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Transurethral Ultrasound Ablation for Treatment of Localized Prostate Cancer and Benign Prostatic Hyperplasia (BPH)

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Abstract

Indications: Transurethral ultrasound ablation (TULSA) is used for treating localized prostate cancer and benign prostatic hyperplasia (BPH). It's particularly suitable for patients with low to intermediate risk, uni- and multifocal organ-confined prostate carcinomas, symptomatic obstructive BPH coinciding with prostate cancer, and postradiation therapy recurrences.

Technique: The TULSA procedure involves meticulous preoperative preparation, precise surgical steps, and comprehensive postoperative care. Treatment is performed under magnetic resonance imaging (MRI) guidance using specialized MRI-compatible instruments, including a transurethrally inserted ultrasound applicator and an endorectal cooling device. Ablation is conducted through robot-driven rotation of the applicator, with real-time MRI thermometry used for monitoring and control.

Outcomes: A retrospective single-center clinical evaluation involved 300 men with primary localized prostate cancer (PCa) confirmed by biopsy. The median age was 66 years, prostate-specific antigen levels were 6.85 ng/mL, cancer length was 7.6 mm, and prostate volume was 49.2 cc. The median follow-up period was 14 months. Treatments included whole-gland (163 men) and focal TULSA (137 men), with neurovascular bundle sparing in 248 men. Additionally, 88 patients received combined therapy for PCa and BPH.

Safety: Grade 1 and 2 complications occurred in 57 patients, resolving within 4 weeks. Grade 3 adverse events were seen in seven patients, resolving within 3 months. No grade 4 or higher adverse events and no bowel-related complications were observed.

Functional Outcomes: The median international index of erectile function score remained stable from 24 to 25 over 48 months. The international prostate symptom score initially worsened post-treatment but improved to better than baseline levels over 48 months. Pad-free continence was preserved in 96% of patients.

Oncological Outcomes: Biochemical failure occurred in 26 men, with residual cancer confirmed by biopsy in 14 men. Salvage therapy was required for 14 patients, with 12 patients under active surveillance.

Keywords: treatment of localized prostate cancer, prostate cancer treatment, MRI techniques in urology, TULSA, interventional urology

Indications

Transurethral ultrasound ablation (TULSA) is utilized for treating localized prostate cancer and benign prostatic hyperplasia (BPH). This procedure is particularly suitable for patients with low to intermediate risk uni- and multifocal organ-confined prostate cancer, symptomatic obstructive BPH coinciding with prostate cancer, postradiation therapy with localized recurrences, and for local palliative treatment of locally advanced and metastasized prostate cancer with local symptoms or severe lower urinary tract symptoms (LUTS).

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Preoperative Preparation

The preparation for the TULSA procedure is meticulously planned to ensure optimal conditions and outcomes. The process takes approximately 45 to 60 minutes and includes the following steps:

- The patient is restricted to a liquid diet 1 day before treatment. On the day of the procedure, a laxative is administered 2 hours prior to the procedure.
- **Equipment Preparation (~20 minutes):** The magnetic resonance imaging (MRI) technician is responsible for preparing the TULSA device, which includes calibrating the equipment and ensuring all components function properly to avoid delays or technical issues during the procedure.
- **Positioning and Anesthesia, Catheter Insertion (~15 minutes):** The patient is positioned supine on the treatment table in the MRI anteroom. Anesthesia is initiated. After disinfecting the operation area and sterile draping, the urethra is instilled with gel, and a transurethral catheter is inserted. The bladder is then either completely emptied or a suprapubic catheter is inserted. If a suprapubic catheter (SPC) is to be placed, the bladder is filled via the transurethral catheter, followed by ultrasound control and sterile suprapubic pre-puncture with a small skin incision before the SPC is inserted in the usual manner, after which the bladder is emptied.
- The patient is then transported to the MRI room and positioned on the MRI table with legs secured in leg supports to facilitate better access for the Endorectal Cooling Device (ECD).
- **Device Introduction (~5 minutes):** The urologist inserts the ECD, filling the balloon with sterile water to stabilize the device. Subsequently, the catheter is removed, and under sterile conditions, the ultrasound applicator (UA) may be introduced. The urethra is first lubricated to facilitate insertion. The applicator may be introduced with or without the use of a guidewire, depending on the specific requirements of the procedure. Once properly positioned, the applicator is secured to the robot. Figure 1
- **Initial Imaging (10–15 minutes):** Once the devices are in place, the MRI technician takes initial images. These initial scans are reviewed by the radiologist, who confirms the correct positioning of the equipment. The urologist makes adjustments to the equipment's position as necessary.

