

Focal ablation therapy presents promising results for selectively localized prostate cancer patients

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Abstract

Due to its lower risk of consequences when compared to a radical approach, focal treatment is a viable and minimally invasive option for treating specific localized prostate cancer. Although several recent good non-randomized trials have suggested that focused therapy may be an alternative choice for some patients, additional high-quality evidence is needed before it can be made widely available as a conventional treatment. As a result, we have summarized the most recent findings from the 38th Annual European Association of Urology Congress, one of the most renowned annual conferences in the area of urology, regarding focal ablation therapy for patients with localized prostate cancer. Additionally, we also provided clinical trials in progress for researchers to better understand the current research status of this field.

Keywords: Prostate cancer; focal ultrasound ablation; focal laser ablation; targeted microwave ablation

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Prostate cancer (PCa) is one of the most common urinary malignancies and the most frequent non-skin malignancy in males (1-4), which had approximately 1,414,259 new cases and 375,304 mortalities worldwide in 2020, ranking third in incidence rate and eighth in mortality rate, respectively (5,6). The number of persons over 65 years old is anticipated to reach about 20% of the world's population by 2030 and an estimated 1.6 billion by 2050, since such elder population is expanding at an unprecedented speed (7,8). In this situation, age-related diseases, including the most three common urinary tumors (prostate, bladder and renal cancers), are anticipated to put great pressure on national healthcare system (9-11).

Radical prostatectomy (RARP) and radical radiotherapy are currently the equally effective treatments for localized PCa, and despite this fact, such patients still experience

biochemical recurrence in 27%–53% of cases (12-16). Moreover, patients undergoing radical surgery are at risk of perioperative complications, such as urinary incontinence and erectile dysfunction (17-19). Focal therapy shows potential of less effect on continence and potency than radical therapy for selected localized PCa patients, which includes eight different sources of energy like high-intensity focused ultrasound (HIFU), irreversible electroporation, cryoablation, focal laser ablation, focal brachytherapy, photodynamic therapy, radiofrequency ablation, and prostatic artery embolization during October 2015 and December 2020 summarized in a previous systematic review (20). This review indicated that despite promising results of favorable functional and oncological outcomes, the vast majority of studies remained in an early research stage (stage 2a), except for HIFU and photodynamic therapy (stage 3) (20). In recent years,

despite the fact that focal therapy is considered to be an alternative option for selected patients in some good non-randomized trials, more high-quality evidence is required before it can become available as a standard treatment (21-24).

Therefore, we have summarized the cutting-edge research of focal ablation therapy for localized PCa patients from the 38th Annual European Association of Urology Congress (<https://urosource.uroweb.org/resource-centres/EAU23/search?event=EAU23&resourceType=Abstract>), one of the most prestigious annual conferences in the field of urology. Additionally, we also provided clinical trials in progress for researchers to better understand the current research status of this field.

Focal ultrasound ablation for localized PCa patients

A multicentric cohort enrolling 3,328 patients (HIFU: 1,967; RARP: 1,361) in 46 centers compared HIFU with RARP for low- or intermediate-risk PCa patients (abstract No. LB08). At 30 months, the salvage treatment-free survival was significantly higher in the HIFU arm (90.1%) compared with RARP arm (86.8%) with a risk of salvage treatment >1.2-fold higher after RARP [hazard ratio (HR): 0.78, 95% confidence interval (95% CI): 0.64–0.96, $P=0.020$]. There was no difference in International Prostate Symptom Score (IPSS) and Quality of Life Questionnaire Core-30 (QLQC-30) summary scores. International Continence Society (ICS) score was significantly lower after HIFU (0 vs. 1, $P<0.001$). International Index of Erectile Function-5 (IIEF-5) score decreased significantly less after HIFU than after RARP. Thus, sub-total HIFU should be discussed as first-line treatment in well-selected patients. Ebner A. *et al.* found that initial T stage represents a clinically feasible and cost-effective determinant of treatment failure in patients treated with HIFU therapy for low- to intermediate-risk PCa (abstract No. A0967).

Three studies indicated that magnetic resonance imaging-guided transurethral ultrasound ablation (MRI-TULSA) was an effective approach for localized PCa patients with favorable adverse events (abstract No. A0964; A0965; A0966). The TACT trial (NCT02766543) reported four-year follow-up of MRI-TULSA in 115 males with localized PCa (abstract No. A0964). At 4 years, median [interquartile range (IQR)] prostate-specific antigen (PSA) was 0.9 (0.4–1.6) ng/mL, reduced by 86% (75%–95%) from baseline and by 96% to the nadir ($n=76$). Median IPSS decreased from 7 at baseline to 5 at 4 years ($n=73$).

