Comparison of Micro-Ultrasound and Multiparametric MRI Imaging for Prostate Cancer: Multicentre Prospective Analysis.

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INTRODUCTION & OBJECTIVES:

This study aims to compare the sensitivity, specificity, NPV and PPV of mpMRI with the novel **high-resolution micro-ultrasound** imaging modality. This approach offers the benefits of simplicity, a single intervention for imaging and biopsy, leveraging the low cost of ultrasound. Micro-ultrasound may be used to image suspicious lesions and **target biopsies in real-time with or without additional MRI**-based targets.

MATERIAL & METHODS:

- **8** institutions in Europe and the USA participating, totaling **784** subjects
- All subjects received both mpMRI and **ExactVu™ micro-ultrasound** imaging**.**
- mpMRI targets sampled per site preference:
  - cognitive fusion with micro-ultrasound
  - separate software-fusion system
  - software-fusion using micro-ultrasound **FusionVu™**
- Micro-Ultrasound targets and systematic samples taken using the **ExactVu™ micro-ultrasound system**.
- Clinically significant cancer was any **Gleason Sum > 6** and targeted samples were taken for **PI-RADS™ > 2** or **PRI-MUS™,[1] > 2** lesions with at least 2 samples per lesion

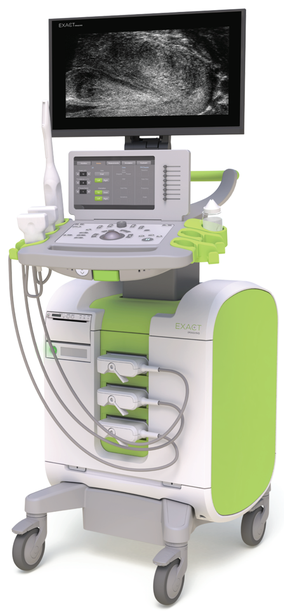


Figure 1: **ExactVu™** 29 MHz Micro-Ultrasound System for targeted prostate biopsies

