

Added Value of mpMRI and High-Resolution 29 MHz Micro-Ultrasound Targeting During Prostate Biopsy on Suspicion of Prostate Cancer

EXA + T

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INTRODUCTION:

Diagnosis of prostate cancer is complicated by the low negative predictive value of conventional ultrasound-guided biopsies, which are unable to exclude clinically significant cancer based on imaging features alone. This has led to unacceptable under-diagnosis rates for systematic biopsies. Recent guidelines changes have advocated for the addition of imaging-based targeted biopsy using multiparametric MRI (mpMRI), which has demonstrated clear benefits over conventional ultrasound-based systematic biopsy. Here we compare the added value in terms of diagnostic potential of mpMRI with the use of a novel high-resolution **29 MHz micro-ultrasound** (micro-US), a novel technique enabling real-time targeting without the complexities, costs and challenges of performing MRI.

METHODS:

- Prospective database study including 22 subjects presenting with elevated PSA or abnormal DRE undergoing prostate biopsy using
 ExactVu™ micro-ultrasound system (Exact Imaging, Markham, Canada)
- These subjects had also received mpMRI imaging which indicated targets for biopsy
- Each case was analyzed to determine whether mpMRI and/or micro-US targeted samples identified the highest **Grade Group (GG)** detected for the subject by any technique.

