sensitivity: 85.0%
Specificity: 96.8%
PPV: 73.9%
NPV: 98.3%

Table 4. *Mycoplasma genitalium*

<table>
<thead>
<tr>
<th></th>
<th>Urethral Positive</th>
<th>Urethral Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penile Positive</td>
<td>23</td>
<td>1</td>
</tr>
<tr>
<td>Penile Negative</td>
<td>6</td>
<td>173</td>
</tr>
</tbody>
</table>

Sensitivity: 79.3%
Specificity: 99.4%
PPV: 95.3%
NPV: 96.6%

Results

- There were no significantly statistical differences in accuracy between self-collected penile swabs and clinician-collected urethral swabs for NAATs
  - p=0.625 for CT
  - p=0.248 for NG
  - p=0.344 for TV
  - p=0.070 for MG

Acceptability (n = 199)

- 100% of men preferred penile-meatal swabs for diagnosis of STIs

Survey Question | Very Easy | Easy | OK | Hard | Very Hard |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease Of Use</td>
<td>58.1%</td>
<td>32%</td>
<td>7.9%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Pay for OTC home test

- $10
- 69.4%

Pay for Mail-in sample kit

- $10
- 68.0%
Conclusions

- Penile-meatal swabs appeared to be as accurate as urethral swabs for CT, NG, TV and MG detection
- Preference for self-collection over urethral swabs was 100%
- Such self-collected swabs could expedite express visits in STD clinics
- They show promise as a method of utilizing one sample for multiple STIs

Acknowledgements Co-Authors

- Laura Dize
- Mathilda Barnes
- Perry Barnes
- Yu-Hsiang Hsieh
- Della Duncan
- Vince Marsigila