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PD17-03

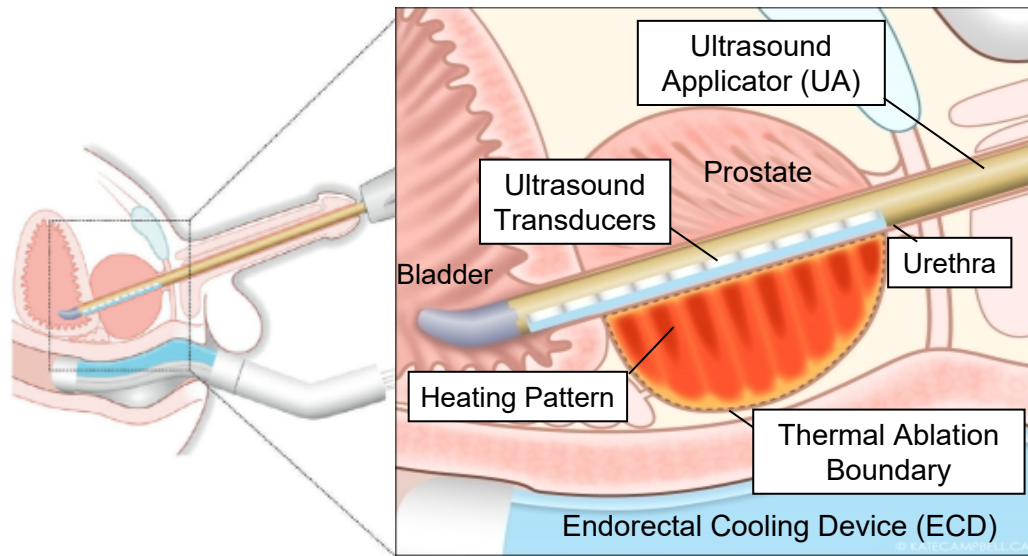
## **Five-year Outcomes from a Prospective Phase I Study of MRI-guided Transurethral Ultrasound Ablation in Men with Localized Prostate Cancer**

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## MRI-guided transurethral ultrasound ablation (TULSA)

- **Incision-free** procedure for customized ablation of prostate tissue
- Conducted within an MRI, offering high-resolution planning images, **real-time MRI guidance** and closed-loop thermal feedback
- Transurethral directional ultrasound under continuous rotational sweep for precise thermal ablation of small or large regions
- Water cooling of urethra and rectum





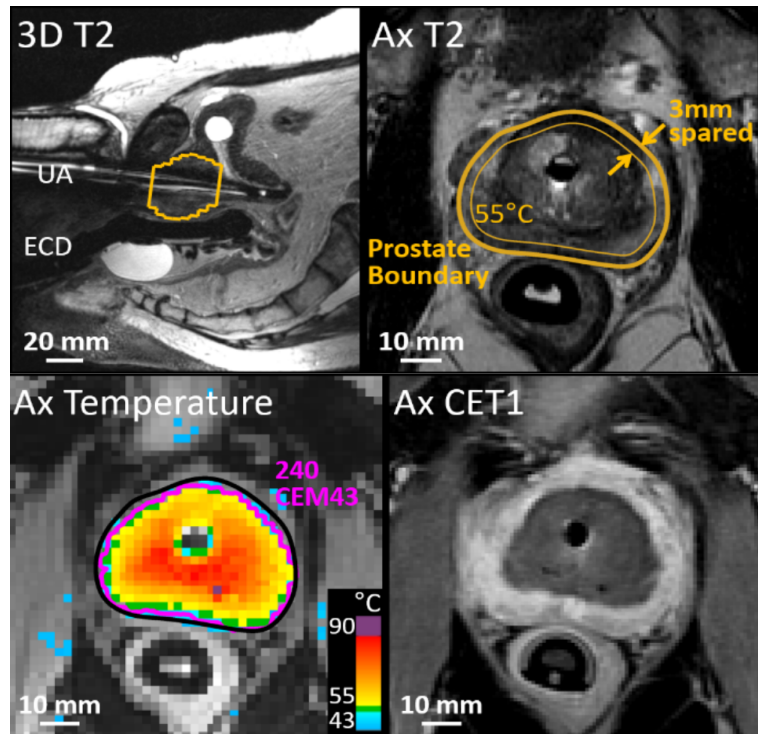
## Phase I Safety and Feasibility: 5-year Outcomes

