

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.
- Clinically significant prostate cancer was defined as any Gleason Grade Group > 1 and/or any core with > 50% cancer

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



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

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

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

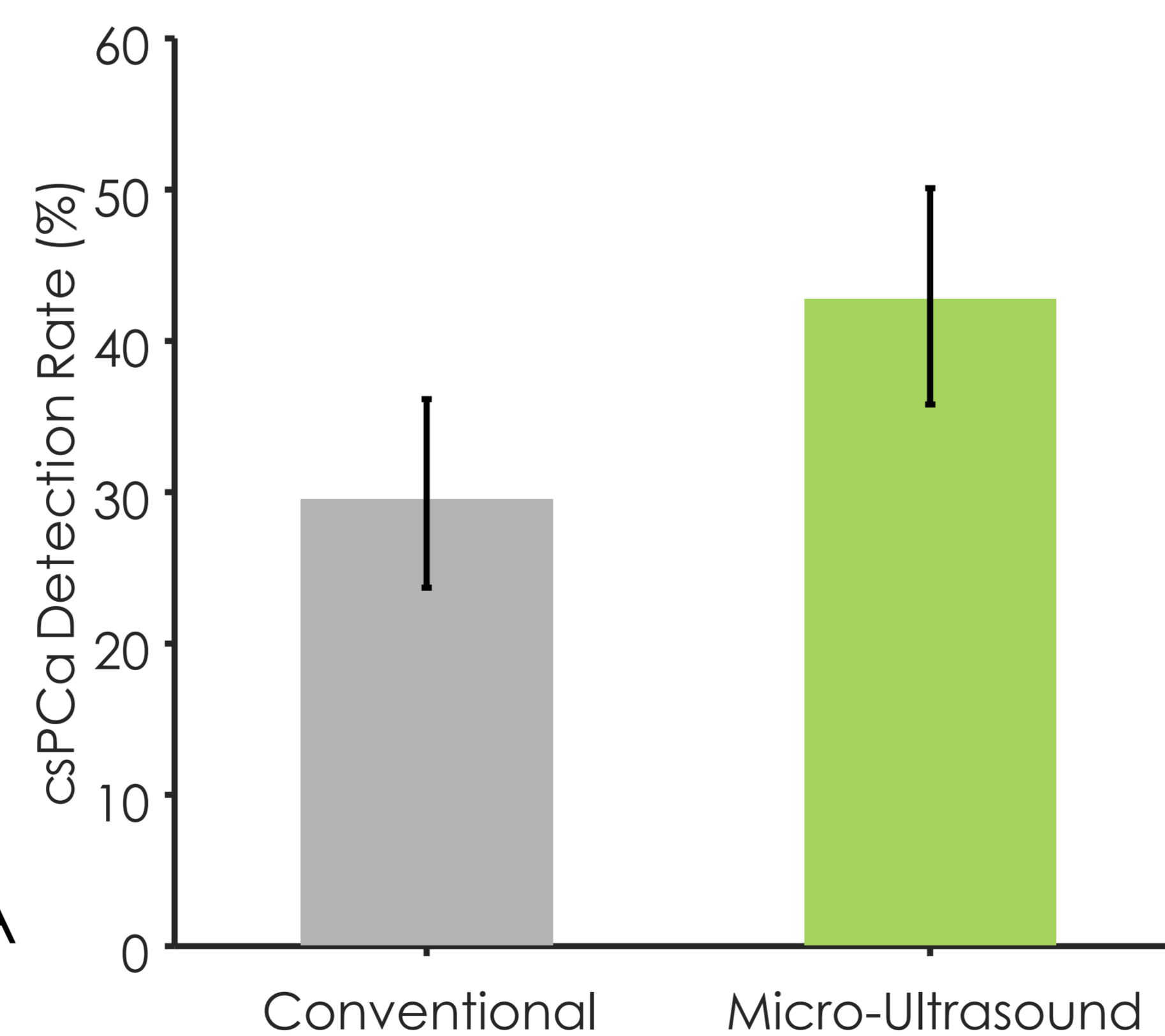


Figure 2: Micro-US demonstrated a significantly higher csPCa rate compared to conv-US in the FH+ subpopulation (p=0.004)

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.

