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Five-year outcomes from a prospective phase I study of MRI-guided transurethral ultrasound ablation in men with localized prostate cancer

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Introduction & Objectives: MRI-guided transurethral ultrasound ablation (TULSA) is a minimally-invasive procedure for customized ablation of benign and malignant prostate tissue. We report five-year (5y) outcomes of a single-arm, prospective phase I study assessing safety and feasibility in men with localized prostate cancer.

Materials & Methods: The study enrolled 30 men with organ-confined prostate cancer (≤T2a, PSA ≤10 ng/ml, Gleason Grade Group 1-2) at 3 centers. TULSA was delivered with 3 mm margins expected to spare 10% viable prostate at the gland periphery. Primary endpoints were safety (adverse events) and feasibility (spatial precision of conformal ablation). Exploratory outcomes included 1y MRI, 1y and 3y 12-core biopsy, and 5y PSA, quality of life, and survival.

Results: Adverse events (AE) to 1y included urinary tract infection (10 men Grade 2), acute retention (3 G1; 5 G2), and epididymitis (1 G3), with no rectal injuries. Between 1y and 5y there were no new serious or severe AE. MRI thermometry confirmed spatial ablation precision of ±1.3 mm, covering the targeted 90% of the gland. By 1y, PSA decreased 90% from 5.8 (3.8-8.0) to nadir of 0.6 (0.3-0.8) ng/ml, with 88% (83-95%) prostate volume reduction. Biopsy at 1y identified 61% reduction in cancer length, significant cancer in 9/29 men (31%), and any cancer in 16/29 (55%). At 3y, 3/22 men refused biopsy, 7/22 were positive (2 significant). By 5y, 16 men completed protocol follow-up, 3 withdrew with PSA <0.4 ng/ml, 10 had salvage therapy without complications (6 prostatectomy, 3 radiation, 1 laser), and 1 died of unrelated cause. Of 16 men with complete data, 5y median (IQR) PSA remained at 0.55 (0.4-1.2) ng/ml. IPSS of 6 (5-13) returned to 5 (4-10) by 3 mo, 6.5 (6-9) at 5y. At baseline, 9/16 had erections sufficient for penetration, 11/16 at 1y, 7/16 at 5y. 16/16 had leak-free, pad-free continence at 1y and 5y. Predictors of salvage therapy included lower ablation coverage and higher PSA nadir.

Conclusions: MRI-guided TULSA in men with localized prostate cancer showed low toxicity with stable quality of life and disease control, while maintaining salvage treatment options. These results have been replicated by a subsequent phase III trial with shorter followup.