Erections sufficient for penetration (IIEF Q2 \geq 2) were recovered by 46/57 (81%). Pad-free urinary continence [Expanded Prostate Cancer Index Composite (EPIC) Q5] was preserved by 68/72 (94%). Social continence was preserved in 71/72 (99%) males. There was no rectal injury or grade \geq 4 adverse events. Grade 3 adverse events were reported for 9 males (8%). These included retention, stricture, infection, pain, urinoma and stricture, all of which resolved before 1 year. Similarly, Anttinen M.H.J. *et al.* (abstract No. A0965; A0966) showed that whole-gland or focal TULSA could be an efficient therapy for localized or radio-recurrent PCa patients with acceptable toxicity profile based on 12-month follow-up analysis. We summarize the above results in *Table 1*.

Targeted microwave ablation (TMA) and focal laser ablation for localized PCa patients

A prospective trial evaluated day-only, fast, focal laser ablation for localized PCa using the novel ProFocal-Rx™ device (Medlogical Innovations, Sydney, Australia) at Nepean Hospital, Australia (abstract No. A0963). All cases were completed as day-only procedures and there were no readmissions to hospital. Interim results indicated that on the 3-month follow-up biopsy, 75% of patients had no evidence of International Society of Urological Pathology (ISUP) 2 or greater PCa on any of their biopsies. Twelve percent of cases proceeded to salvage RARP and 2% underwent salvage radiotherapy. Forty percent of cases with ISUP 2 PCa on the 3-month biopsy were placed under active surveillance due to the small volume of cancer detected on these biopsies. Of the cases who underwent salvage RARP, there was no significant difference in their outcomes compared to their contemporary cohort. Patient reported functional outcomes were excellent with no significant worsening in quality-of-life scores, lower urinary tract symptoms or sexual function between the pre-operation, 3-month or 6-month assessment. Oderda M. *et al.* (abstract No. A0969) preliminarily evaluated functional and oncologic outcomes of TMA in 11 patients with newly diagnosed low- to intermediate-risk PCa at 6 months. They found that 9 of 11 (82%) patients had absence of tumor in the treated area at 6-month target biopsy without any complications. Similar results were reported by Chiu P.K-F. *et al.* (abstract No. A0968). We summarize the above results in *Table 2*.

Clinical trials in process

To date, most of studies about the effectiveness of focal

Table 1 Focal ultrasound ablation for localized PCa patients

Author	Country	Study type	Eligibility criteria	Intervention	Outcomes and complications
Klotz L.H. <i>et al.</i> (A0964)	Multiple countries	Prospective trial	Stage equal or smaller than T2b, PSA equal or smaller than 15 ng/mL, and GG 1–2.	MRI-guided TULSA in males with localized PCa. Inside-out thermal coagulation of prostate tissues under real-time, closed-loop MRI thermometry control enables precise and automatic adjustment of treatment parameters.	Median prostate volume reduced to 2.8 mL after one year and median PSA reduced to 0.9 ng/mL after four years. Effective disease control up to four years, good adverse event profile.
Anttinen M.H.J. <i>et al.</i> (A0965)	Finland	Prospective study	mpMRI and 18-F PSMA-1007 PET-CT were used to rule out extra prostatic diseases.	Patients underwent either whole-gland or partial sTULSA, by mpMRI, PSMA PET-CT, and prostate biopsy targeting the treatment area plus areas suspicious in imaging.	Median PSA at 12 months after sTULSA was 0.19 ng/mL, 23/26 without any PCa in the treated area. Post-void residual volume improved by 33.3% and degradation of 41%, 37% and 37% were recorded for average flow rate, Qmax and voided volume, respectively.
Yli-Pietilä E.H.M. <i>et al.</i> (A0966)	Finland	Prospective study	MRI-visible and csPCa, high volume ISUP 1 (>2 positive cancer cores or ≥50% cancer in a core) or ≥ISUP 2.	Receive whole gland or focal MRI-guided transurethral ultrasound ablation. At 6 and 12 months' follow-up, mpMRI was performed. At 12 months, biopsies were acquired.	Twenty-eight of 39 (72%) patients were free of in-field csPCa, with median (IQR) PSA of 0.81 ng/mL, stable median average flow rate and Qmax, but with low impact on QoL.
Ebner A. <i>et al.</i> (A0967)	Austria, Sweden, Switzerland	Prospective trial	Clinically significant, localized, unilateral and low- or intermediate-risk PCa.	Focal high-intensity focused ultrasound therapy	Three of ten cores taken at initial biopsy were positive. Sixteen percent of TFs occurred. In multivariable-adjusted analysis, only T stage evolved as an independent predictor of TF [HR, 5.57 (1.52–20.32)].
Rischmann P. <i>et al.</i> (LB08)	France	Cohort study	Low- or intermediate-risk PCa (cT1–2NxM0, GG 1 or 2, PSA<15 ng/mL) not eligible for active surveillance, with 4/6 sextants invaded and a prebiopsy mpMRI with or without target. Patients were >69 years old in HIFU arm (French guidelines) and had a life expectancy >10 years in RP arm.	HIFU vs. RP	At 30 months, the salvage treatment-free survival was significantly higher in HIFU arm (90.1%) compared with RP arm (86.8%) with a risk of salvage treatment >1.2-fold higher after RP and better continence and erectile function outcomes after HIFU.