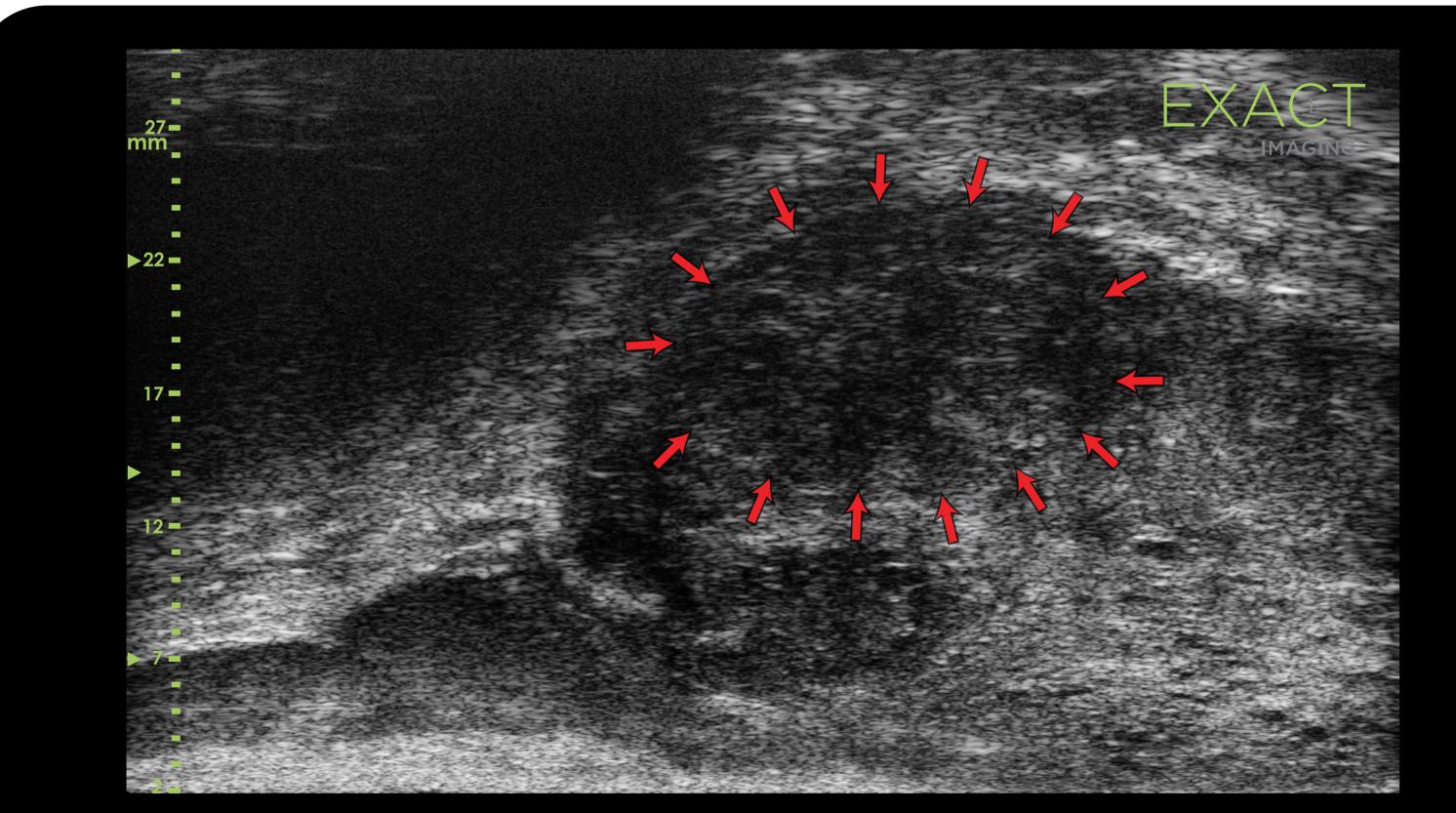


Figure 2: Micro-ultrasound image showing large anterior GG 3 lesion not visualized on mpMRI. In this case mpMRI suggested a target at the contralateral apex only, which was found to contain a lower grade cancer with GG 1.



