Comparison of Conventional TRUS, MRI and Micro-Ultrasound for Visualizing Prostate Cancer in an Active Surveillance Population: A Feasibility Study

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Introduction & Objectives

Active Surveillance monitoring of prostate cancer provides unique clinical challenges in that most patients have low grade disease which is not well visualized by any common imaging technique.

This study compares high resolution (29 MHz) micro-ultrasound imaging with mpMRI and conventional ultrasound for visualizing prostate cancer in an active surveillance program.

Methods:

- 9 patients on active surveillance were imaged with mpMRI prior to biopsy (*Figure 1*)
- After target identification with conventional and micro-ultrasound (**ExactVu™**, Exact Imaging), the mpMRI report was un-blinded and cognitive fusion (using micro-ultrasound) was used to locate targets identified by all modalities. The **PRI-MUS™** (**p**rostate **r**isk **i**dentification using **m**icro-**u**ltra**s**ound) protocol[1] was used to assess micro-ultrasound images, while **PI-RADS™** v2 was used for mpMRI
- Using micro-ultrasound, biopsy samples were taken from targets in each modality, in addition to 12 systematic samples

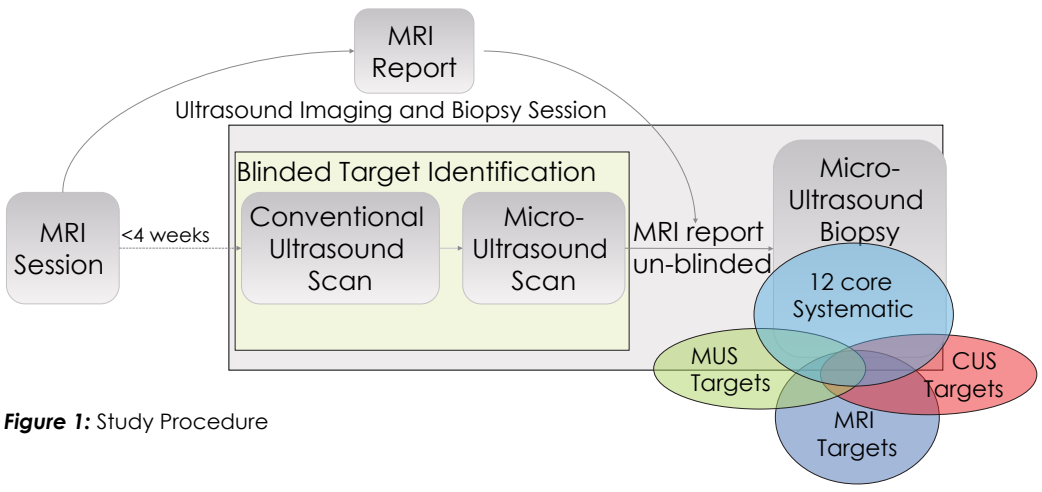

Figure 1: Study Procedure

	Positive Micro-Ultrasound	Negative Micro-Ultrasound	Positive Conventional Ultrasound	Negative Conventional Ultrasound
Positive mpMRI (Reader 1)	2	0	0	2
Negative mpMRI (Reader 1)	6	1	1	6
Positive mpMRI (Reader 2)	4	1	1	3
Negative mpMRI (Reader 2)	4	0	0	5
Positive Conventional Ultrasound	1	0		
Negative Conventional Ultrasound	7	1		

Table 1: McNemar data tables showing positive and negative targets (**PI-RADS** or **PRI-MUS ≥ 3**) for all significant Gleason 7+ lesions identified during study (Systematic and Targeted)

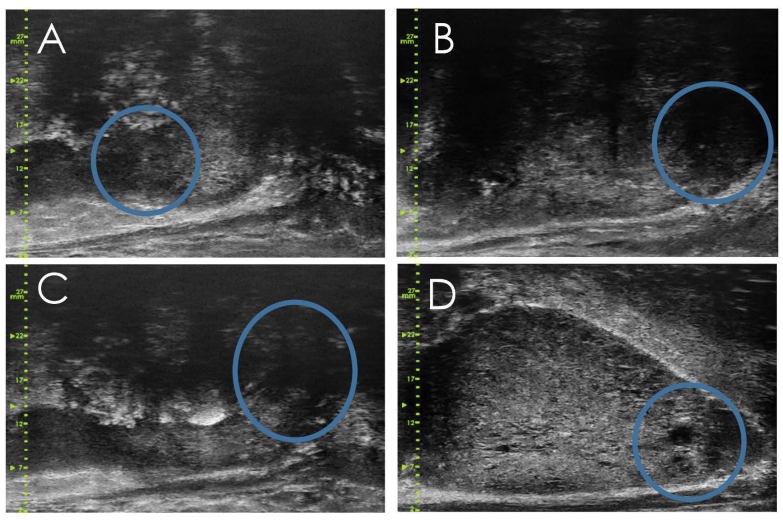

Figure 3: **Lesions prospectively identified on micro-ultrasound only.** PRI-MUS lesions are circled in blue. (***A***) PRI-MUS 3 (mild heterogeneity) lesion found to contain 5% Gleason 7. (***B***) PRI-MUS 3 (mild heterogeneity) lesion found to contain 10% Gleason 7. (***C***) PRI-MUS 3 (mild heterogeneity) found to contain 5% Gleason 7.(***D***) PRI-MUS 5 (mixed echo lesion) found to contain 5% Gleason 7.

