INTRODUCTION

- MRI-guided transurethral ultrasound ablation (MRI-TULSA) is a new minimally-invasive modality to ablate the prostate in patients with localized prostate cancer (PCa).
- This novel approach has the potential to offer disease control of localized PCa with a low morbidity profile.
- MRI-TULSA consists of a transurethral ultrasound applicator generating a precise volume of thermal ablation shaped to patient-specific prostate anatomy, using real-time active MRI thermometry feedback control.
- A multi-centre Phase I Clinical Trial of MRI-TULSA was performed, which enrolled patients between March 2013 and March 2014.
- The aim of this Phase I study was to determine clinical safety and feasibility of MRI-TULSA for whole-gland prostate ablation in the primary treatment setting of patients with localized PCa.

STUDY DESIGN

- Prospective, multi-centre, single-arm trial to evaluate safety and feasibility of MRI-TULSA (TULSA-PRO, Profound Medical Inc.)
- Clinical trial sites in 3 jurisdictions, all under same protocol

INCLUSION CRITERIA

- Age ≥ 65 years; Biopsy-proven prostate cancer (cT1c-T2a)
- Prostate size: ≤ 5 cm sagittal length & ≤ 6 cm axial diameter
- Eligible for MRI and general anesthesia; No prior PCa treatment

PRIMARY ENDPOINTS (1-year follow-up)

- Safety: Frequency and severity of treatment related AE
- Feasibility: Accurate & precise conformal heating of the prostate

EXPLORATORY ENDPOINTS (5-year follow-up)

- Efficacy: PSA response and biopsies at 1 and 3 years
- Quality of life: IPSS, IIEF, Bowel habits domain of UCLA-PCI-SF

TREATMENT PLANNING

- Therapeutic intent of conservative whole-gland ablation
- 3 mm safety margins at the glans periphery
- 10% residual viable prostate expected around the capsule

MATERIALS AND METHODS

- Ultrasound Applicator (UA)
- Endorectal Cooling Device (ECD)

RESULTS

- Feasibility
  - Accurate and precise prostate heating: 0.1 ± 1.3 mm, n=30
  - Prostate volume mean 47 cc (95% CI 41–54, range 21–95)
  - Treatment time 36 min (95% CI 32–40, range 24–61)
  - Acute cell kill on MR thermometry matches the Non-Perfused Volume on acute Contrast-Enhanced MRI

- Safety (NCI CTCAE v4)
  - No cases of intraoperative complications, severe urinary incontinence, rectal injury or fistula
  - No Grade (G) ≥ 4 AE’s; Total of one attributable G3 AE
  - Hematuria G1 (13 patients), G2 (2 patients), resolved
  - UTI G2 (10 patients), resolved with oral antibiotics
  - Epididymitis G3 (1 patient), resolved with IV-antibiotics
  - Urinary retention G1 (3 patients) and G2 (5 patients), resolved with prolonged or re-catheterization
  - All patients were discharged on or prior to POOL, median suprapubic catheterization time was 2.2 wk as per protocol

- IPSS
  - Mean 22.9 (12–42)
  - Median 24 (10.6–36.6)
  - Maximum 40

- PSA
  - Mean 4.6 ng/mL (1.2–19.9)
  - Median 3.0 (1.2–17.8)
  - Maximum 41.0

- IIEF-15 Erectile Function Domain
  - Mean 15.8 (2–30)
  - Median 19 (5–24)
  - Maximum 30

CONCLUSIONS

- MRI-TULSA provides detailed planning, real-time thermal dosimetry, and precise feedback control of prostate ablation
- MRI-TULSA is a safe and well tolerated procedure with a low morbidity profile for a whole-gland ablation of PCa.
- A larger multicenter TULSA-PRO Ablation Clinical Trial (TACT), with reduced safety margins, completed enrolment Feb 2018