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Focal High-Intensity Focused Ultrasound Ablation of the Prostate

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Abstract

With the advancement of early detection tools for prostate cancer and ability to better localize disease, there has been increased interest in focal or targeted therapies that carry less morbidity than traditional whole-gland treatments. The Sonablate® high-intensity focused ultrasound (HIFU) device has Food and Drug Administration (FDA) 510(K) clearance in the United States for ablation of prostate tissue. HIFU utilizes an ultrasound (US) transducer that focuses US beams on a preset point as much as 4 cm from the energy source without injuring intervening tissue. The Sonablate system guides the surgeon step-by-step to perform effective ablation of a target lesion. The surgeon can assess treatment effect with tissue change monitoring, and care is taken to prevent rectal wall injury. We believe hemiablation is the most favorable focal HIFU treatment to optimize cancer control and minimize the side effects associated with whole gland therapy. We recommend considering HIFU ablation as an extension of active surveillance rather than definitive treatment. Further research on long-term oncologic and functional outcomes is warranted.

Keywords: focal therapy, prostate cancer, prostate, image guided therapy

Introduction

With an estimated incidence of over 191,000 new cases in 2020, prostate cancer comprises over 10% of all new cancer cases each year in the United States.[1] Historically, whole gland treatment has been offered in the form of radical prostatectomy and radiation therapy. With these treatment modalities, men are at risk for collateral damage to surrounding nerves, sphincter, and other adjacent organs such as bladder and rectum. A prospective multicenter trial of 434 patients demonstrated that 23% of patients reported clinically significant treatment regret after radical prostatectomy, external beam radiotherapy, and brachytherapy.[2] Treatment regret correlated with the presence of hormonal and masculinity-related symptoms, educational level, and positive margins.

Whole gland high-intensity focused ultrasound (HIFU) ablation has notable downsides, including risk of urethral stricture and erectile dysfunction. The prostatic urethra is treated requiring extended catheterization (e.g., 2 weeks), and there is a significant risk of requiring a post-HIFU procedure (e.g., urethral dilation). With the advancement of early detection tools for prostate cancer, including multiparametric MRI (mpMRI) and MRI-ultrasound (US) fusion targeted biopsies, urologists have the ability to better localize prostate cancer within the prostate. There has been increased interest in focal or targeted therapies that carry less morbidity than traditional whole-gland treatments. A 2016 consensus panel concluded that the ideal prostate cancer for focal therapy is a Gleason 3+4 lesion that is location and size favorable to the specific treatment modality.[3] We believe that hemiablation is the most favorable focal HIFU treatment to optimize cancer control and minimize side effects (e.g., erectile dysfunction).

History

HIFU technology was pioneered at Indiana University in the 1970s with the first device being built in 1996.[4] In 2000, the first research protocol for HIFU treatment in the United States was drafted at a cancer symposium at the Indiana University School of Medicine. In 2007, Dr. Michael Koch, Dr. Thomas Gardner, and others published the first 20 patients treated with HIFU and reported few side effects and the potential benefits in treatment of early stage prostate cancer.[5] The Sonablate® HIFU device has Food and Drug Administration (FDA) 510(K) clearance in the United States for ablation of prostate tissue since 2015.

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How It Works

HIFU utilizes an US transducer that focuses US beams on a preset point as much as 4 cm from the energy source without injuring intervening tissue.[4] This generates a temperature of at least 55°C, which leads tissue destruction by coagulative necrosis and cavitation of target.[6] The heat denatures the proteins and lipoproteins in cell membranes leading to coagulative necrosis.[7] Microbubble formation and collapse in these tissues lead to cavitation of the target. These microbubbles appear hyperechoic on US and allow for visualization of treatment effect.

