Micro-Ultrasound Imaging of Men with Family History of Prostate Cancer: Subpopulation Analysis from a Multi-Institution Randomized Clinical Trial

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OBJECTIVE
To investigate the relative efficacy of high-frequency 29 MHz transrectal micro-ultrasound (“micro-US”) to conventional low-frequency 7–12 MHz transrectal ultrasound (“conv-US”) in men with self-reported family history of prostate cancer.

METHODS
• 1,676 men without known prostate cancer were randomized 1:1 to micro-US or conv-US guided biopsy at 5 sites in North America from 2013-16
• Exactly 12-cores were taken transrectally from each subject
• Each core taken systematically or from a target near the systematic position.

RESULTS
• Men with Positive Family History:
  - Conv-US arm: 203/839 (24%)
  - Micro-US arm: 180/837 (22%)
• Family History positive men had a lower risk profile
  - PSA 5.4 vs 6.2 (p<0.001)
  - Age 61 vs 64 (p<0.001)
• No significant differences in age or PSA between the family history positive conv-US or micro-US groups (PSA p=0.31, age p=0.76)
• Clinically significant cancer rate in micro-US arm was significantly higher than in conv-US arm (43% vs. 30% p=0.004)
• Relative improvement of 45% higher than improvement seen in full population

CONCLUSIONS
• Micro-US detected more significant prostate cancers than conv-TRUS in men with positive family history
• Since the same number of biopsy samples were taken, the accuracy of micro-ultrasound targeting appears improved in these men; though the reasons for this remain unclear
• Further work will be required to confirm this phenomenon and identify the causes.

Table 1: Comparison of the Family History (FH) positive and negative groups. The FH+ group showed slightly lower risk indicators, but achieved the same csPCa detection rate overall

<table>
<thead>
<tr>
<th>Demographic</th>
<th>FH+</th>
<th>FH-</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>61</td>
<td>64</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PSA</td>
<td>5.4</td>
<td>6.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DRE abnormal</td>
<td>66%</td>
<td>71%</td>
<td>0.86</td>
</tr>
<tr>
<td>Prior negative biopsy</td>
<td>15%</td>
<td>17%</td>
<td>0.36</td>
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<tr>
<td>Prostate volume</td>
<td>41cc</td>
<td>43cc</td>
<td>0.06</td>
</tr>
<tr>
<td>csPCa rate</td>
<td>36%</td>
<td>36%</td>
<td>0.98</td>
</tr>
</tbody>
</table>

Figure 1: First-generation ExactVu™ micro-ultrasound system used in this study

Figure 2: Micro-US demonstrated a significantly higher csPCa rate compared to conv-US in the FH+ subpopulation (p=0.004)

Figure 3: Micro-US image showing PRI-MUS 5 mixed echo lesion positive for csPCa