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

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1,676 men presenting for prostate biopsy at 5 sites

1:1 randomization

12-core biopsy using conventional ultrasound

12-core biopsy using ExactVu micro-ultrasound

29 MHz micro-ultrasound provides a 300% improvement in resolution to 70 microns.

Provides a more sensitive approach to detect prostate cancer than conventional ultrasound

First-generation micro-ultrasound system used in this study

Second-generation micro-ultrasound system now used clinically
RESULTS

- 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)
  - But family history positive group lower risk than family history negative group (Age and PSA lower p<0.001)
- Clinically significant cancer rate in micro-US arm higher than in conv-US arm (43% vs. 30% p=0.004)

Micro-US may be more sensitive in men with positive family history and offer a more dramatic benefit over conventional ultrasound in this risk group.

<table>
<thead>
<tr>
<th>Demographic</th>
<th>FH+</th>
<th>FH-</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>61</td>
<td>64</td>
<td>&lt;0.001</td>
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<tr>
<td>PSA</td>
<td>5.4</td>
<td>6.2</td>
<td>&lt;0.001</td>
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<tr>
<td>DRE abnormal</td>
<td>66%</td>
<td>71%</td>
<td>0.86</td>
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<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>
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<td>csPCa rate</td>
<td>36%</td>
<td>36%</td>
<td>0.98</td>
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