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Pivotal Trial of MRI-guided Transurethral Ultrasound Ablation in Men with Localized Prostate Cancer: Three-Year Follow-Up

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Interventional Oncology

Session: Men's Health 2

Pivotal Trial of MRI-guided Transurethral Ultrasound Ablation in Men with Localized Prostate Cancer: Three-Year Follow-Up

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Featured Presenter(s)

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Disclosure: Profound Medical (**Employment**, Stock Shareholder (excluding mutual funds))

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Purpose:
MRI-guided transurethral ultrasound ablation (TULSA) of prostate tissue is a novel directional ultrasound heating under real-time MRI thermometry feedback control. We report 3-year outcomes from the pivotal TULSA-PRO Ablation Clinical Trial.

Materials and Methods:
With IRB approval and HIPAA compliance, 115 men with organ-confined prostate cancer (≤T2b, PSA ≤15 ng/ml, Grade Group [GG] 1-2) across 13 centers underwent whole-gland ablation sparing the urethra, bladder neck, and urinary sphincter. Primary endpoints were safety and PSA reduction at 1 year. Secondary endpoints: prostate volume reduction, mpMRI, and 10 core biopsy at 1 year; quality of life, PSA, and salvage to 3 years. Cases with persistent GG2 or salvage treatment were reviewed to identify causes of treatment failure.

Results: Median (IQR) PSA was 6.3 (4.6-7.9) ng/mL, with GG ≥2 disease in 72/115 men (63%). Targeted prostate volumes of 40 (IQR 32-50) cc were ablated in 51 (IQR 39-66) min. At 1 year MRI and biopsy, median prostate volume decreased from 37 to 3 cc, GG2 disease was eliminated in 54/68 (79%) men, and 72/111 (65%) had no evidence of any cancer. Median PSA decreased 95% to a nadir of 0.26 ng/mL, stable from 0.53 ng/mL at 1 year to 0.70 ng/mL (n=56) at 3 years. By 3 years, 15 men (13%) received salvage treatment. The odds ratio for salvage therapy in men with visible lesions on follow-up mpMRI was 31 (p≤0.001; CI [6.4,150]). On review we identified the following modes of treatment failure: acoustic shadowing due to intraprostatic calcifications, unintentional prostate tissue sparing, and ablation misalignment caused by prostate swelling or patient motion. Complications included Grade 3 adverse events in 9 (8%) men resolved before 1 year without rectal injuries or Grade ≥4 events. Grade 2 adverse events: moderate urinary incontinence (Grade 2, pads) in 3 men (2.6%) at 1 year persisted to 3 years in 1 patient, with no new incontinence past 1 year; moderate erectile dysfunction (Grade 2, responding to medication) was 23% at 1 year and 24% at 3 years. Median change in IIEF-5 was -2 from baseline to 1 year, and nil from 1 to 3 years (n=61). Erections sufficient for penetration (IIEF Q2 ≥2) were maintained by 69/92 (75%) and 38/50 (76%) men at 1 and 3 years.

Conclusion:
With 3-year follow-up, TULSA achieved durable control of localized prostate cancer with low toxicity and stable quality of life. Treatment failure modes included screening and intraprocedural factors. Salvage therapy was associated with presence of a visible lesion on follow-up mpMRI.

Table Builder:

References: