Initial Results Comparing 29 MHz Micro-Ultrasound with Multi-Parametric MRI for Targeted Prostate Biopsy: Relative Sensitivity to Clinically Significant Prostate Cancer

Astobieta A, Sanchez A, De la Cruz I, Pereira JG, Gamarra M, Urdaneta F, Mora G , Ibarluzea G.
Urología Clínica, IMQ, Bilbao, Spain

IMQ Tu seguro médico

EXACT IMAGING

INTRODUCTION & OBJECTIVES

Prostate cancer (PCa) lacks a reliable diagnostic imaging technique as conventional ultrasound has poor sensitivity and MRI demonstrates significant inter-reader variability and may not be able to see smaller aggressive lesions. MRI also adds additional costs, procedural complexity, and has a significant learning curve.

High resolution micro-ultrasound, a novel modality with 70 micron resolution, allows visualization of the prostate in real time and can be used to perform targeted biopsies of suspicious lesions in a simple, cost and time-effective manner. 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.

METHODS:

To compare the diagnostic accuracy of Micro-Ultrasound and mpMRI in detecting clinically significant prostate cancer:

Figure 2: Study set-up

- 79 patients presenting for prostate biopsy were imaged with mpMRI and then biopsied using micro-ultrasound (**ExactVu™**, Exact Imaging)
- mpMRI targets were blinded until micro-ultrasound lesions had been recorded
- Sensitivity of each modality to clinically significant cancer (G7+) was compared

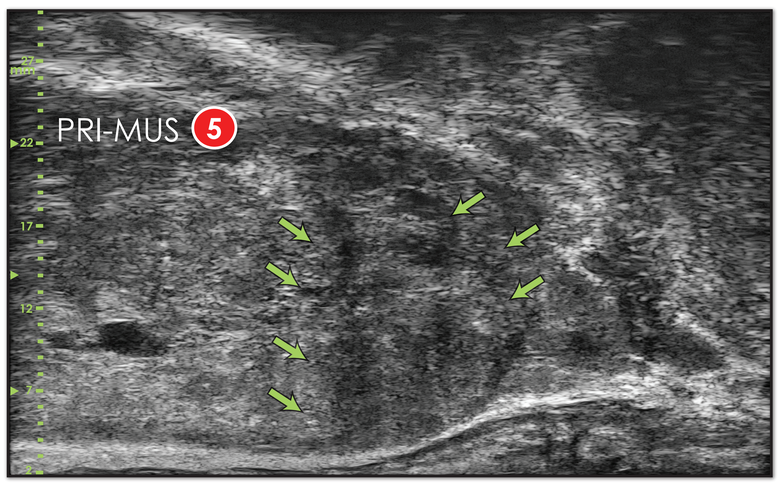

Figure 3: Micro-ultrasound image of a patient which was assigned a **PRI-MUS 5** score (significant target with irregular shadowing). This core was shown to be positive on Pathology (GS 7). MRI missed this target assigning it a **PI-RADS 2** score (not suspicious).

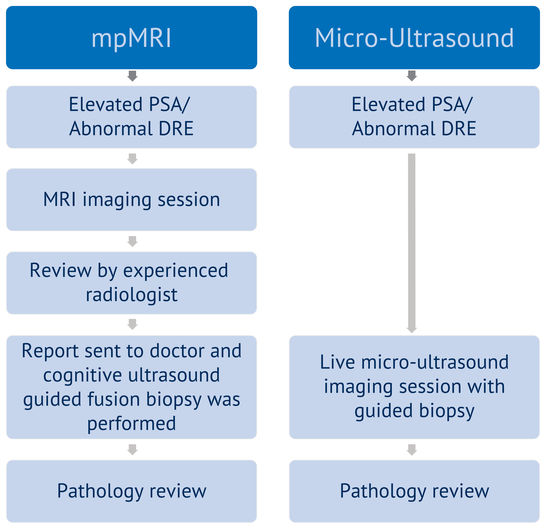

Figure 1: Comparison of MRI (*left*) and Micro-Ultrasound (*right*) workflows

	Pathology	Micro-Ultrasound	MRI
Zone	Gleason Sum ≥7	PRI-MUS ≥3	PI-RADS ≥3
Patient	Gleason Sum ≥7	≥1 True Positive Zone	≥1 True Positive Zone

Table 1: Criteria for true positives for Pathology, Micro-Ultrasound and mpMRI

	N=144 (PCa)	NPV	PPV	Sensitivity	Specificity
Micro-Ultrasound	117	93%	19%	82%	40%
mpMRI	43	88%	36%	30%	91%

Table 2: Zone-level results showing the positive predictive values (PPV) of Micro-Ultrasound and mpMRI are comparable, whereas the sensitivity of Micro-Ultrasound is higher than mpMRI, as is the negative predictive value (NPV).

	N=41 (PCa)	NPV	PPV	Sensitivity	Specificity
Micro-Ultrasound	40	0%	51%	98%	0%
mpMRI	28	43%	59%	68%	26%

Table 3: Patient-level Results where the PPV and sensitivity of Micro-Ultrasound are higher than mpMRI. At least one zone of each patient was considered **PRI-MUS ≥ 3**, resulting in 0% NPV and specificity for the patient-level results. Targeting one sample per patient may reduce the effectiveness of the technique for avoiding biopsy, but is acceptable in the context of standard systematic biopsy.

RESULTS:

Sensitivity of micro-ultrasound was significantly higher than mpMRI in both the per zone (p<0.001) (*Table 2*) and per patient (p=0.001) analysis (*Table 3*). Specificity was lower (40% micro-ultrasound vs. 91% mpMRI), though this is expected to be less of an issue as final diagnosis is determined by pathology. The high sensitivity should ensure all suspicious samples are collected at time of biopsy for proper pathological analysis.

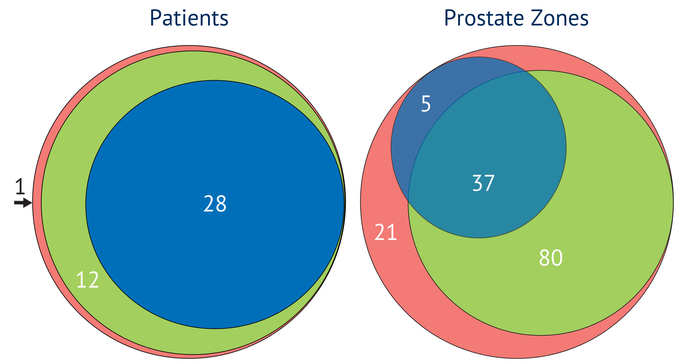

Figure 4: Comparison of **PRI-MUS** and **PI-RADS** performance on samples positive for significant cancer

- Clinically significant cancer according to biopsy pathology
- **PRI-MUS** score 3 or above (micro-ultrasound)
- **PI-RADS** score 3 or above (mpMRI)

CONCLUSIONS:

- **Micro-ultrasound shows promising relative sensitivity and NPV for detecting clinically significant prostate cancer when compared to mpMRI**
- The small sample size and retrospective nature of this work prevents a definite conclusion from being drawn; larger studies are warranted

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.