High resolution micro-ultrasound of the prostate, PRI-MUS™ protocol guidance along with clinical variables: Combined approach for reducing unnecessary biopsies

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Introduction & Objectives

• A novel 29 MHz high resolution micro-ultrasound system (ExactVu™) has been developed enabling ~ 300% higher resolution than conventional TRUS systems for prostate imaging.
• The PRI-MUS™ (prostate risk identification using micro-ultrasound) protocol has been developed to aid in the analysis of the new, more detailed images generated by this system. (Fig 1)
• Combining patient screening data with micro-imaging data (by applying PRI-MUS™ to real-time micro-ultrasound imaging) may allow forgoing biopsy of certain low-risk areas of the prostate without substantially increasing false negative rates

Material & Methods

Cine loops of transrectal micro-ultrasound-guided (TRUS) biopsies were examined from an large multicenter clinical trial of high-resolution TRUS vs standard TRUS for detection of clinically significant prostate cancer using the 29 MHz Exact Imaging system. Subjects underwent TRUS biopsy for suspicion of cancer due to PSA elevation and/or abnormal DRE. 300 loops were read according to the PRI-MUS protocol by 2 investigators. These loops were divided into a training set (200) and test set (100).

Clinical screening data and PRI-MUS scores were analyzed in the training set to determine criteria for potentially avoiding biopsy of certain low-risk areas of the prostate. This criteria selected 4 samples for exclusion. These criteria were then applied to the test set to determine the outcome of simulated biopsies where samples below the threshold were omitted.

Results

The test set contained 45 biopsy samples which pathology identified as clinically significant cancer, and 55 biopsy samples which were identified as benign. If biopsy samples meeting either criteria above had been skipped, the result would have been 11/100 samples avoided for each investigator (22/200 overall). 3 of these 22 samples were positive for cancer on histopathologic analysis resulting in a 96% per-sample sensitivity. 1 of the missed samples was a low-risk Gleason 6 lesion, another was a Gleason 9 lesions which was identified by surrounding high-PRI-MUS score samples leading to the same overall diagnosis for the patient. The third missed sample was a small Gleason 7 sample with 35% core length which would have been missed.

In total, diagnosis of cancer and grade of the index lesion would have been changed in 1 of the 100 subjects for investigator 1, and for none of the 100 subjects for investigator 2. This suggests an overall per-subject sensitivity of 98.7% (specificity 19.4%) and NPV of 95.5% (PPV 47.0%).

Conclusions

• Clinical variables and micro-ultrasound imaging (with PRI-MUS™ provide synergistic information about cancer risk
• Avoiding certain systematic samples in low-risk individuals with low-risk micro-ultrasound imaging may be feasible (per-subject sensitivity 98.7%) and yield improved patient care
• Application of this technique (and PRI-MUS in general) is easily performed live and in real-time during the biopsy procedure with no additional equipment or personnel other than the micro-ultrasound system

References

1. Multi-Center Trial of High-resolution Transrectal Ultrasound Versus Standard Low-resolution Transrectal Ultrasound for the Identification of Clinically Significant Prostate Cancer. clinicaltrials.gov ID NCT02079205