Indications

HIFU for prostate cancer has been applied to various clinical scenarios, including partial and whole gland treatment, as well as in primary and salvage settings. Medicare covers HIFU for postradiation salvage therapy in the setting of a rising prostate specific antigen (PSA), negative staging imaging, and positive postradiation prostate biopsy. The focus of this video is on the focal treatment (hemiablation) of localized prostate cancer (Fig. 1). Indications for HIFU treatment of localized prostate cancer include a visible lesion on mpMRI that is concordant with biopsy pathology. This allows for MRI-US fusion targeting of the lesion during HIFU treatment. Generally, we recommend focal HIFU in patients with a single-side, low volume Gleason 3 + 4 lesion and avoid treatment of patients with Gleason 4 + 3 disease or greater unless life expectancy is less than 15 years. All focal therapies carry risk of incomplete treatment or failure to completely eradicate the cancer both within (inadequate heat) and without (missed biopsy) the targeted treatment zone. Patients with $a > 15$ years life expectancy are at increased risk of symptomatic metastatic prostate cancer. As with any treatment, urologists must counsel patients on the balancing of risks and benefits. Contraindications to treatment include a large prostate (greater than 4 cm distance of treatment, generally not larger than a 40 g gland); presence of calcifications greater than 1 cm, metal implants, stents, or brachytherapy seeds which can interfere with therapeutic sound waves; preexisting inflammatory disease of the colon or rectum; and prior significant rectal surgery.

Preoperative Preparation

HIFU ablation of the prostate is performed as an outpatient surgery. After extensive counseling on the nature of prostate cancer and treatment risks, benefits, and alternatives, informed consent is obtained. All patients have previously undergone mpMRI and MRI-US fusion guided biopsy. Patients

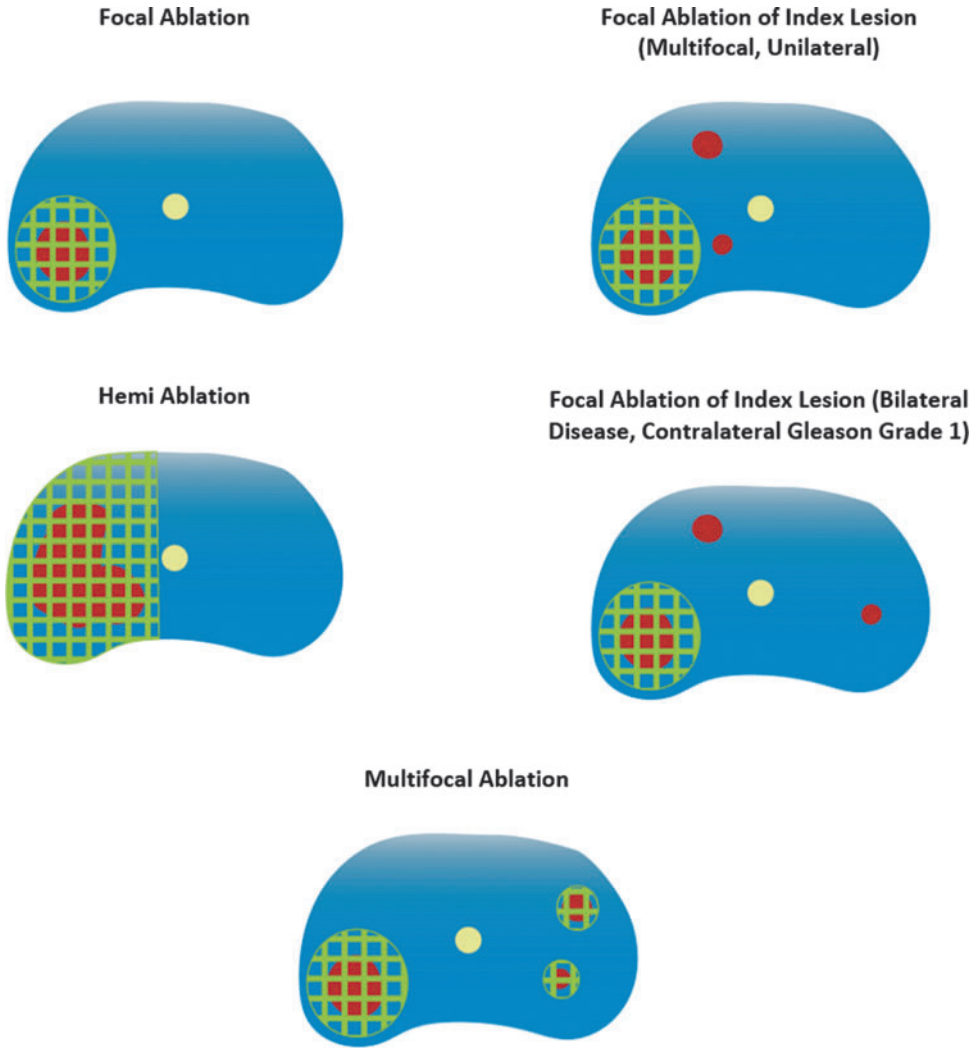

FIG. 1. Ablation strategies for HIFU based on location of clinically significant prostate cancer. Images courtesy of SonaCare Medical, LLC.[4] HIFU = high-intensity focused ultrasound.

