**Title**: Changes in mpMRI and PSA parameters at multiple follow-up time points after whole prostate MRI-guided transurethral prostate ultrasound ablation

**Authors**: Afshin Azadikhah, M.D¹ (AAzadikhah@mednet.ucla.edu), Holden Wu, PhD¹ (HoldenWu@mednet.ucla.edu), Melina Hosseiny, M.D¹ (MHosseiny@mednet.ucla.edu), Nicholas J. Jackson, PhD MPH¹ (NJJackson@mednet.ucla.edu), Steven R. Raman, M.D¹ (SRaman@mednet.ucla.edu)

1. David Geffen School of Medicine at UCLA

**Introduction and objective:** The purpose of this study is to evaluate the changes of 3 Tesla (3T) mpMRI and PSA parameters before and during multiple time points after whole gland prostate cancer (PCa) treatment using MRI-guided directional transurethral ultrasound ablation (TULSA).

**Specific aims**: To describe the volumetric and functional change on serial MR after MR-guided transurethral US-guided whole gland prostate ablation for biopsy-proven prostate cancer.

**Rationale and background:** Traditional whole gland treatment for prostate cancer, are complicated by urinary incontinence and erectile dysfunction in up to 30-50% of the patients<sup>1,2</sup>. MR Guided Transurethral US has been previously shown to be safe and effective for whole gland prostate ablation for patients with prostate cancer and might be a novel whole gland ablation technique.

**Methods and materials:** This IRB approved, HIPAA compliant study included 9 men (45 to 80 years) with biopsy-confirmed PCa, clinical stage <T2b, Gleason score (GS)  $\leq$  3+4, PSA  $\leq$  15 ng/ml and prostate volume  $\leq$  90 cc. The whole prostate was ablated with 3T MRI guided TULSA along with a rectal cooling probe. Patients were followed-up (F/U) at 1, 3, 6, and 12 months after the treatment with measurements of PSA and 3T mpMRI. The prostate non-perfused volume (NPV) was measured on contrast-enhanced T1-weighted images at each F/U. A paired T-test was used to compare each subjects pre-treatment measurements to their last value F/U measurement (p<0.05 considered significant). TRUS-guided 10-core prostate biopsy was performed at the 12-month (F/U).

**Results:** In 17 PCa lesions from 9 patients, 8 were GS 3+3, and 9 were 3+4. The mean prostate ablation time was 89 min. (range 30-120 min). There was reported a negative prostate biopsy at the 12-month F/U for all of the patients. There were no immediate intra-procedural or post-procedural complications. Mean prostate volume on T2-weighted MRI decreased from 46cc at baseline to 32cc (29%), 24cc (49%), 21cc (54%) and 13cc (70%) at 3, 6, & 12-month F/U, respectively (p=0.01). The mean prostate NPV decreased from 33.7cc (range 13-83cc) to 21cc (38.3%), 15cc (56.6%), 11cc (68.8%) and 2cc (94.2%) at 1, 3, 6, and 12-month F/U, respectively. The 68.4% difference between mean PSA density=0.19 at baseline and 0.06 at 12-month was significant (p=0.041). The mean ADC value decreased 7.4% from 1460 mm-6/s2  $\pm$  117 at baseline to 1351 mm-6/s2  $\pm$  130 at 12-month F/U (p=0.079).

**Discussion and conclusion:** In this study, we have shown that MR guided transurethral ultrasound was safe and resulted in a significant decrease in prostate volume at 1, 3, 6, and 12

months with a corresponding significant decrease in PSAD. Further, ADC decreased in the post ablated prostate, as shown in prior studies. Jakob et al³ reported decreases in post-treatment ADC values for non-treated fibroid tissue (1685mm-6/sec2  $\pm$  468) compared to post-treatment ADC values for fibroid tissue (1078 mm-6/sec2  $\pm$  293) (p=0.001). Kim et al⁴ also reported decreases in ADC values in Canine prostates from baseline (1630 mm-6/sec2  $\pm$  210) after treatment (1030 mm-6/sec2  $\pm$  90). In conclusion, the new MRI-guided TULSA procedure treated the whole prostate gland in an outpatient setting without significant complications in patients with low-intermediate grade PCa, with a significant, predictable decrease in prostate volume and PSA density, and with considerable changes in mpMRI parameters at multiple F/U time points.

## References

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