

American Urological Association Education & Research, Inc.

AUA VIRTUAL EXPERIENCE



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

Scott Eggener, M Koch, D Penson, C Pavlovich, J Chin, Y Lotan, S Raman, G Hatiboglu, A Oto, J Relle, J Fütterer, M Serrallach, A Heidenreich, M Haider, D Bonekamp, T Tirkes, S Arora, A Pantuck, G Zagaja, M Sedelaar, K Macura, D Costa, T Persigehl, A Purysko, L Klotz



### **MRI-guided transurethral ultrasound ablation (TULSA)**

- Customized prostate ablation using real-time MRI planning and thermometry
- Transurethral directional ultrasound for thermal ablation of the prostate; urethral and rectal cooling
- Robotic closed-loop control with real-time temperature feedback





# **TULSA-PRO Ablation Clinical Trial (TACT)**

#### **Clinically Significant Study Population**

- 115 men, 13 institutions, 5 countries
- Intermediate-risk (67%) and Low-risk (33%) localized PCa
- PSA ≤15 ng/ml, Gleason ≤3+4, age 45-80 years
- Whole-gland ablation sparing urethra and apical sphincter

#### **Primary Endpoints (1 year)**

- Safety: Frequency and severity of adverse events
- Efficacy: PSA reduction ≥75% in 50% of patients

#### **Secondary Endpoints (to 5 years)**

- 1 year prostate volume reduction, biopsy, and mpMRI
- EPIC, IIEF, IPSS, and adverse events



## **1 Year PSA and MRI Outcomes**

- Primary endpoint of PSA reduction ≥75% met in 110 of 115 (96%)
  - Median (IQR) PSA reduction 95% (91-98%)
  - Median (IQR) PSA nadir 0.34 (0.12-0.56) ng/ml
- Prostate volume on mpMRI decreased 91% (median 37 to 3 cc)



12-months Post T2w MRI



PSA < 0.1 ng/ml 0.5 cc



# **1 Year Local Histological Control**

- 10-core biopsy with high sampling density (median 3.5 cores per cc)
- Among men with pre-treatment
  - Clinically significant GG2, 54 of 68 (79%) free of GG2 disease
  - High volume GG1, 20 of 26 (77%) free of high volume GG1 or worse
  - Low volume GG1, 13 of 17 (76%) free of any disease
  - Overall, 72 of 111 (65%) free of any disease



Clinically significant GG2+ High volume GG1 (≥3 cores or ≥50% per core) Insignificant disease (low volume GG1) No histological evidence of disease Missing biopsy



# PSA (ng/ml)



- Median (IQR) PSA reduction to nadir 95% (91–98%), stable to 2 years
- Eight men (7%) underwent post-TULSA salvage (4 RP, 4 RT) by 2 years





- No grade  $\geq$  4 adverse events
- No intraoperative complications, no rectal injury, no rectal fistula
- 12 Grade 3 (severe) events in 9 men (7.8%) resolved by 1 year:
  - 5 genitourinary infection, 2 urinary retention, 2 urethral stenosis,
    1 bladder pain, 1 urethral calculus, 1 urinoma
- Grade 2 (moderate) events typically resolved by 1 year included:
  - Urinary tract infections (25%), urinary retention (9%), abdominal or rectal discomfort (3.5%), urethral stricture (2.6%)



## **Urinary Continence**



#### Surgeon-Assessed:

 2.6% moderate incontinence (G2, pads indicated) at 1 year, <u>No new onset at 2 years</u>

#### **EPIC** patient-reported:

- 7% wear a security pad / day
- 1% leak one or more times / day
- <1% incontinent (> 1 pad / day)



### **Erectile Function**

- 23% moderate ED at 1 year (Grade 2, medication indicated), <u>One new onset at 2 years</u>
- 0% severe ED (Grade 3, medication not helpful)
- <u>Continued recovery</u> of erection firmness sufficient for penetration (75% at 1 year, 83% at 2 years)





## **Urinary and Bowel Symptoms**



• No significant changes in IPSS or EPIC bowel scores from baseline to 2 years



### Conclusions

 With two-year follow-up in men with localized PCa, whole-gland TULSA showed effective disease control with low toxicity and stable quality of life

• Further studies ongoing of TULSA for BPH, partial gland ablation, and radio-recurrent salvage.