

Comparison Between the Diagnostic Accuracy of Micro-Ultrasound Versus Multiparametric MRI in the Detection of Prostate Cancer: Preliminary Results from a Single-Institutional Ongoing Prospective Trial

INTRODUCTION

mpMRI and MRI/ultrasound fusion biopsies have been increasing in popularity in patients with suspected prostate cancer (PCa). These methods are however limited by cost ineffectiveness and indeterminate results.

High-resolution micro-ultrasound is a new, promising alternative as it operates at 29 MHz, resulting in higher resolution down to 70 microns, allowing for real time targeting and potentially improved diagnostic capabilities.

OBJECTIVE

Compare the diagnostic accuracy of micro-ultrasound vs mpMRI within a prospective cohort of patients with suspected PCa.

METHODS:

- 24 consecutive patients with at least one mpMRI target ROI (PI-RADS™ ≥ 3) were enrolled (Figure 2)
- Targeted TRUS-guided biopsy was performed using **ExactVu™** micro-ultrasound system (ExactVu™, Exact Imaging, Figure 1), by a urologist blinded to mpMRI results
 - **PRI-MUS™** (prostate risk identification using micro-ultrasound) protocol¹ was used to locate targets (PRI-MUS ≥ 3) (Figure 3, 4)
- All patients also received a standard 12-core random biopsy and targeted biopsy to MRI ROIs
- The overall presence of PCa and of clinically significant PCa (csPCa; Gleason ≥ 7) was assessed; concordance rate between mpMRI and micro-ultrasound findings and biopsy results were determined

