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

Lughezzani G[1], Maffei D[1], Lazzeri M[1], Colombo P[2], Lista G[1], Cardone P[1], Hurle R[1], Casale P[1], Saita A[1], Buffi N[1], Guazzoni G[1].

Departments of Urology[1] and Pathology[2], Istituto Clinico Humanitas IRCCS, Humanitas Clinical and Research Center, Rozzano, Italy.

HUMANITAS RESEARCH HOSPITAL

EXACT IMAGING

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.
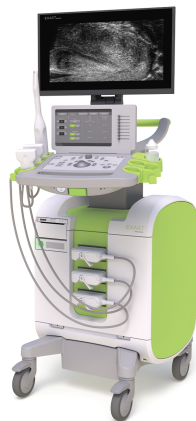

Figure 1:
Exact Imaging's
ExactVu™ 29 MHz
Micro-Ultrasound

METHODS:

- 60 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**™ (**p**rostate **r**isk **i**dentification using **m**icro-**u**ltra**s**ound) protocol[1] 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
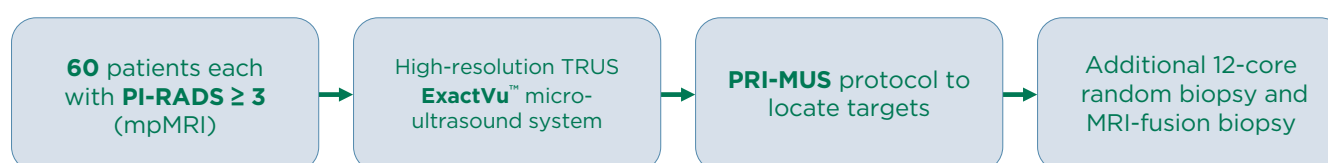
| **60** patients each with **PI-RADS ≥ 3** (mpMRI) | → | High-resolution TRUS **ExactVu**™ micro-ultrasound system | → | **PRI-MUS** protocol to locate targets | → | Additional 12-core random biopsy and MRI-fusion biopsy |

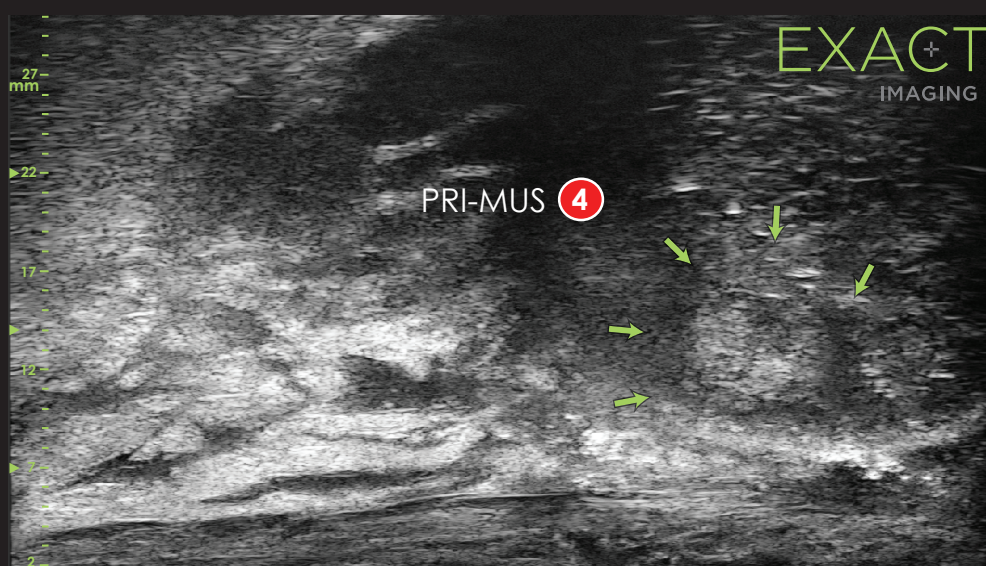**Figure 2:** Micro-ultrasound vs mpMRI study procedure