Surgical Steps

- **Planning (45 minutes):**
  - **Device Alignment (~5 minutes):** The radiologist registers the position of the UA in the TULSA software using 3D T2-weighted images.
  - **Coarse Plan (~5 minutes):** The radiologist adjusts the position of the UA using the TULSA robot and confirms the correct placement with additional 3D T2-weighted images.
  - **Detailed Plan (~15 minutes):** The radiologist uses transverse T2-weighted images and a test THERM scan to precisely define the boundaries of the desired ablation volume for each of the 10 independent treatment elements. The urologist subsequently confirms this plan. Figure 2

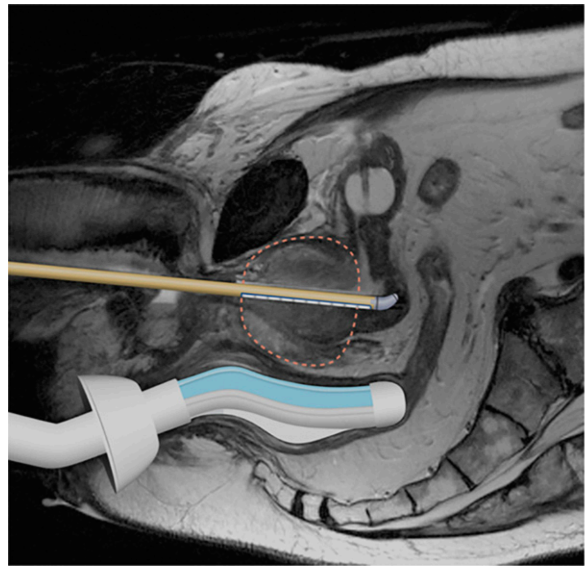

FIG. 1. MRI image illustrating the placement of the TULSA applicator and the Endorectal Cooling Device (ECD). The TULSA applicator is precisely positioned within the prostate, indicated by the overlay illustration, ensuring targeted ultrasound ablation. The ECD, visible in the rectal area, helps maintain a stable temperature during the procedure. To enhance visualization, both the applicator and the cooling device have been added as graphical overlays on the MRI image. The MRI provides a clear view of the applicator's alignment and the surrounding anatomical structures, confirming the correct positioning essential for effective treatment. TULSA, transurethral ultrasound ablation; MRI, magnetic resonance imaging.

- **Treatment and Confirmation (40–90 minutes):**
  - **Treatment (30–90 minutes, depending on the ablation volume):** The radiologist sets the starting angle and prepares for treatment. The system automatically executes the prescribed treatment plan, controlling the device's rotation speed and power output based on real-time temperature images. The radiologist monitors the real-time images and adjusts or pauses the treatment as necessary.
  - **Confirmation (~10 minutes):** The radiologist uses contrast-enhanced T1-weighted images to confirm the treatment effect. Figure 3
  - **Patient Transfer (~10 minutes):** Following treatment completion, the urologist removes the devices. If an SPC was not placed, the urologist inserts a Foley catheter. The anesthetist prepares the patient for recovery from sedation.

Postoperative Care

Patients typically stay in the hospital overnight following the TULSA treatment, although the procedure may also be conducted as a day case, depending on individual recovery and clinical guidelines. Continuous monitoring for potential postoperative complications is essential. Consultation for antibiotic and antithrombotic therapy is necessary to manage and prevent any adverse outcomes effectively.