Results:

- mpMRI and micro-ultrasound both demonstrated superior sensitivity (p=0.02) to Gleason 7+ cancer compared to conventional ultrasound (*Table 1*)
- Micro-ultrasound detected 89% of clinically significant cancers, compared to 56% for mpMRI

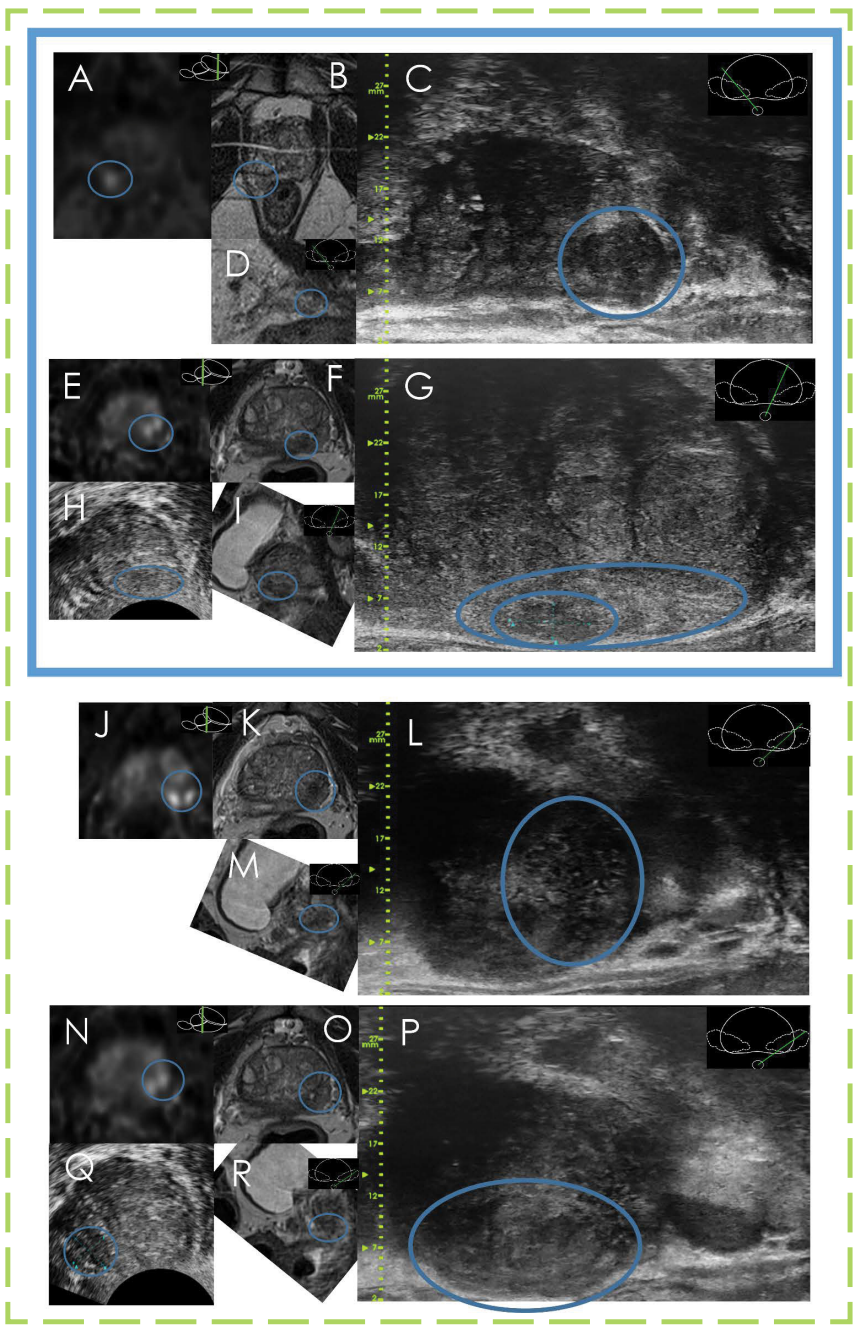

Figure 2: **Lesions prospectively identified on both mpMRI and Micro-Ultrasound.** The MRI is shown in panels A (DWI), and B (axial T2-wieghted) with a blue circle highlighting the lesion. ***Panel D*** shows the same data resliced to match the para-sagittal view of the micro-ultrasound, along with the same circle highlighting the lesion. ***Panel C*** shows the micro-ultrasound image. This lesion was labeled as a PI-RADS 4 on mpMRI and a PRI-MUS 5 (mixed echo lesion) on micro-ultrasound. Pathology determined the lesion to be Gleason 9 with 20% core length.

Similarly, the image panels for the second grouping (***E-G***) illustrate the lesion on mpMRI (***E,F,I***), conventional ultrasound (***H***), and micro-ultrasound (***G***). This lesion was labeled a PI-RADS 4 on mpMRI, and a PRI-MUS 5 on micro-ultrasound. Pathology determined this lesion to be a Gleason 7 with 10% core length.

The lower two groupings show lesions that were identified as a PI-RADS 5 / PRI-MUS 5 (bulging capsule) which was found to contain 10% Gleason 8 (***J-M***), and 90% Gleason 7 (***N-R***). These lesions were missed by MRI reader 1, but found by both MRI reader 2 and by micro-ultrasound.

Conclusions

- **Micro-ultrasound may be more sensitive to clinically significant prostate cancer than mpMRI, as it visualized nearly all significant mpMRI targets**
- **Unlike mpMRI, micro-ultrasound is performed in the urologist office, in real-time during the biopsy procedure, and is more time- and cost-effective**
- **Although the sample size is small, the results are promising in illustrating the potential utility of micro-ultrasound as a viable modality for active surveillance**

References

1. Ghai S, Eure G, Fradet V, et al: *Assessing Cancer Risk on Novel 29 MHz Micro-Ultrasound Images of the Prostate: Creation of the Micro-Ultrasound Protocol for Prostate Risk Identification.* J. Urol. 2016; 196: 562–569.