MRI-Guided TULSA Shows Faster Recovery Than Robotic Prostatectomy in CAPTAIN Trial

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Summarize This Article

MRI-guided transurethral ultrasound ablation (TULSA) resulted in significantly faster recovery, less perioperative morbidity, and better early functional outcomes than robotic radical prostatectomy in men with intermediate-risk prostate cancer, according to early results from the randomized CAPTAIN trial.

The findings represent the first fully recruited phase 3 multicenter randomized controlled trial directly comparing ablative therapy with prostatectomy in prostate cancer, according to the researchers, who presented the data at the European Association of Urology (EAU) 2026 Annual Meeting.

“At least in the short term, the recovery outcomes consistently favor transurethral ultrasound ablation,” Laurence Klotz, MD, of Sunnybrook Health Sciences Centre, in Toronto, Ontario, Canada, told attendees. “We saw essentially no blood loss, no overnight hospital stay, less pain, faster return to work, and earlier recovery of function.”

The results represent an important milestone in prostate cancer research because randomized trials comparing ablation with surgery have historically struggled to recruit patients, Klotz said.

“It’s very difficult to pull off a trial like this,” he said. “But this study was quite successful in terms of accrual, and it is the first fully recruited randomized trial comparing an ablative therapy with prostatectomy.”

TULSA: A Minimally Invasive Alternative

TULSA (marketed as TULSA-PRO by Profound Medical) is performed robotically under real-time MRI guidance, using directional ultrasound energy delivered through the urethra to thermally ablate prostate tissue while minimizing damage to surrounding structures involved in urinary and sexual function.

The CAPTAIN trial enrolled 211 men with localized intermediate-risk prostate cancer, randomizing them in a 2:1 ratio to ablation (148 patients) or radical prostatectomy (63 patients), most commonly robotic-assisted surgery.

Eligible participants had International Society of Urological Pathology grade group 2 or 3 disease and prostate-specific antigen (PSA) levels of 20 ng/mL or lower. Baseline characteristics were well balanced between groups.

Median age was 63 years in the ablation group and 65 years in the surgery group, with median PSA levels of 6.5 ng/mL and 7.2 ng/mL, respectively. Approximately three quarters of patients had grade 2 disease, and the remainder had grade 3.

During the ablation procedure, the median proportion of the prostate gland reaching ablative temperatures was 78%. Whole-gland ablation was performed in 68% of patients, while 32% underwent subtotal treatment. In the prostatectomy group, most procedures were nerve-sparing (95%) and pelvic lymph node dissection was performed in 77% of patients, according to the researchers.

The trial has two primary endpoints comprising a functional safety endpoint at 1 year, measuring preservation of urinary continence and erectile function, and an oncologic endpoint at 3 years, assessing freedom from additional treatment for prostate cancer. Patients will be followed for 10 years to assess long-term cancer control.

Perioperative Outcomes Favor Ablation

Early perioperative outcomes strongly favored the minimally invasive approach. Median blood loss was essentially zero with TULSA compared with 150 mL (interquartile range, 100-200 mL) during radical prostatectomy ($P < .0001$), Klotz and his colleagues reported.

Hospital stay also differed significantly between groups. Ablation was typically performed as an outpatient procedure with a median stay of 0.3 days compared with 1.1 days following prostatectomy ($P < .0001$).

Postoperative pain was lower during the first week after treatment among patients undergoing ablation, although the difference between groups diminished after approximately 10 days.

“The differences in early recovery are really quite striking,” Klotz said. “When you see essentially no blood loss, no overnight stay, and faster return to normal activity, it reflects the minimally invasive nature of the treatment.”

Faster Recovery, Fewer Complications, Superior Function

Patients treated with TULSA also returned to work sooner. Median time off work was 10 days (interquartile range, 4-15 days) following the procedure compared with 19 days (10-41 days) after prostatectomy ($P < .05$).

Complications requiring hospital admission within 90 days were also less common in the group that underwent ablation. Hospitalization occurred in 0.7% of patients treated with the approach, compared with 6.3% in the prostatectomy group, while no patients in the ablation group required admission to the ICU, compared with 1.6% in the surgery group.

“For patients, the difference is very tangible,” Klotz said. “They recover more quickly, return to work sooner, and generally feel back to normal earlier.”

Overall health scores on a patient-reported measure of health-related quality of life showed significantly faster recovery following ablation during the first 30 days after treatment ($P < .05$).

Patients undergoing surgery experienced a larger decline in perceived health immediately after treatment and took longer to return toward baseline levels, Klotz reported. Overall health at Day 30 showed considerably less impairment with ablation, and “somewhat surprisingly, the overall health score actually went above baseline on average, probably reflecting the patient’s relief at having had his prostate cancer treated,” Klotz said.

Although long-term results are still pending, early functional outcomes at x6 months also favored ablation. The trial’s primary composite safety endpoint comprised of preservation of both pad-free urinary continence and erections sufficient for penetration was achieved in 50% of patients treated with the procedure compared with 24% of those undergoing prostatectomy (risk ratio, 2.1; $P < .05$). Approximately 85% of men in the ablation group remained pad-free at 6 months compared with about 50% of patients undergoing prostatectomy, while rates of erections sufficient for penetration were also higher following ablation.

“These data show that transurethral ultrasound ablation was statistically superior to radical prostatectomy on the primary safety endpoint at 6 months,” Klotz said.

Oncologic Outcomes Still Pending

The key question for ablative therapies remains long-term cancer control. Among patients in the prostatectomy group, pathological findings showed 63% had pT2 disease, while 35% had pT3 tumors. Positive surgical margins were observed in 33% of cases, confirming the study population included clinically significant cancers.

Whether the early functional advantages of TULSA can be maintained without compromising cancer control will become clear with longer follow-up. “Surgery is not going away,” Klotz said. “But the sweet spot for transurethral ultrasound ablation is men with intermediate-risk disease where there is still room for salvage treatment if needed. Transurethral ultrasound ablation is bilateral or multifocal cancers because other focal therapies are designed more for single lesions.”

For patients treated with ablation, oncologic outcomes will be assessed using MRI and mandatory biopsy at 12 months, with longer follow-up required to

evaluate recurrence and disease progression. “The primary oncologic endpoint comprising freedom from additional prostate cancer treatment will be reported at 3 years,” Klotz said. “The early recovery advantages are very clear,” Klotz said. “The key question now is whether we can maintain those benefits while achieving equivalent long-term cancer control.”

Martin Schostak, MD, PhD, from the uro-oncological study center of LOGICURO GmbH, in Potsdam, Germany, said recruitment and retention are often major challenges in randomized trials comparing surgery with newer minimally invasive treatments.

“Trials comparing very different treatment approaches, such as surgery and focal or ablative therapies, often struggle with dropout after randomization because patients have strong preferences,” Schostak said, adding that dropout in CAPTAIN was “relatively modest,” at only about 10%-15%.

According to Klotz, one factor that may have helped maintain participation was that participants were mostly heading for radical prostatectomy and that ablation was provided free of charge within the trial, whereas in some healthcare systems patients must otherwise pay for the procedure themselves. “This likely helped reduce the risk of patients withdrawing after randomization and will not undermine the trial conclusions.” he said.

Schostak added that the modest dropout rate strengthens confidence in the early findings but the long-term oncologic outcomes will ultimately be key to determining the role of ablation in the treatment of prostate cancer.

Klotz reported receiving research support and consulting income from Profound Medical. Schostak reported receiving honoraria, research funding, and other support from companies including Bayer, Merck, AstraZeneca/MedImmune, Janssen Oncology, and Pfizer.

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