### Conservative whole-gland ablation (90%)

- Targeted prostate volume defined with **3-mm safety margin** from prostate capsule
- Intentionally sparing 10% viable prostate tissue at periphery

### Inclusion Criteria

- Age  $\geq 65$  years, PSA  $\leq 10$  ng/ml
- No prior PCa treatment
- Gleason Score 3+3 (3+4 in Canada)
- Eligible for MRI, and anesthesia
- Prostate length  $\leq 5$  cm, width  $\leq 6$  cm





## Primary Outcomes (1-Year)

### Safety

- No intraoperative complications, no rectal injury or fistula, and no severe urinary incontinence
- Urinary tract infection (10 G2), acute retention (3 G1; 5 G2), epididymitis (1 G3).  
No new serious/severe adverse events between 1y and 5y

### Feasibility

- Accuracy  $\pm$  precision of heating:  $0.1 \pm 1.3$  mm (n=30)
- Prostate volume mean 47 cc (95% CI 41–54, range 21–95)
- Treatment time mean 36 min (95% CI 32–40, range 24–61)
- PSA decreased from 5.8 (3.8-8.0) ng/ml to 0.8 (0.5-1.1) ng/ml at 1 month, stable at 1 year 0.8 (0.6-1.1) ng/ml.



## Exploratory Endpoints (1 and 3-Year)

### 1-Year MRI and Biopsy

- 88% prostate volume reduction, matching 90% planned ablation volume.
- Significant PCa in 9/29, any disease 16/29, 61% reduction in PCa length, risk of residual disease was accepted by conservative treatment protocol

### 3-Year Biopsy

- 3/22 refused biopsy, 12/22 negative
- Significant PCa in 2/22, any disease in 7/22



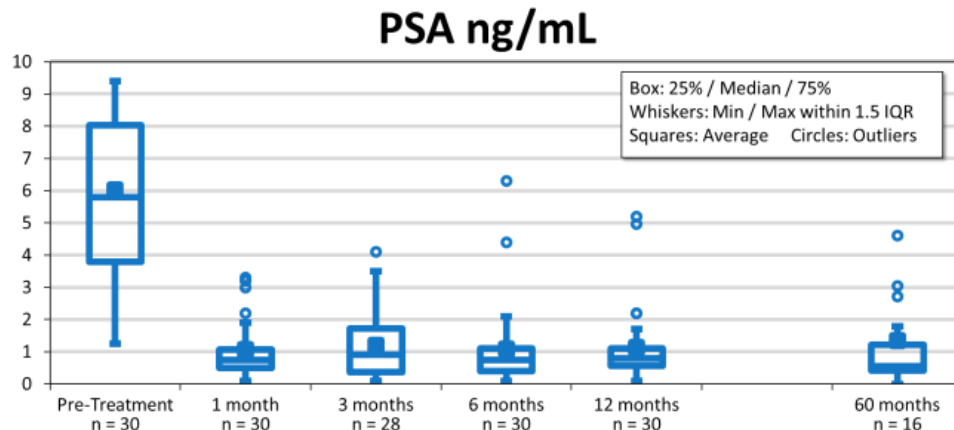
## 5-Year Follow-Up

### Salvage-free survival

- 16 men completed 5y follow-up, 3 left with PSA <0.4 ng/ml, 1 died (unrelated)
- 10 underwent salvage treatment: 6 RP, 3 EBRT, 1 laser
- Estimated **5-year salvage free survival**: 65% (95CI: 50-85%).

### PSA

- Stable to 5y in 16 men with complete follow-up:  
Median 0.6 ng/ml  
(IQR 0.4-1.2 ng/ml)
- Estimated **5-year biochemical failure free survival**:  
66% (95CI: 50-87%).



