

## Pivotal Trial of MRI-Guided Transurethral Ultrasound Ablation (TULSA) in Patients with Localized Prostate Cancer

Monday 11:30-11:40 AM | SSC07-07 | Room: E260

### PURPOSE

MRI-guided transurethral ultrasound ablation (TULSA) is an incision-free method for customized prostate ablation using directional ultrasound under MRI thermometry feedback control. We report 12-month (12mo) outcomes from the TULSA-PRO Ablation Clinical Trial (TACT) Pivotal study.

### METHOD AND MATERIALS

TACT enrolled 115 men with localized prostate cancer at 13 sites. Treatment intent was whole-gland ablation sparing the urethra and urinary sphincter. Primary endpoints were adverse events and proportion of men with PSA reduction  $\geq 75\%$ . Secondary endpoints included 12mo 10-core biopsy, mpMRI, prostate volume reduction, and quality of life.

### RESULTS

Median (IQR) age was 65 (59-69) years and PSA 6.3 (4.6-7.9) ng/ml. Pre-treatment, 72/115 (63%) men had Grade Group 2 (GG2) disease. PI-RADSv2 score  $\geq 3$  lesions were present in 98/115 (85%) men,  $\geq 4$  in 77 (67%). Ablation times were 51 (39-66) min for targeted prostate volumes of 40 (32-50) cc. MRI thermometry during treatment indicated 98% (95-99%) thermal coverage with ablation precision of  $\pm 1.4$  mm, confirmed qualitatively by post-treatment CE-MRI. Grade 3 adverse events occurred in 8% of men (all resolved), with no rectal injuries or Grade  $\geq 4$  events. At 12mo, 1% of men were incontinent ( $>1$  pad/day), and 69/92 (75%) maintained erections sufficient for penetration (IIEF Q2  $\geq 2$ ). PSA reduction  $\geq 75\%$  was achieved in 110/115 (96%), with median reduction of 95% and nadir of 0.34 ng/ml. Median perfused prostate volume decreased from 41 to 4 cc at 12mo MRI. Of 68 men with baseline GG2 disease, 54 (79%) were free of GG2 on 12mo biopsy. Overall, 72/111 (65%) had no evidence of any cancer. Of 98 men with PI-RADSv2  $\geq 3$  at baseline, 26 had MRI lesions at 12mo, 11/26 with biopsy-confirmed GG2 (negative predictive value, NPV 93%). Multivariate predictors of residual GG2 included intraprostatic calcifications at screening, MRI thermal coverage of target volume, and PI-RADSv2  $\geq 3$  at 12mo ( $p < 0.05$ ).

### CONCLUSION

The TACT Pivotal study of MRI-guided TULSA for whole-gland ablation in men with localized prostate cancer met its primary PSA endpoint in 96% of patients, with low rates of severe toxicity and residual GG2 disease. MRI at 12mo detected residual disease with NPV of 93%.

### CLINICAL RELEVANCE/APPLICATION

Whole-gland ablation using MRI-guided TULSA achieves predictable PSA and prostate volume reduction. Multiparametric MRI is promising for post-TULSA follow-up.