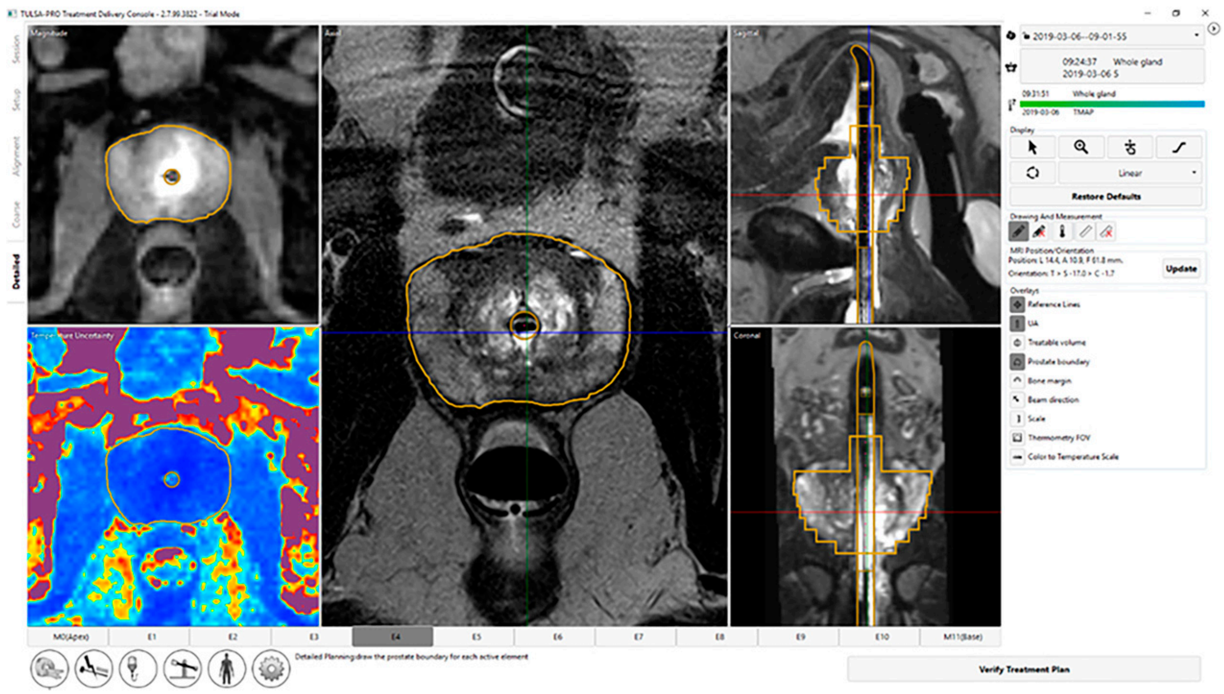

FIG. 2. MRI image showing the delineated treatment area of the prostate. The targeted region for ablation is clearly marked, indicating the precise boundaries for the TULSA procedure. This delineation ensures that the ultrasound energy is accurately focused on the affected area, maximizing treatment efficacy while preserving surrounding healthy tissue. The overlay illustrates the extent of the ablation zone within the prostate, as confirmed by the MRI imaging. In the bottom left corner, the thermal map prior to the treatment is visible, showing the initial temperature distribution.

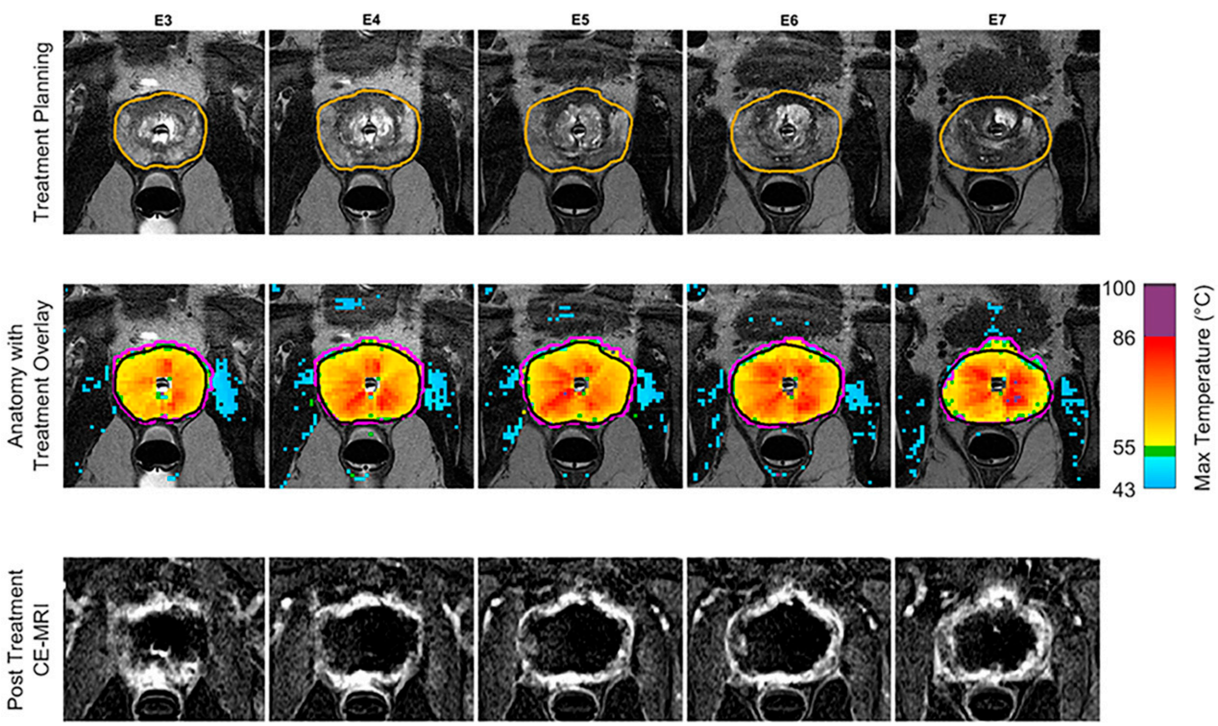

FIG. 3. MRI images displaying the thermal distribution during the TULSA treatment and post-treatment MRI images of the treated area. The thermal map illustrates the cumulative heat spread within the targeted region of the prostate, ensuring effective ablation. Post-treatment MRI images confirm the ablated area, showing changes in tissue characteristics indicative of successful treatment. The thermal distribution overlay highlights the precision of the procedure, with controlled and focused energy delivery to the intended zones.