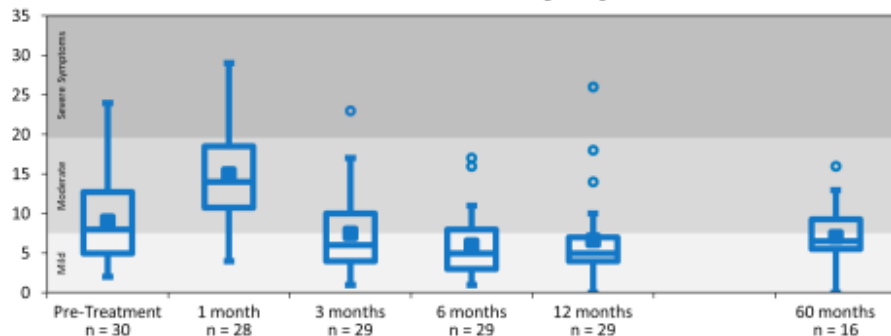


## 5-Year Follow-Up: Quality of Life

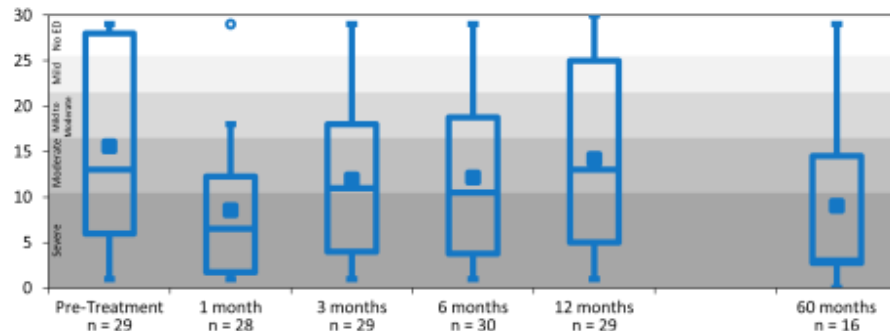
In 16 men who completed 5 year follow-up:

- **Continence:** 16/16 leak-free, pad-free at 1 and 5y
- **Erections** sufficient for penetration: 9/16 at baseline, 7/16 at 5y

### International Prostate Symptom Score



### IIEF-15 Erectile Function Domain

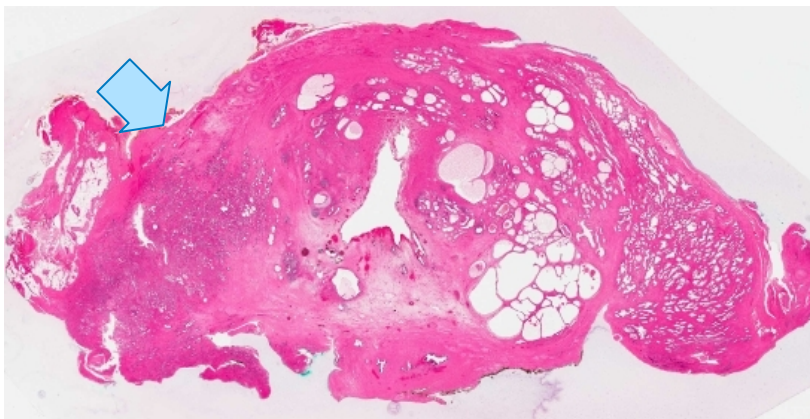






## Salvage Radical Prostatectomy

- 4 salvage RP at 1 site: minimal fibrosis, no complications or rectal injury
- Whole mount histology showed 2 pT2b and 2 pT3a consistent with persistent cancer in untreated peripheral safety region



Peripheral tumor near right posterior and bladder neck margins, with extensive EPE

Mean operating time (min)	191 (165-217)
Blood loss (ml)	900 (700-1000)
Length of stay (days)	3.5 (2-6)
Perioperative complications	None
Tumor Stage	pT2b (2/4), pT3a
Tumor Grade	(2/4) 4+3 (1/4), 3+4 (3/4)
Stress urinary incontinence	Mild 2/4, Implant 1/4
Erect Dys. unresponsive to PDE-5i	2/4
Biochemical recurrence	2/4





## Conclusions

- Five-year follow-up of MRI-guided TULSA in men with localized PCa demonstrates low toxicity, stable quality of life and disease control, while maintaining salvage treatment options.
- Phase I safety and feasibility protocol with only 90% ablation accepted risk of residual disease. Larger pivotal study used intensified treatment parameters for complete whole-gland ablation (AUA Virtual Experience PD17-02).