

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



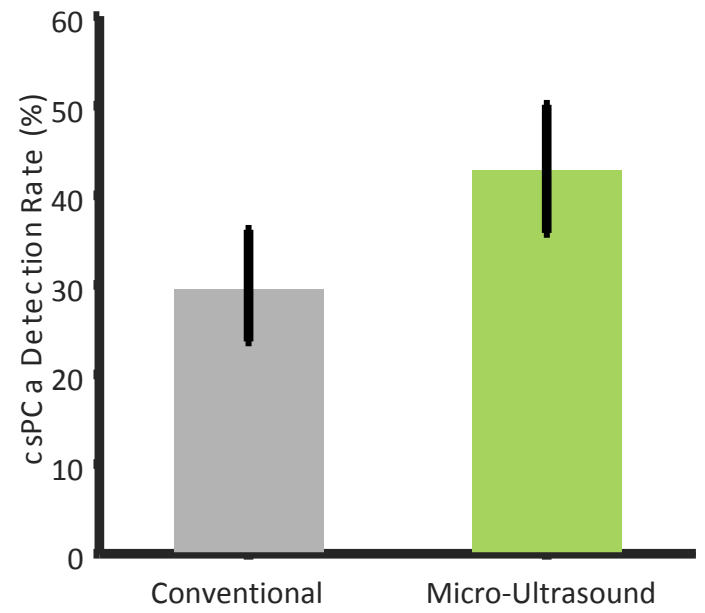
Second-generation micro-ultrasound system now used clinically



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



Demographic	FH+	FH-	p-value
Age	61	64	<0.001
PSA	5.4	6.2	<0.001
DRE abnormal	66%	71%	0.86
Prior negative biopsy	15%	17%	0.36
Prostate volume	41cc	43cc	0.06
csPCa rate	36%	36%	0.98