FIG. 2. Sonasource® and Sonachill (*left*), Sonablate® transducer probe (*right*). Images courtesy of SonaCare Medical, LLC.[4]

undergo routine preoperative medical assessment, as well as urine culture. Patients may continue anticoagulants. Patients maintain a clear liquid diet on the day before surgery and complete a bowel prep, drinking 10 ounces of magnesium citrate in the morning and evening before surgery. The procedure may be performed under spinal or general anesthesia. Our practice prefers general anesthesia, which ensures precision of device calibration and treatment due to absence of movement during the procedure. Nitric oxide must not be given during the procedure. The patient is given antimicrobial prophylaxis, generally a first-generation cephalosporin.

Patient Positioning

The following treatment description is for the Sonablate system. Ablatherm is another FDA-approved device that allows for treatment in the right lateral decubitus position. The patient is positioned in dorsal lithotomy, and a warming blanket is applied. A malecot catheter is inserted into the rectum and irrigated copiously with normal saline until the effluent is clear ($\sim$2 L). A urethral foley (e.g., 14F) is inserted under sterile conditions.

List of Instruments (Fig. 2)

- Sonablate System (SonaCare Medical, LLC).
  - Sonasource® console, Sonachill rectal cooling system, Sonablate transducer probe.
  - Sonablate Probe Tip Kit and Water Path Kit.

Surgical Steps

Treatment times range from 1.5 to 3 hours and depend on the volume of tissue being ablated. The operating room team is trained on probe setup, which includes steps to ''de-gas'' the circulating water in Sonachill. The HIFU probe is inserted into the rectum with US-specific jelly. The probe is held in place by the multiaxis stepper and probe arm. The Sonablate software can be calibrated with MRI images from prior fusion biopsy. The prostate is mapped using US, and treatment area is defined (Fig. 3). The Sonablate probe has a dual-sided transducer with focal lengths of 3 or 4 cm allowing for near (posterior) or far (anterior) ablation, respectively. Each thermal lesion is 10–12 mm in length and 1–2 mm wide. Sequentially positioned lesions comprise the treatment target area.

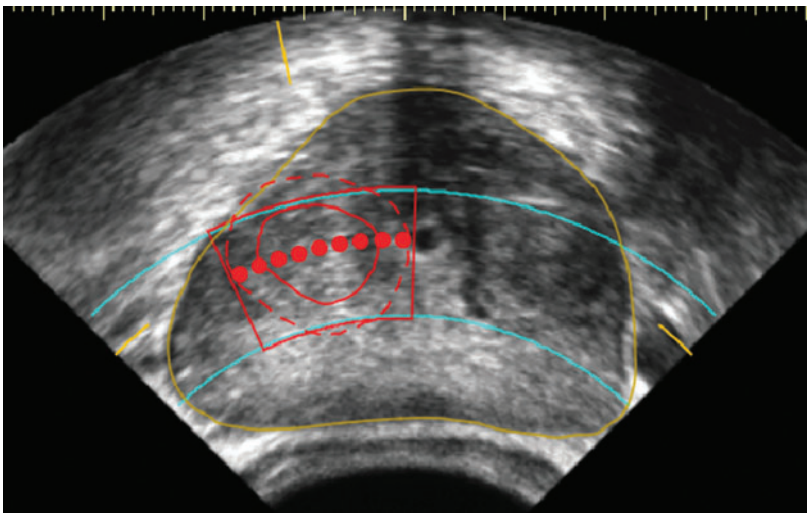

FIG. 3. Sample treatment planning. Treatment area defined in *red*. Ablation zone defined in *blue*. Prostate borders defined in *yellow*. Image courtesy of SonaCare Medical, LLC.[4]