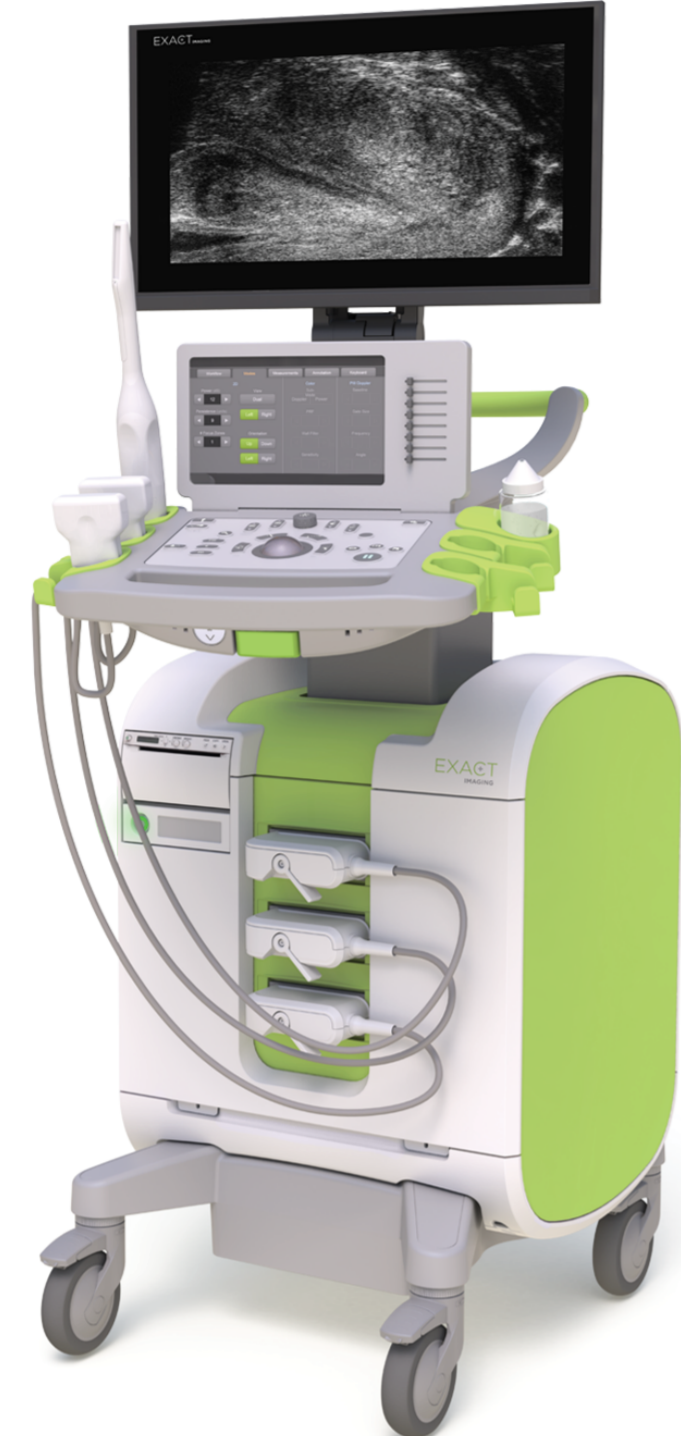


Figure 1: Exact Imaging's ExactVu™ 29 MHz Micro-Ultrasound System

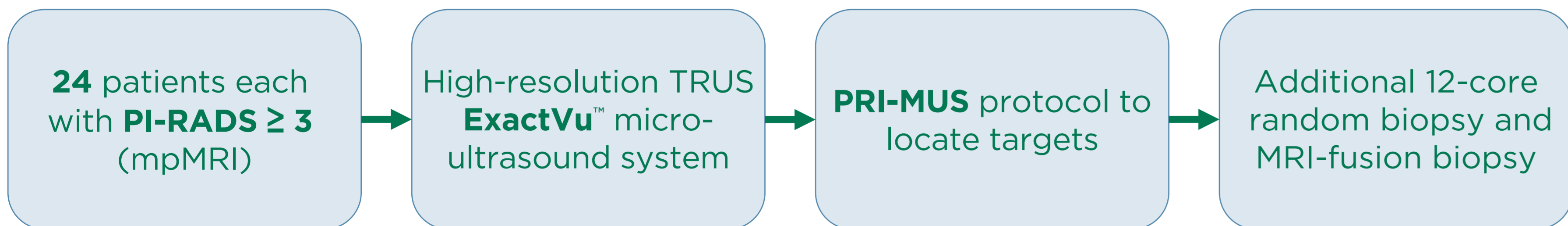


Figure 2: Micro-ultrasound vs mpMRI study procedure

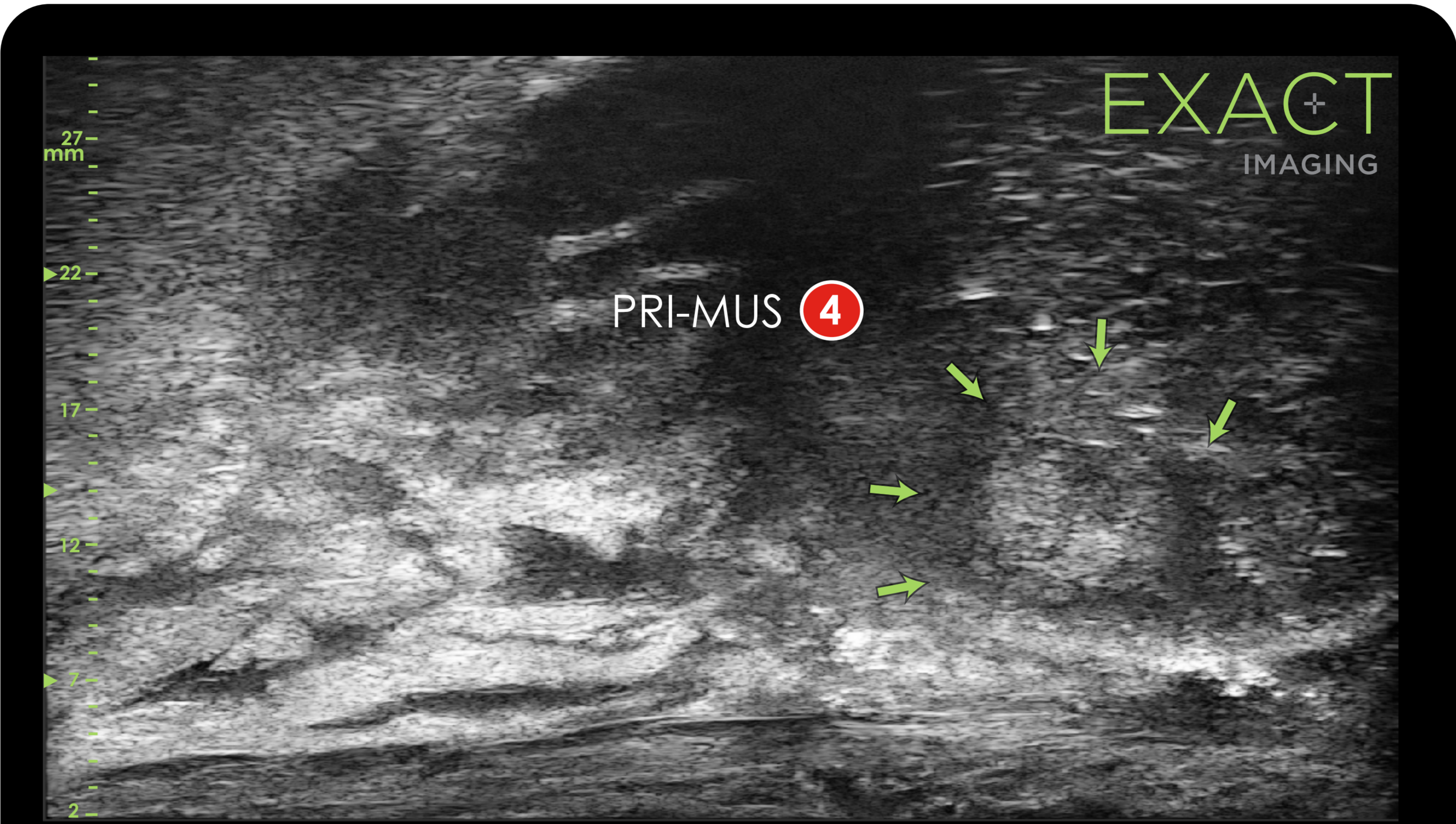


Figure 3: Micro-ultrasound image of the left-base-lateral PRI-MUS 4 lesion (suspicious target with mottled