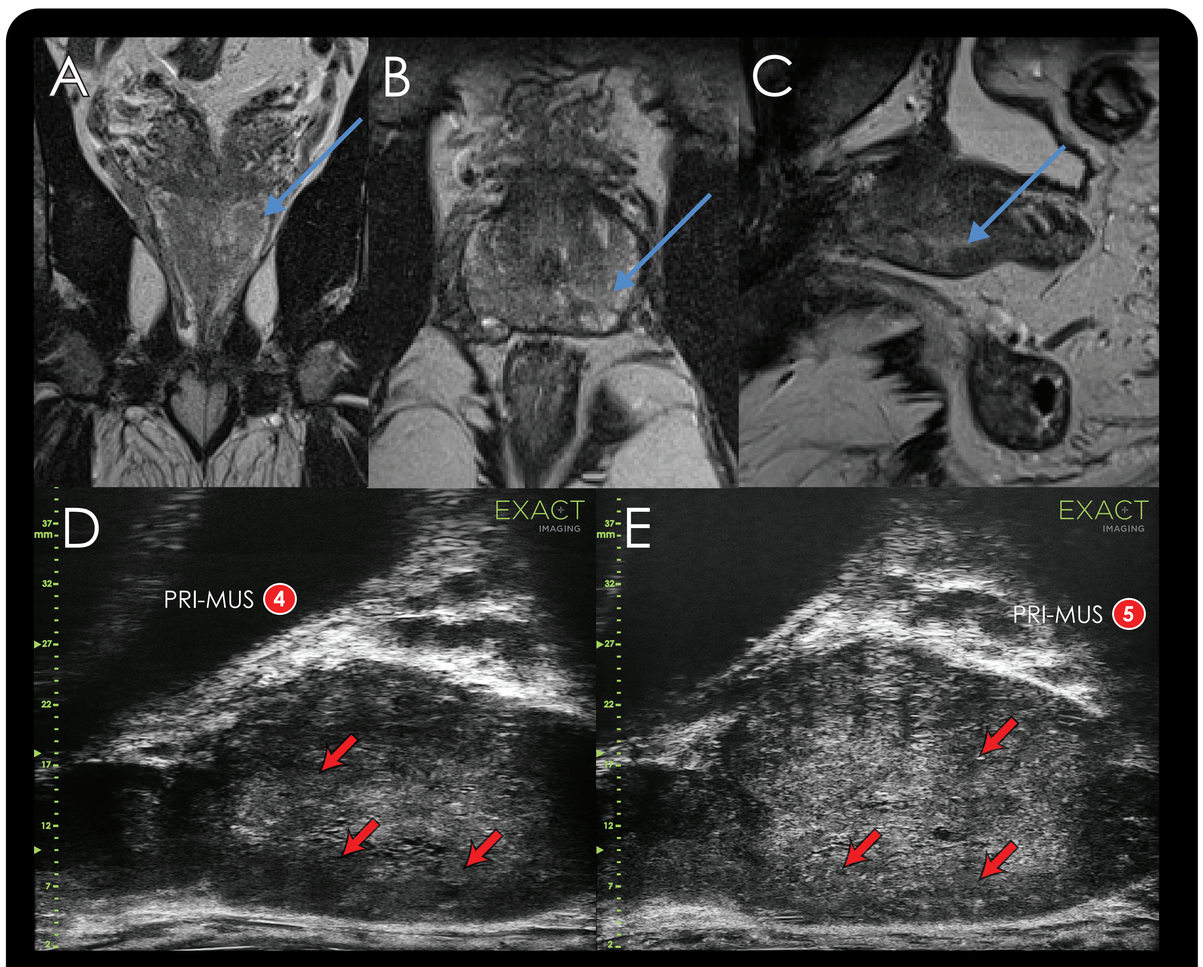


Figure 1: **Comparative MRI and Micro-ultrasound images of index lesion.**
(***A***) Coronal T2 MRI. (***B***) Axial T2 MRI. (***C***) Sagittal T2 MRI. (***D***) Parasagittal micro-ultrasound of left lateral edge of prostate. (***E***) Parasagittal micro-ultrasound of left medial edge of lesion. The Micro-ultrasound images show mottled tissue consistent with **PRI-MUS 4**, along with suspicious shadowing consistent with **PRI-MUS 5**. Suspicious findings in all images are marked with arrows.

CONCLUSIONS:

- **Micro-ultrasound is an attractive option for screening and targeted biopsy. Sensitivity and NPV appear superior to MRI**, but specificity is mildly reduced.
- Further larger-scale studies are required for validation of these findings.

RESULTS:

- 40% of cases were positive for clinically significant PCa
- mpMRI sensitivity 89% and NPV 75%
- **Micro-ultrasound sensitivity 94%** and **NPV 83%** both higher (p<0.01)
  - Micro-ultrasound less specific (19% vs 23% for mpMRI)
  - PPV 44% for both

Modality	Sensitivity	Specificity	PPV	NPV
mpMRI	89%	23%	44%	75%
Micro-ultrasound	**94%**	19%	44%	**83%**

***Table 1*: Summary statistics comparing ability to detect clinically significant prostate cancer (Gleason > 6) between mpMRI and micro-ultrasound.**
Micro-ultrasound demonstrated a higher sensitivity than mpMRI (p<0.01), as well as a higher negative predictive value (NPV). Positive predictive value (PPV) was equivalent between the two modalities, while specificity was low on both though slightly lower with micro-ultrasound suggesting a higher rate of false positives.