PCa, prostate cancer; PSA, prostate-specific antigen; GG, grade group; MRI, magnetic resonance imaging; TULSA, transurethral ultrasound ablation; PET-CT, positron emission tomography-computed tomography; csPCa, clinically significant PCa; ISUP, International Society of Urological Pathology; mpMRI, multiparametric magnetic resonance imaging; QoL, quality of life; TF, treatment failure; HR, hazard ratio; HIFU, high-intensity focused ultrasound; RP, radical prostatectomy.

ablation therapy on localized PCa are in their early stage. Thus, we summarize the ongoing trials of this procedure to help clinicians keep abreast of the latest progress in *Table 3*.

Conclusions

Focal therapy is a feasible and minimally invasive

method for treating selected localized PCa due to its reduced risk of complications compared to radical approach. Unfortunately, the preponderance of current studies has a low level of evidence, suggesting that larger size of randomized control trials is urgent to determine whether this approach presents non-inferior

Table 2 Targeted microwave ablation and focal laser ablation for localized PCa patients

Author	Country	Study type	Eligibility criteria	Intervention	Outcomes and complications
Kam J. <i>et al.</i> (A0963)	Australia	Prospective trial	PSA≤15 ng/mL, stage ≤T2c, ISUP 2–3, and 1–2 MRI visible lesions	Focal laser ablation utilizing ProFocal-Rx™ via a transperineal route and with an MRI/US fusion targeting platform.	Eighty-five percent of patients avoiding radical treatment with no worsening in any patient reported outcomes after treatment.
Oderda M. <i>et al.</i> (A0969)	Italy	Prospective, interventional phase I–II trial	Single MRI-visible lesion ≤12 mm diagnosed as ISUP≤2, PSA<20 ng/mL, 5-mm safety distance from apex and rectum, no signs of capsular involvement.	Transperineal targeted microwave ablation with a very low-loss microwave ablation system (TATO3) guided by 3D ultrasound/MRI fusion imaging achieved with Koelis Trinity.	Nine of eleven had absence of tumor in the treated area. No significant changes in PSA levels, IPSS or IIEF-5 scores were reported.
Chiu P.K-F. <i>et al.</i> (A0968)	Hong Kong	Prospective phase 2 trial	Males with low- to intermediate-risk PCa	Undergoing transperineal TMA was performed with MRI-ultrasound fusion guidance and organ-based tracking using the Koelis Trinity machine.	Thirty-five of 39 ablated areas had no cancer in 6-month targeted biopsy. Six of 8 with normal preoperative erectile function had no deterioration. Complications (all grade 1) included hematuria (18.5%), transient dysuria (3.7%), and transient perineal discomfort (7.4%).

PCa, prostate cancer; PSA, prostate-specific antigen; ISUP, International Society of Urological Pathology; MRI, magnetic resonance imaging; US, ultrasound; TMA, targeted microwave ablation.

Table 3 Clinical trials in process investigating effects of focal ablation therapy on PCa

Title	Trial ID	Sample	Estimated study completion date
Study of focal ablation of prostate with NanoTherm® therapy system for intermediate-risk PCa	NCT05010759	30	October 2027
An evidence-based focal cryotherapy protocol for focal ablation of intermediate-risk PCa	NCT05454488	30	January 31, 2024
Outcomes of focal ablation for PCa	NCT05478694	225	August 2026
HIFU for focal ablation of prostate tissue: An observational study	NCT03620786	100	June 30, 2023
Fusion-guided focal laser ablation of PCa	NCT02759744	14	January 21, 2026
An extension study MRI/US fusion imaging and biopsy in combination with nanoparticle-directed focal therapy for ablation of prostate tissues	NCT04240639	60	June 2023
Focal prostate ablation vs. radical prostatectomy	NCT03668652	200	September 30, 2024
Safety and efficacy evaluation of trans-perineal IRE of anterior PCa	NCT05512663	10	September 2024
Pilot study to investigate MRI-guided focal therapy in PCa	NCT04808427	15	September 1, 2027
Focal laser ablation of low to intermediate PCa	NCT02600156	20	December 2025
Focal laser ablation for treatment of focal low-intermediate risk PCa	NCT04045756	50	August 2, 2024
Focal laser ablation of PCa	NCT04305925	10	October 31, 2024
Investigator initiated trial to further evaluate safety and efficacy of trans-perineal focal laser ablation of localized PCa using high frequency micro-ultrasound imaging	NCT05826470	15	May 30, 2025
MRI-guided focal laser ablation (Unicorn)	NCT04379362	53	July 1, 2024
Comparative health research outcomes of novel surgery in PCa (IP4-CHRONOS)	NCT04049747	2,450	May 2027
Focal prostate ablation with androgen deprivation and novel hormonal therapy for intermediate-risk PCa	NCT05790213	57	April 1, 2028