appearance). This core was positive on Pathology (GS 7=3+4). MRI assigned this area a PI-RADS 3 score.

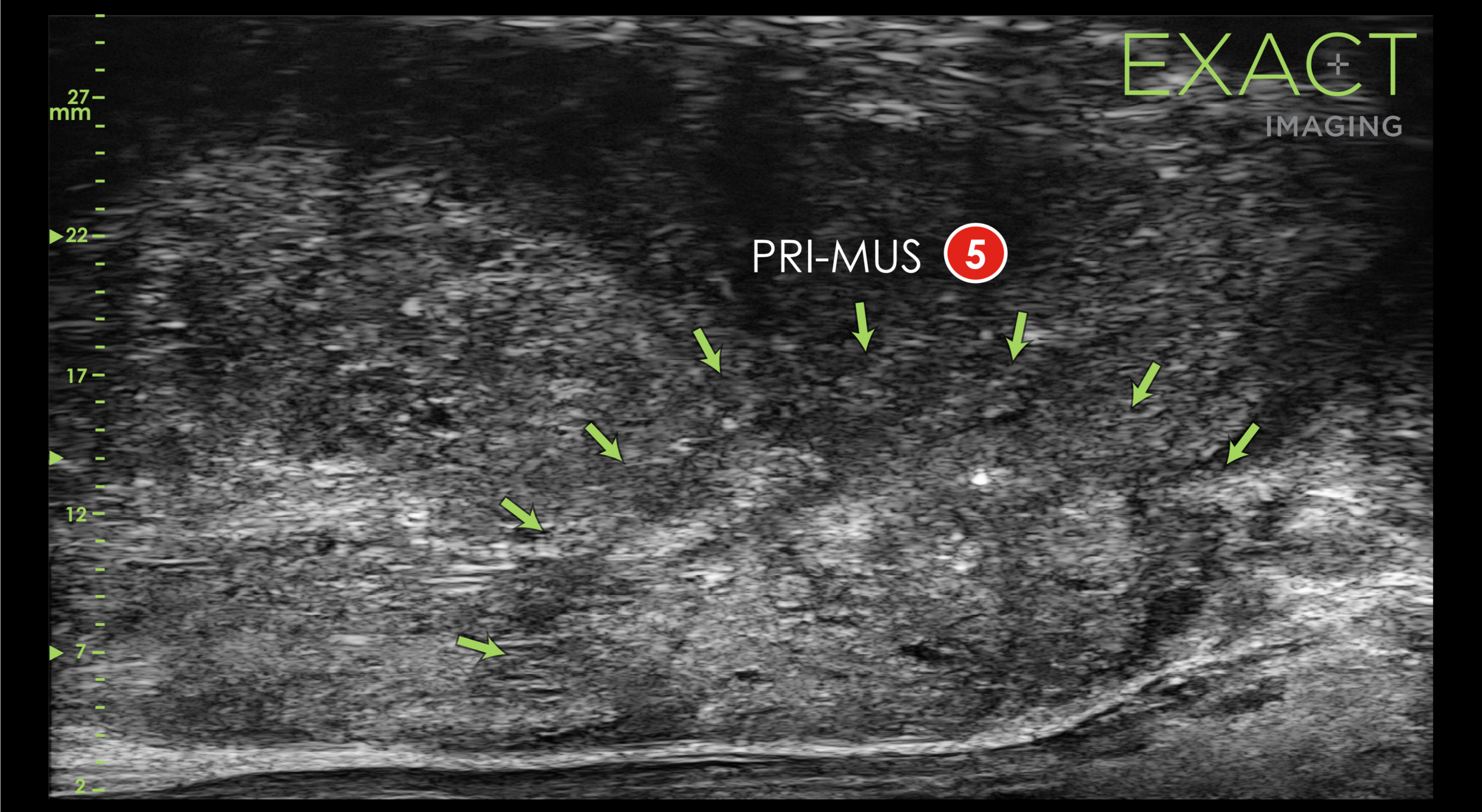


Figure 4: PRI-MUS 5 micro-ultrasound lesion (suspicious target with smudgy appearance and irregular shadowing). This core was positive on Pathology (GS 7=4+3). MRI assigned this target a PI-RADS 5 score.

