Title: Retrospective analysis of MRI-guided transurethral ultrasound ablation (TULSA) in prostate cancer lesions at the extreme apex

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Purpose: Maintenance of urinary continence when treating prostate cancer (PCa) at the extreme apex is a challenge for surgery, radiation, and focal therapy. In regulatory studies TULSA spared 3 mm at the apex, and the impact of the transurethral dual-frequency ultrasound approach with MRI-controlled ablation is unknown. We report functional, imaging, and cancer surveillance outcomes in TULSA patients with extreme apical lesions.

Materials and Methods:
Men with apical PCa lesions abutting or involving the external sphincter were identified among 138 men with ≥ 6 months follow-up after lesion-targeted or whole-gland TULSA at our clinic. The target volume was defined based on disease factors and patient preference, using intraoperative DWI and ADC maps in addition to T2w imaging. A 10mm margin was targeted around the visible lesion when feasible. At the sphincter, a 5mm margin was targeted, including ≤50% of the external sphincter. Post-op foley catheterization was used. Patients were followed with daily communication for 2 weeks, PSA every 3 months, and MRI, IPSS, IIEF at 6-9 months. Post-TULSA mpMRI was assessed for local recurrence using PI-RR.

Results:

42 patients with treatment of apical lesions (37 primary PCa, 5 salvage) were identified, with median age of 63 (IQR 59-68) years, and follow-up availability of 9 (6-16) months. The proportion of men with primary GG 1-5 PCa were: 7%, 54%, 20%, 12%, and 7%, all having an associated MRI visible lesion. Median target volume was 29cc (IQR 22-34, range 10-70), with 99% (IQR 98-99%) of the target volume achieving lethal thermal dose ≥240CEM43. PSA decreased from median 6.7 (IQR 4.7-9.7) to 0.9 (0.3-2.0) ng/mL. 93% of patients with follow-up mpMRI (n=28) had no evidence of residual disease; PI-RR scores 1-5 were: 8, 18, 0, 2, 0. Both men with PI-RR=4 underwent a repeat TULSA; 6 months after repeat ablation both had PI-RR=2 with PSA of 0.2 and 1.0 ng/mL. All patients are pad-free; two experienced urine leakage that resolved by 3 months. 82% maintained baseline erection firmness sufficient for penetration (IIEF Q2≥2). IPSS symptom scores were stable. 10 patients experienced Grade 1-2 adverse events (LUTS, mild hematuria, bladder spasms, and hydrocele) resolving within 4 weeks with oral medication. Two patients had Grade 3 events requiring endoscopic intervention (1 retention, 1 retention and bladder neck contracture). No grade ≥4 events and no rectal injuries occurred.

Conclusions:

This retrospective analysis demonstrates promising safety and efficacy of TULSA in patients with extreme apical lesions, preserving urinary continence despite ablation near the external sphincter.

Clinical Relevance/Application:

TULSA is a promising prostate cancer treatment with minimal impact on urinary continence for thermal ablation of extreme apical lesions.

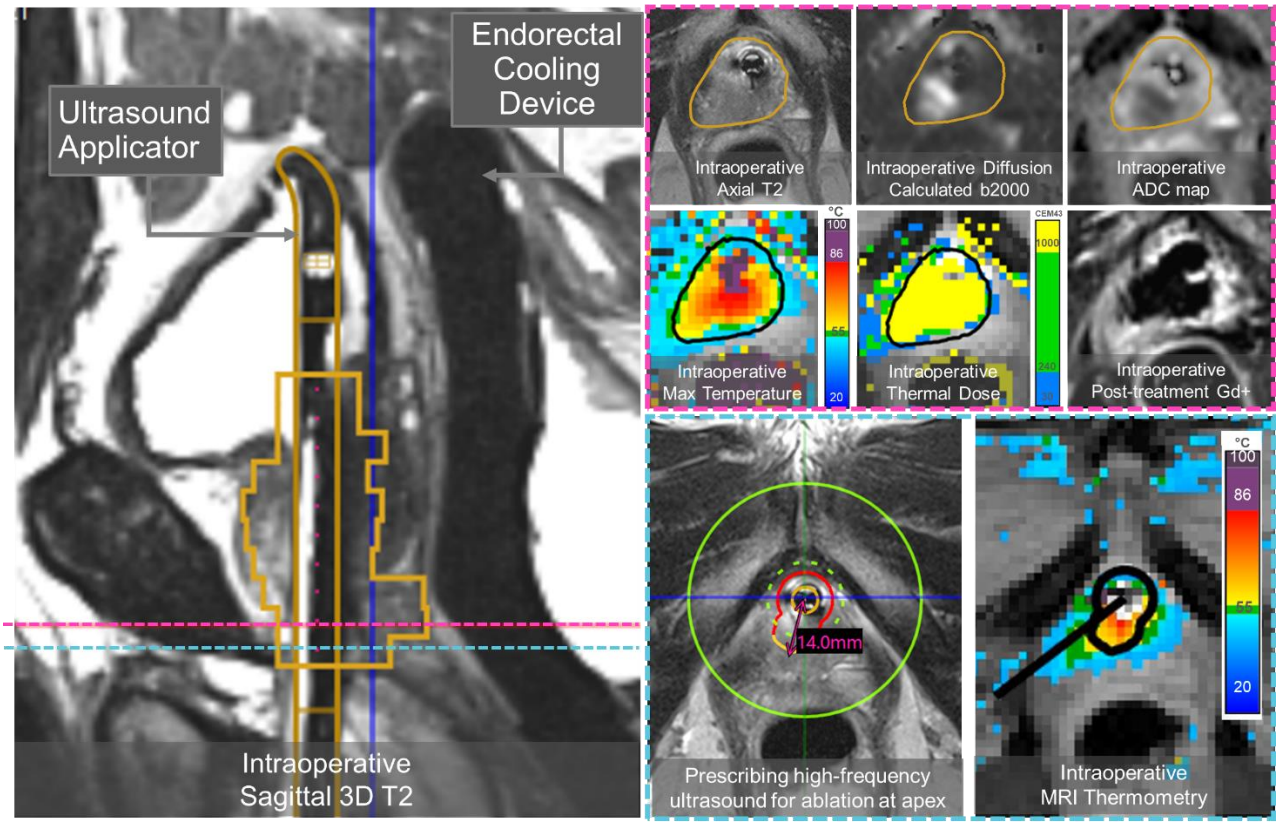

Figure 1: Ablation of GG2 abutting right apex using TULSA. Negative 9-month mpMRI (PI-RR=1), PSA 0.2 ng/mL at 14 months, no changes in urinary continence, and no significant changes in erectile function (IIEF-Q2: 4→3).