Retrospective analysis of the performance of MiPS in patients having had multi-parametric MRI

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Introduction & Background: Current prostate cancer detection methods are limited by their ability to predict disease progression, hence; new biomarker tests are of clinical utility. Tools to enhance clinical decision-making for patients with elevated PSA are limited. Multi-parametric MRI (mpMRI) has become a mainstay in diagnostic clinical decision making. This study investigates the efficacy of a urine biomarker in conjunction with mpMRI.

Urine provides an excellent source to non-invasively detect biomarkers. We have developed a urine detection assay, quantitating the RNA-expression levels of the T2-ERG fusion and the lncRNA PCA3 in post-DRE urine samples. This test has potential to significantly enhance prognostication of patient outcomes for those with elevated PSA (particularly for identifying Gleason 7+ disease).

We developed a large retrospective cohort of post-DRE urine collected from 743 patients at time of fusion guided prostate biopsy at the University of Michigan. MiPS was run on all samples and the diagnostic performance of MiPS in conjunction with mpMRI was assessed.

Methods & Design:

Urine was collected at time of biopsy for 511 undergoing MRI-guided fusion biopsy. Levels of urine PCA3 and TMPRSS2:ERG fusion were retrospectively quantitated in these urine samples. The MiPS risk score was calculated using a logistic regression model including urine PCA3, urine TMPRSS2:ERG, and serum PSA. Performance of MiPS in this population was assessed.

Results: MiPS shows improved diagnostic potential when paired with multi-parametric MRI. MiPS exhibited ability to further risk stratify patients following MRI and classification of PIRADS score, differentiating samples from patients who were found to have Gleason 7+ lesions on biopsy versus those with Gleason 6 or negative biopsy. The MiPS score was significantly elevated in high-grade samples with PIRADS 4 and PIRADS 5 lesions identified on MRI. A striking separation of the high-grade population was observed for samples with PIRADS 2 and PIRADS 3 lesions, with 50% of the high-grade tumors identified with almost no false negatives

Conclusions & Future Directions: The strong negative predictive value of MiPS suggests clinical utility in enhancing decision to perform MRI or biopsy in patients with elevated PSA. Additionally, MiPS has the potential to provide substantial clinical insight in risk stratifying patients with PIRADS <4 lesions. Overall this test is capable of preventing many unnecessary biopsies, which benefits both patient morbidity and clinical cost.

Conflict of Interest: LynxDx – diagnostic company working to commercialize prostate cancer diagonstics.

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