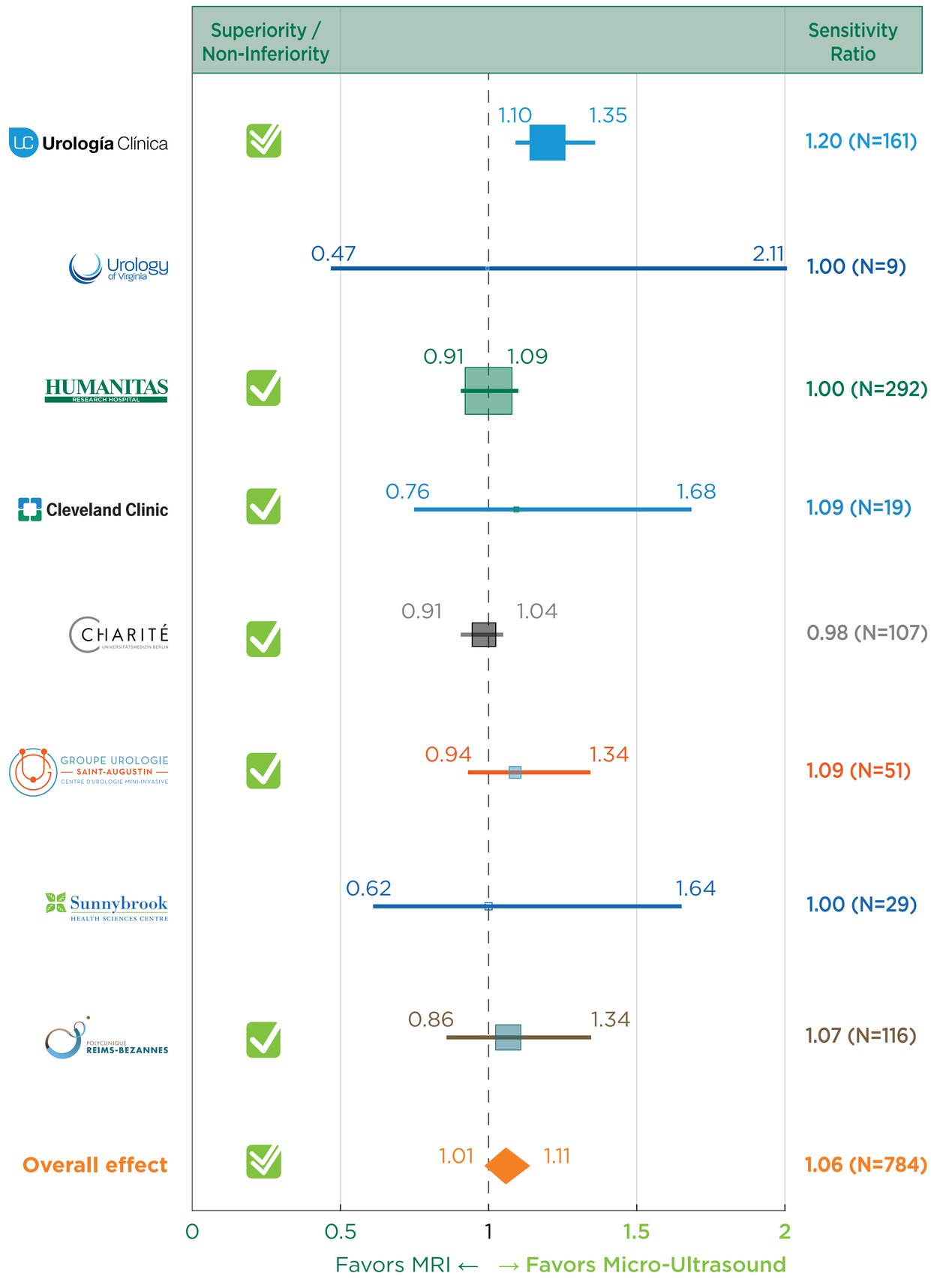


***Figure 2*: Forest plot showing results for each institutional cohort.**
Most groups achieved non-inferiority independently with aggregate results showing **superiority sensitivity of micro-ultrasound** over MRI with sensitivity ratio of **1.06** (p=0.007).

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.