Table 3 (continued)

Table 3 (continued)

Title	Trial ID	Sample	Estimated study completion date
MRI-guided focal laser ablation PCa	NCT05370482	10	April 11, 2025
Focal US-guided cryo-ablation using DynaCAD/UroNAV preplanning/Guidance of intermediate-risk PCa	NCT04656678	45	October 30, 2024
Trans-perineal laser ablation for low- and intermediate-risk PCa: A single cohort analysis	NCT05584787	20	May 30, 2023
Prospective clinical safety and efficacy study of lesion-targeted MRI-TULSA for localized PCa (PRO-TULSA-PC)	NCT03814252	62	December 31, 2023
Efficacy assessment of a novel 3D cartography-based targeted focal microwave therapy in men with localized intermediate-risk PCa (VIOLETTE)	NCT04582656	65	May 2023
Pivotal study of MRI-guided transurethral ultrasound ablation in patients with localized PCa (TACT)	NCT02766543	150	June 2026
MRI-guided transurethral ultrasound ablation of localized PCa (MRI-TULSAP)	NCT03996005	25	October 2023
Water vapor ablation for localized intermediate-risk PCa (VAPOR 2)	NCT05683691	400	April 2029
Evaluation of HIFU hemiablation and short-term androgen deprivation therapy combination to enhance PCa control (ENHANCE)	NCT03845751	20	January 2025
TPLA treatment for PCa registry	NCT05163197	200	October 1, 2027
A comparison of TULSA procedure vs. radical prostatectomy in participants with localized PCa (CAPTAIN)	NCT05027477	201	December 1, 2032
Study of nano-knife for ablation of PCa in intermediate-risk patients	NCT01972867	6	May 2024
Microwave needle thermos-ablation for treatment of localized PCa	NCT04113811	30	December 31, 2023
Ablative therapy in management of PCa	NCT03492424	200	September 2039
MRI-guided transurethral urethral ultrasound ablation for treatment of intermediate-grade PCa	NCT05438563	10	March 7, 2026
Performance of prostate MRI and following biopsy to detect PCa recurrence after focal therapy (IRMPProf)	NCT04773821	260	October 2024
Androgen ablation therapy with or without niraparib after radiation therapy for treatment of high-risk localized or locally advanced PCa	NCT04947254	200	June 7, 2026
MRI-guided cryoablation for focal native PCa	NCT04797039	100	December 2030
Focal therapy for PCa using HIFU (INDEX)	NCT01194648	35	June 2029
Neoadjuvant ADT with TULSA in treatment of intermediate-risk PCa (neo-ADT-TULSA)	NCT05917860	15	December 31, 2030
Evaluation of different methods of ultrasound image analysis for real-time monitoring of HIFU PCa treatment (ELASTO-US)	NCT05714774	40	September 14, 2024
MRI-guided trans-urethral HIFU for various prostate diseases (HIFU-PRO)	NCT03350529	87	December 2024
Focal therapy with SBRT for patients with a single prostate tumor	NCT05616650	42	December 1, 2028
Continued access of focal MRI-guided focused ultrasound for localized intermediate-risk prostate lesions	NCT03998657	14	December 30, 2022
Pivotal study of nano-knife system for ablation of prostate tissues (PRESERVE)	NCT04972097	118	June 2024
Detection of clinically significant PCa with 18F-DCFPyL PET/MR (PSMA-DOCS)	NCT03149861	56	May 9, 2023
Single-center study of single-port trans-vesical partial prostatectomy versus FLA for focal treatment of localized PCa	NCT05610852	276	July 1, 2028
	DRKS00025500	10	/

PCa, prostate cancer; HIFU, high-intensity focused ultrasound; MRI/US, magnetic resonance image/ultrasound; IRE, irreversible electroporation; TULSA, transurethral ultrasound ablation; TPLA, trans-perineal laser ablation; SBRT, stereotactic body radiation therapy; FLA, focal laser ablation.

functional and oncological outcomes compared to radical surgery. Additionally, the criteria of selected

patients are needed to be more refined to better guide clinical practice.

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Footnote

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