Figure 1: ExactVu™ 29 MHz Micro-Ultrasound System

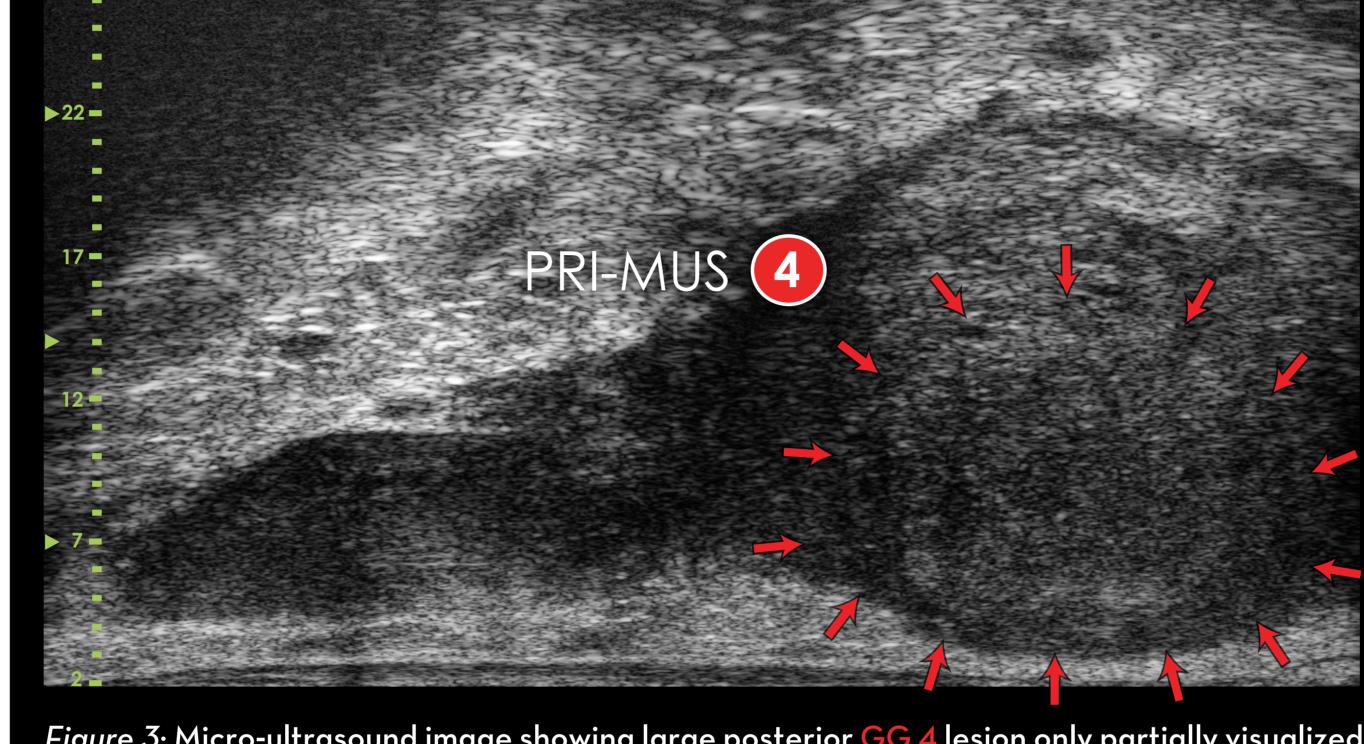


Figure 3: Micro-ultrasound image showing large posterior GG 4 lesion only partially visualized mpMRI.

In this case mpMRI suggested a target at the apex only, which was found to contain a lower grade cancer with **GG 3**, while the more serious **GG 4** lesion was focused at the base.

