Trichomonas vaginalis Nucleic Acid Clearance Following Treatment of HIV Negative Women

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Disclosure: Consultant to Hologic/Gen-Probe

Trichomonas vaginalis

Diagnosis

• Wet mount
• Culture
• Point of care antigen detection
• DNA probes
• Nucleic acid amplification tests

Gen-Probe Aptima Trichomonas vaginalis (GPATV) Assay

• Targets ribosomal RNA.
• Chemistry - transcription mediated amplification.
• High sensitivity and specificity
• FDA cleared and EU CE marked

Study Design

• Primary study – Randomized trial of the single 2 gram dose of metronidazole vs. the 500 mg twice daily for 7 days regimen in HIV negative women.
• This sub study was designed to determine rate of clearance of rRNA following treatment.
  – Enrolled women returned to clinic to self obtain a vaginal swab weekly for 4 weeks.
  – Sexual histories were obtained at each visit and women were excluded from further participation following unprotected sexual intercourse.
  – Specimens were tested using the GPATV assay
Patient Population

- 65 women enrolled in the randomized treatment trial agreed to participate in the clearance study.
- One woman withdrew from the study and 3 were withdrawn for non-compliance with treatment.
- 4 women did not return for any follow-up visits.

Characteristics of the 57 women completing at least 1 follow-up visit

- 96% were African American.
- Mean age was 31.2 +/- 10.9 years
- Nugent score distribution:
  - Normal 3 (5%)
  - Intermediate 24 (47%)
  - BV 30 (53%)
- Treatment assignments
  - Single dose 35 (61%)
  - 7 day course 22 (39%)

Women Censored from the Clearance Study

- Five women were culture positive at the first or second follow-up visit and were dropped.
- An additional 5 had unprotected sex prior to the first return visit.
- 47 women returned for at least one follow-up visit prior to sexual re-exposure.

Results

<table>
<thead>
<tr>
<th>Visits</th>
<th>Total Evaluable</th>
<th>TMA Positive</th>
<th>% Clearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>38</td>
<td>8</td>
<td>79%</td>
</tr>
<tr>
<td>Week 2</td>
<td>34</td>
<td>1</td>
<td>97%</td>
</tr>
<tr>
<td>Week 3</td>
<td>26</td>
<td>0</td>
<td>100%</td>
</tr>
<tr>
<td>Week 4</td>
<td>28</td>
<td>0</td>
<td>100%</td>
</tr>
</tbody>
</table>

Clearance of *T. vaginalis* DNA Detected by PCR

<table>
<thead>
<tr>
<th>Days Since Treatment</th>
<th>Cumulative Clearance Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6</td>
<td>40%</td>
</tr>
<tr>
<td>7-13</td>
<td>75%</td>
</tr>
<tr>
<td>8-20</td>
<td>86%</td>
</tr>
<tr>
<td>21-27</td>
<td>93%</td>
</tr>
<tr>
<td>28-34</td>
<td>97%</td>
</tr>
</tbody>
</table>

Conclusions

- Within 3 weeks following completion of metronidazole treatment *T. vaginalis* rRNA as measured by the GPATV assay appears to be cleared from vaginal secretions
- If these data can be confirmed, this assay may be useful for *T. vaginalis* tests-of-cure.

Prevalence *T. vaginalis* detected by Culture in 394 Women Evaluated at the New Orleans STD Clinic Stratified by Nugent Score

Gen-Probe Second Generation
APTIMA™ Assays

- Target Capture sample processing partially purifies target nucleic acid
- Transcription-Mediated Amplification—amplifies target
- Dual Kinetic Assay (DKA) technology simultaneously detects two organisms