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.
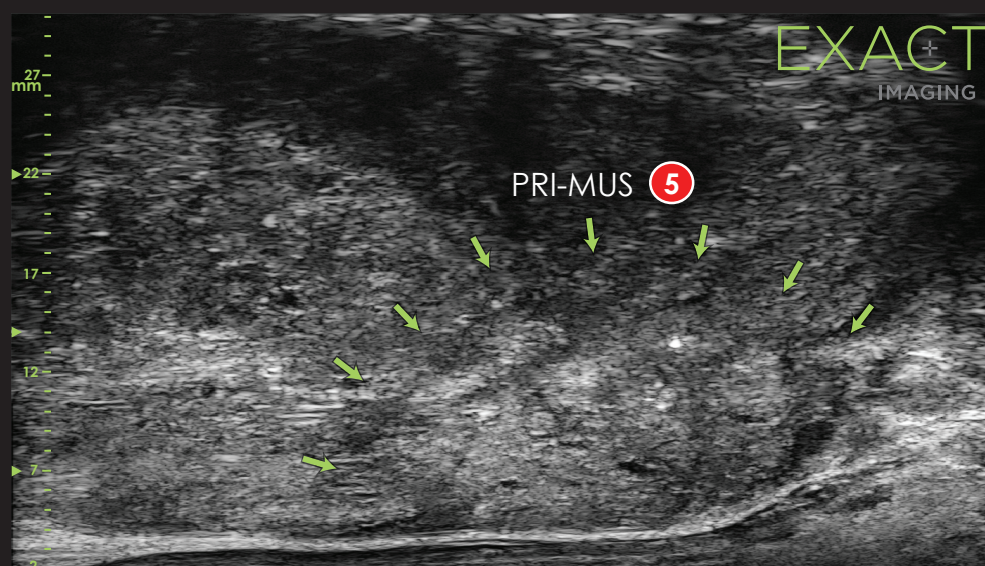

Figure 4: **PRI-MUS 5** micro-ultrasound lesion (suspicious target with smudgy appearance and irregular shadowing). This core was positive on Pathology (**GS 7=4+3**). MRI assigned this target a **PI-RADS 5** score.

RESULTS:

MRI identified **60** patients with targets
6 Unknown
17 PI-RADS 3
28 PI-RADS 4
9 PI-RADS 5

- 14 PCa **18 csPCa**
- 28 benign

Micro-Ultrasound

Identified **47** patients with PRI-MUS ≥ 3
- 8 PCa **17 csPCa**
- 22 benign

Identified **13** patients with no targets
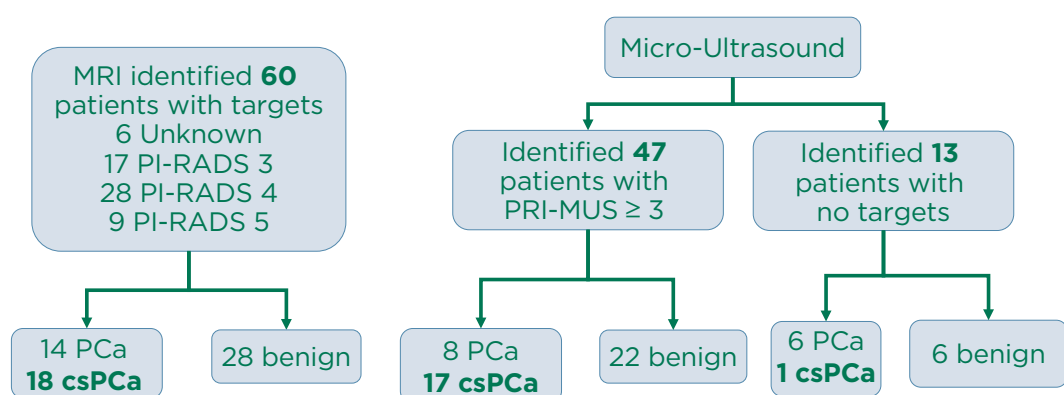- 6 PCa **1 csPCa**
- 6 benign

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 62.7% (37/59), of the 22 discordant lesions,

  - 7/22 were positive for significant cancer. In 5/7 cases micro-ultrasound found a separate lesion of significant cancer in the same subject.

  - In the remaining 15/22 cases, the lesion was benign or clinically insignificant prostate cancer.

CONCLUSIONS:

- Micro-ultrasound sensitivity and NPV in detecting csPCa was **83%**, while specificity was **29%** (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**

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.