RESULTS:

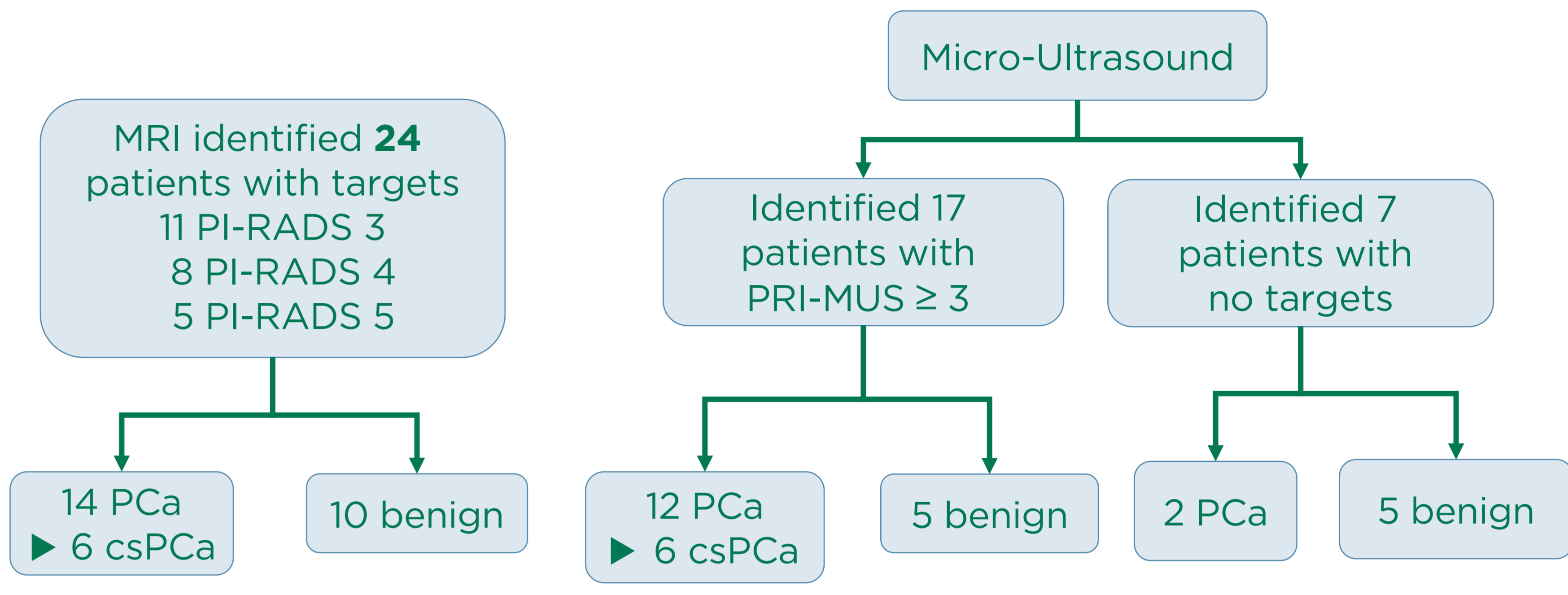


Figure 5: Diagnostic accuracy for detection of csPCa between mpMRI, micro-ultrasound, and random biopsy

- mpMRI identified more “insignificant” cancer than micro-ultrasound
- The concordance rate for micro-ultrasound to find mpMRI targets was 76.5% (13/17), of the 4 discordant cases,
 - 1 patient showed Gleason 7 = 3+4 in transitional zone in MRI/US fusion biopsy, however micro-ultrasound caught a separate Gleason 7 lesion in this subject
 - 2 patients had clinically insignificant PCa
 - 1 patient was negative at fusion and random biopsies

CONCLUSIONS:

- Micro-ultrasound sensitivity and NPV in detecting csPCa was **100%**, while specificity was **38.8%** (possibility attributed to learning curve)
- Micro-ultrasound appears to be a valuable tool to identify the presence of csPCa in patients with suspected PCa determined by mpMRI