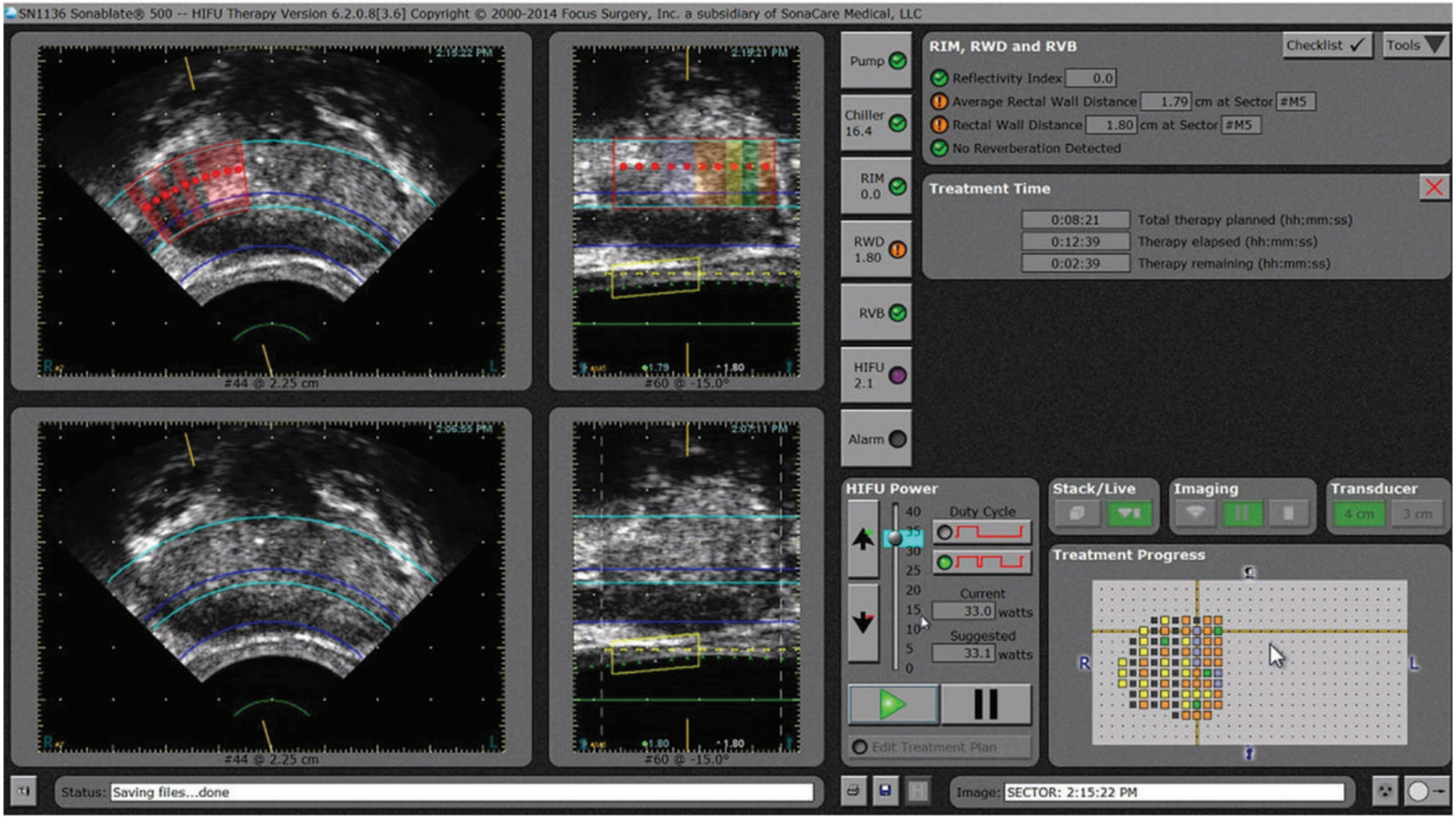

FIG. 4. Example of hemi gland ablation plan with TCM. Image courtesy of SonaCare Medical, LLC.[4] TCM = tissue change monitoring.