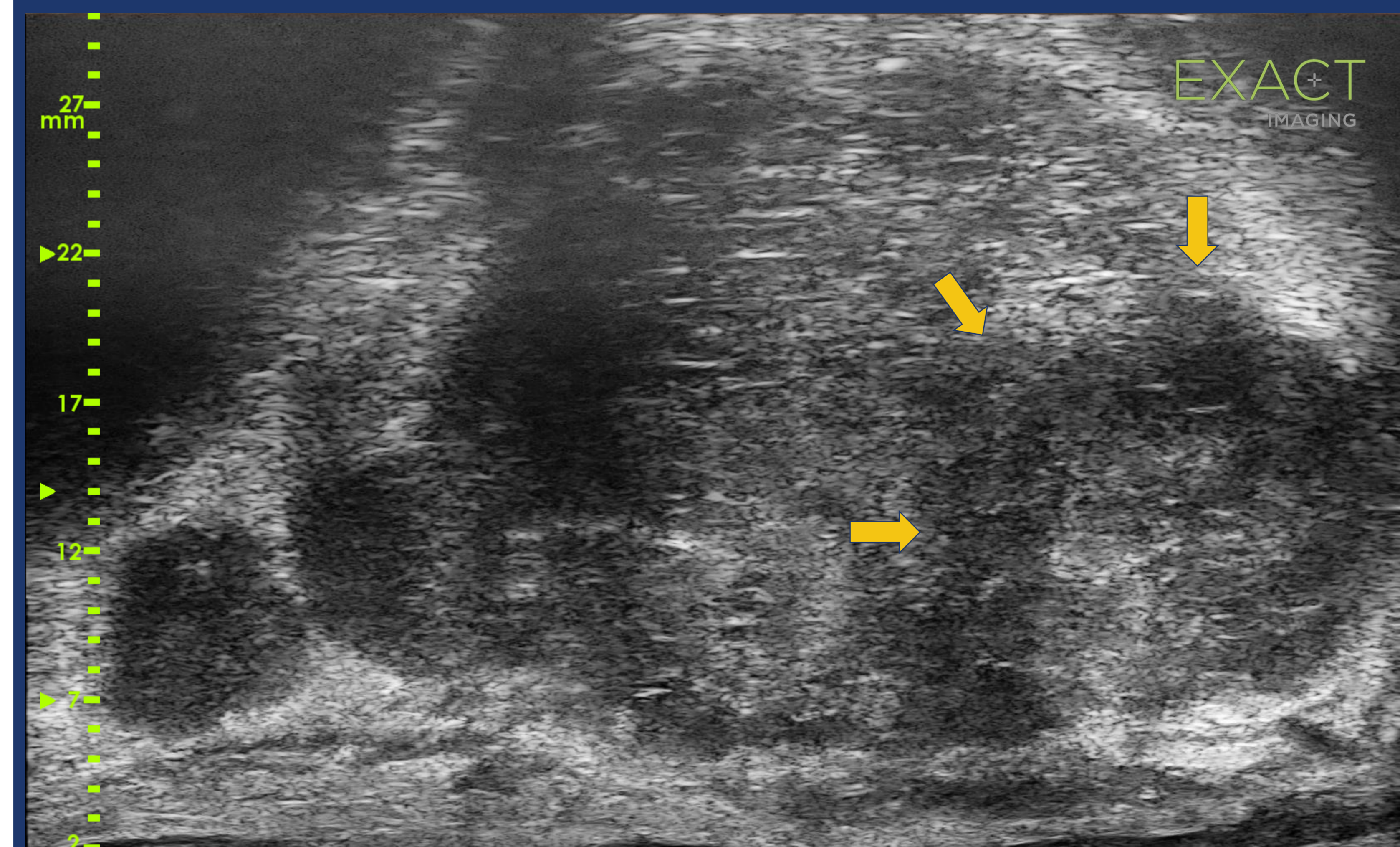


Figure 3: Micro-US image showing PRI-MUS 5 mixed echo lesion positive for csPCa