Troubleshooting

Adjustments are made in cases of anatomical anomalies, such as the presence of calcifications that could block the ultrasound beam path. Previous surgical interventions are also considered during the planning of the ablation route.

Instrument List

Specific MRI-compatible instruments are used for conducting the TULSA procedure, including TULSA robots from the ALTA Clinic and various ultrasound devices and catheters. Detailed information on the manufacturers of these instruments will be included in the final manuscript.

- **Ultrasound Applicator (UA)**
  - 10 independent ultrasound transducer elements; 4 & 13 MHz; 0 to 4 W acoustic/element
  - Rigid catheter; Size 22 French; Sterile, single-use
- **Endorectal Cooling Device**
  - Cooling; non-sterile, single-use
- **Robotic Arm**
  - Robotically driven
  - Linear control of UA (Coarse Planning)
  - Rotational control of UA (Treatment)
- **System Cart**
  - Fluid circuit for UA and ECD
  - System electronics to power and control all system components
- **Treatment Delivery Console**
  - Computer with proprietary software
  - Treatment planning
  - Real-time thermometry images
  - Ablation feedback control algorithm

Clinical Results

Our retrospective single-center clinical service evaluation of MRI-guided TULSA for the treatment of organ-confined prostate cancer involved 300 men with primary localized PCa visible on MRI and confirmed by biopsy. The baseline characteristics included a median age of 66 years (IQR 60–73), PSA of 6.85 ng/mL (IQR 4.64–9.5), overall cancer length of 7.6 mm (IQR 4.35–10), and prostate volume of 49.2 cc (range 11–180). The median follow-up period was 14 months (IQR 4–30). Based on patients' preferences and disease characteristics, 163 men received whole-gland treatments and 137 focal TULSA, with neurovascular bundle sparing attempted in 248 men. A subset of 88 patients with LUTS suggestive of BPH received combined therapy for both PCa and concurrent BPH in a single treatment.

Regarding safety outcomes, 57 patients experienced Grade 1 and 2 complications, mostly resolving within 4 weeks through prolonged catheterization and/or antibiotics. Grade 3 adverse events (urinary retention requiring surgical intervention) occurred in seven patients, resolving within 3 months. Notably, no grade 4 or higher adverse events and no bowel-related complications were observed.

Functional outcomes were promising. The median IIEF score of 24 [IQR 14–29] (n = 234) at baseline remained stable at 25 (IQR 13–30) (n = 28) by 48 months. The baseline IPSS of 8 (IQR 4–15) (n = 250) initially worsened post-treatment to 12 (IQR 5–19) but recovered to 8 (IQR 2.5–10.5) (n = 47) by 12 months and further improved to 6 (IQR 3–11) (n = 46) by 48 months. Importantly, pad-free continence was preserved in 96% (160/185) of patients based on surgeon assessment.

In terms of oncological outcomes, 26 men experienced biochemical failure (Phoenix ≥ 2) after a single TULSA treatment. MRI findings showed suspicion of residual cancer in 26 men, 14 of which were confirmed by positive biopsy. Subsequently, 14 patients received salvage therapy (3 surgery, 11 single repeat TULSA), 12 patients remained under active surveillance.

These results demonstrate that TULSA is a safe and effective therapy option for the treatment of organ-confined prostate cancer, offering minimal impact on patients' quality of life while providing promising oncological outcomes.[1]

Authors' Contributions

L.E. and R.M.: Conceptualization; L.E. and R.M.: Methodology; L.E. and R.M.: Investigation; L.E.: Writing—original draft preparation; R.M.: Writing—review and editing; R.M.: Supervision. All authors have read and agreed to the published version of the article.

Author Disclosure Statement

All other authors have no conflicts of interest.

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Abbreviations Used

BPH	=	benign prostatic hyperplasia
ECD	=	endorectal cooling device
IIEF	=	international index of erectile function
IPSS	=	international prostate symptom score
LUTS	=	lower urinary tract symptoms
MRI	=	magnetic resonance imaging
PSA	=	prostate-specific antigen
SPC	=	suprapubic catheter
TULSA	=	transurethral ultrasound ablation
UA	=	ultrasound applicator