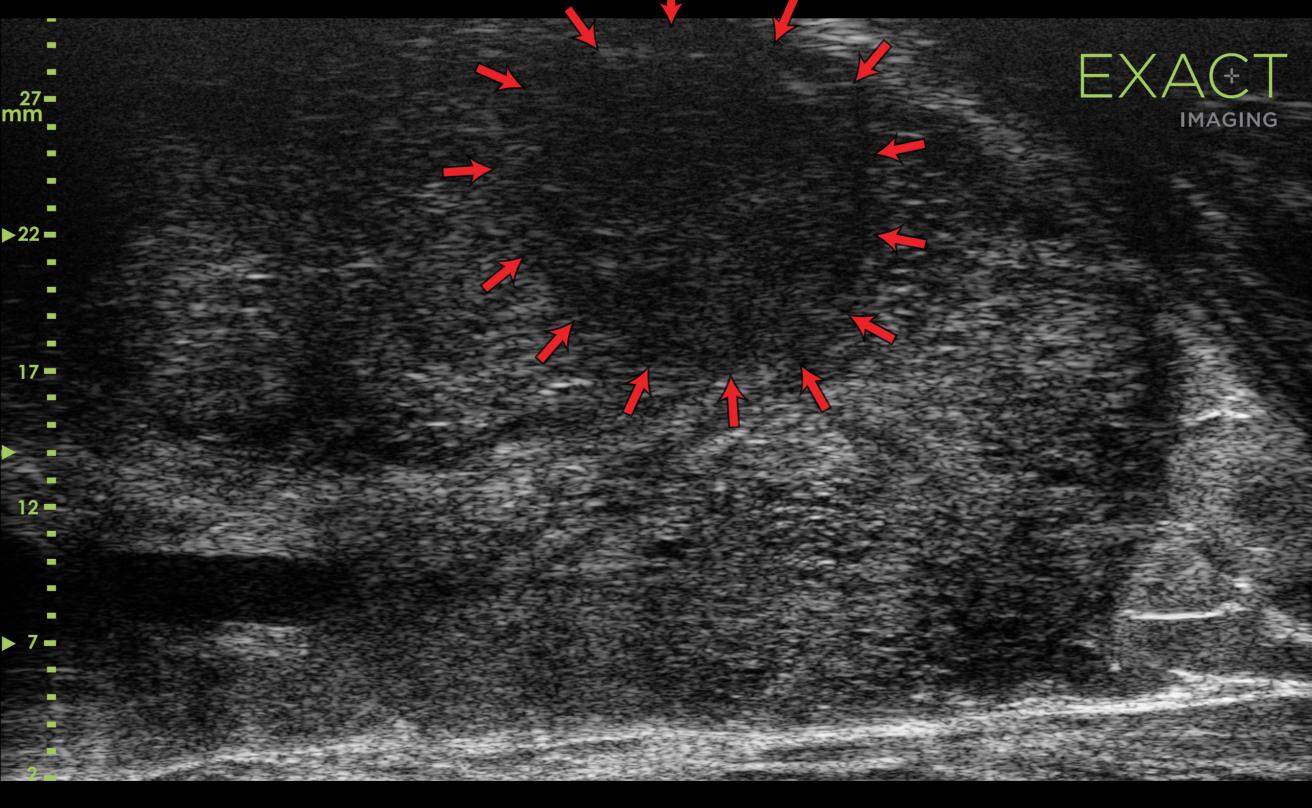


Figure 4: Micro-ultrasound image showing large anterior GG 4 lesion also visualized on mpMRI. This patient had a negative biopsy in 2016, followed by a negative MRI in 2017. A repeat MRI in 2018 showed a lesion in the left anterior zone. Micro-ultrasound biopsy targeted this anterior lesion, which given a GG 4 by pathology. Radical prostatectomy confirmed the location of the lesion but downgraded it to GG 3.

RESULTS:

- Prostate cancer was identified in 15/22 (68%) subjects, and was clinically significant (GG≥2) in 11/22 (50%)
- In 11/15 (73%) of all cancers and 9/11 (82%) GG≥2 cancers, both micro-US and MRI targets identified the highest GG cancer
- MRI alone detected 2/15 (13%) GG 1 cancers which were not identified by micro-US
- Micro-US alone detected higher grade group lesions in 2/15 (13%, GG 2 and 4) cases which were not identified by MRI

Detection Rate	Overall	Micro-US	mpMRI
All Cancer	15/22 (68%)	13/22 (59%)	15/22 (68%)
csPCa (GG>1)	11/22 (50%)	11/22 (50%)	10/22 (45%)
Highest GG per patient	N/A	13/15 (87%)	13/15 (87%)
Highest GG per patient (csPCa only)	N/A	11/11 (100%)	9/11 (82%)

Table 1: Detection rate results overall and per modality.

Both modalities showed strong concordance in identifying csPCa at the patient level, however micro-ultrasound targets upgraded 2 cases of clinically significant cancer to a higher Grade Group than MRI targets.

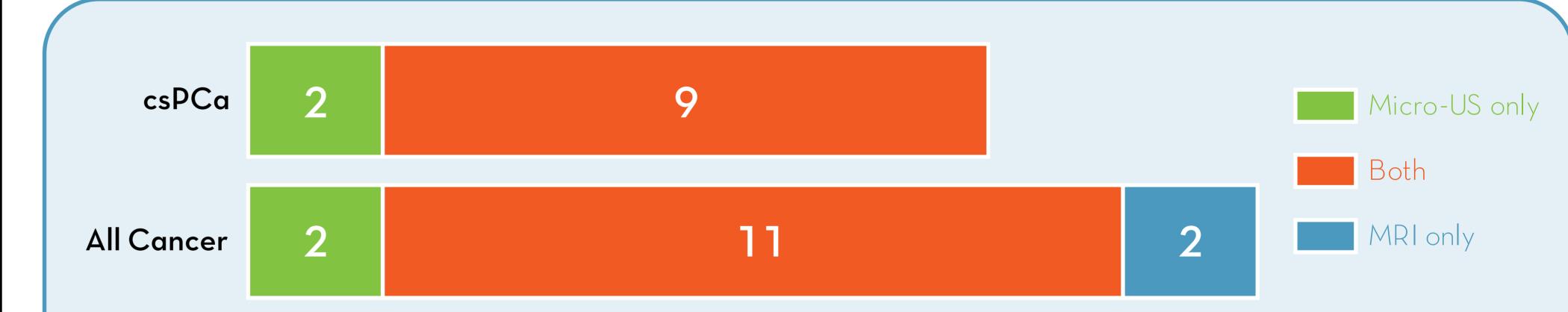


Figure 5: Patient-level detection of All Prostate Cancer and Clinically Significant Prostate Cancer by Modality.

Micro-ultrasound alone detected higher grade group cancer in 2 cases above mpMRI and systematic samples. mpMRI alone detected 2 cases of insignificant (GG1) prostate cancer which were not detected by micro-US. Both modalities were highly concordant, detecting the same grade lesions in 9/11 cases of csPCa.

CONCLUSIONS:

- > Image-based targeting of prostate biopsies added significant value with high rates of clinically significant cancer detection
- With strong agreement between MRI and micro-US in most cases, micro-US may be a reasonable alternative to MRI for targeted biopsy