The most anterior tissue (farthest from probe) is treated first. We typically retreat the anterior tissue as the venous plexus can act as a heat sink that prevents proper heat buildup. Retreating creates an insulating layer ensuring proper heat buildup as the treatment progresses. US waves are delivered in a treatment cycle of 3 seconds on, 6 seconds off, or conversely with 6 seconds on, 3 seconds off. We use the slower 3 seconds on, 6 seconds off to prevent heat buildup in the foreground or periprostatic adipose tissue. The prostate tissue is monitored for temperature and treatment effect. Sonablate software uses Tissue Change Monitoring software that assesses radiofrequency signal changes in tissue (Fig. 4). This is color coded for the physician to interpret the degree of tissue change to guide HIFU delivery (Fig. 5). Treatments labeled in ''green'' are considered minimal change and can be retreated. The total ablation time is typically between 30 and 60 minutes for focal/hemiablation.

The Sonachill cooling system circulates cold water within the probe to cool the rectal wall and provides US coupling between transducer and tissue. Rectal wall distance is continually measured between the therapy transducer and rectal wall, and reflectivity index monitor can detect undesired cavitation bubble formation at the rectal well. During treatment planning and delivery, care is taken to avoid the rectum, neurovascular bundle, and urethra. The urinary catheter is generally left in during treatment. If treatment near or across the urethra is desired, the catheter must be removed.

Postoperative Care

Postoperatively, the patient is awoken from anesthesia and discharged home after convalescence in the postanesthesia care unit. He is discharged with Foley catheter in place and instructed on removal at home or in the office on postoperative day 3. An alpha-blocker (e.g., tamsulosin) and antibiotics are prescribed for 5–7 days postoperatively. The patient returns to the urologist office 2–3 months after treatment for clinical evaluation and a PSA test. Ideally, at 6 months postoperatively, the patient will undergo post-treatment MRI and fusion biopsy to confirm treatment effect.

Troubleshooting

Sonablate systems include Sonalink™ monitoring by SonaCare support personnel. Two-way audiovisual communication is provided along with screen mirroring to guide treatment and troubleshoot.

A clean apposition between the rectal wall and Sonablate balloon is critical. Any interference at the wall could result in heat and should be addressed. Sometimes pausing the HIFU probe and performing a simple ''finger sweep'' between the rectum and probe balloon are effective, but the probe may need to be removed and rectal irrigation performed in extreme cases.

The Sonachill device is critical to avoid heat at the rectal wall. The tubing is clear to allow for visual inspection of kinking and should feel ''cool'' on digital inspection. Ensure the tubing is not obstructed or kinked if the digital dashboard shows that the temperature is rising.

The apex of the prostate is difficult to treat as it is hard to visualize on US. Due to this and the risk of sphincter injury and incontinence, treating apical tumors is not advised.

For focal HIFU, we prefer the hemiablation approach to minimize risk of untreated cancer. Prostate cancer is typically multifocal. The limits of treatment are then defined as prostate base to prostate apex, anterior to posterior capsule, and lateral capsule to urethra on the affected side. A small margin is typically left untreated alongside the urethra. A 1-cm treatment margin is preferred and occasionally requires treatment across the urethra. The catheter must be removed when treating across the urethra and replaced at the end of the case. We have seen few to no side effects from treatment across the urethra when the treatment is applied along <50% of the urethral length.

Clinical Outcomes

Patients with unilateral localized intermediate-risk prostate cancers are optimal candidates for focal HIFU ablation of the prostate. HIFU may also be offered to carefully selected men with low- and high-risk prostate cancer. Our group recommends considering HIFU ablation as an extension of active surveillance rather than definitive treatment—that is, as a treatment modality that will prolong a man's ability to remain on surveillance without radical (whole gland) therapy. Following HIFU treatment, patients are maintained on a follow-up protocol consisting of clinical examinations, routine PSA monitoring, mpMRI, and post-treatment biopsy. If there is concern for biochemical recurrence, abnormal digital rectal examination, and clinically significant prostate cancer on post-treatment biopsy, we recommend progression to whole gland therapy (e.g., radical prostatectomy, radiotherapy).

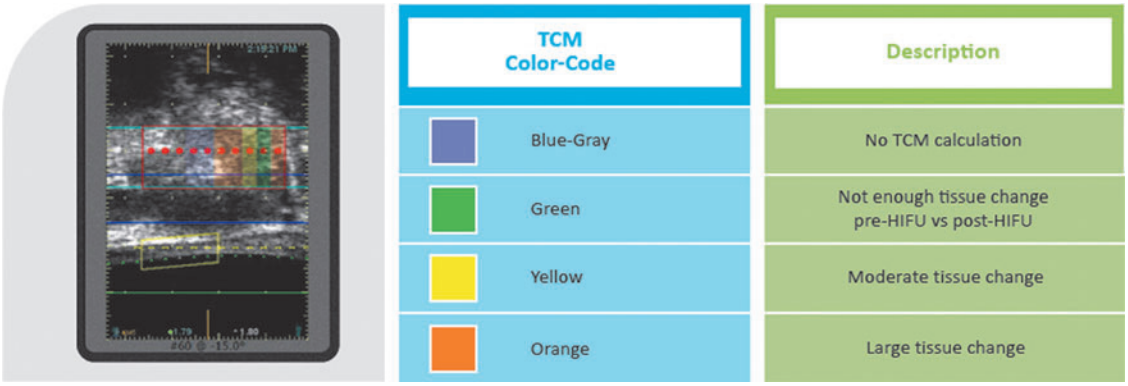

FIG. 5. TCM color legend. Image courtesy of SonaCare Medical, LLC.[4]

Table 1. Summary of Published Series on Focal High-Intensity Focused Ultrasound Ablation of Prostate

Refs.	N	*Ablation plan*	*Inclusion criteria*	*Demographics*	*Follow-up protocol*	*Median follow-up (months)*	*Oncologic outcomes*	*Complications*
El Fegoun et al.[12]	12	Hemi	PSA ≤10 ng/mL ≤3 positive biopsies with only one lobe involved clinical stage ≤T2a Gleason score ≤7 (3+4)	Low risk: 10 (83%) Intermediate risk: 2 (17%)	3- and 6-month PSA, then 6-monthly. Six-monthly clinical assessments for 5 years, then annually. 6-core mandatory biopsy at 1 year or if PSA rising	127	RFS: 90% at 5 years and 38% at 10 years; 41.7% positive biopsy	Retention (8.3%)
Ahmed et al.[13]	56	Focal	PI-RADS 4/5 with concordant biopsy findings Gleason ≤4+3 PSA ≤20 Stage ≤T3a	Low risk: 7 (12.5%) Intermediate risk: 47 (83.9%) High risk: 2 (3.6%)	Clinical review and PSA at 1, 3, 6, 9, and 12 months. Mandatory targeted biopsy of treated area at 6 months. Contrast MRI at 2 weeks and mpMRI at 6 months.	12	34.6% (infield), 11.5% (CSPCa), and 7.7% (outfield) positive biopsy	Transient dysuria (16.1%) Transient hematuria (64.3%) Passage of debris (42.9%) UTI (17.9%) Endoscopic procedure (7.2%)
van Velthoven et al.[14]	50	Hemi	Concordant biopsy with mpMRI Stage ≤T2 PSA <15 Prostate volume <40 mL Life expectancy ≥5 years	Low risk: 24 (48%) Intermediate risk: 26 (52%)	Clinical review and PSA at 1, 3, and 6 months, then 6-monthly. TRUS biopsy if PSA recurrence (Phoenix)	39.5	BPFS: 72% (Phoenix) and 64% (Stuttgart) 6% (infield) and 10% (outfield) positive biopsy	Retention (8%) UTI (6%) LUTS (18%) stricture (4%)
Feijoo et al.[15]	71	Hemi	Unilateral disease Stage T1c–T2a, Positive biopsies <33% Gleason score ≤3+4 PSA <15 Life expectancy >10 years	Gleason 3+3: 58 (86.6%) Gleason 3+4: 9 (13.4%)	Clinical review and PSA at 3, 6, and 12 months, then 6-monthly. Mandatory 12-core TRUS biopsy at 12 months	12	15.5% (infield) and 9.9% (outfield) positive biopsy	Retention 8.5% (2 required TURP) UTI 8.5%
Rischmann et al.[16]	111	Hemi	Unilateral cancer Gleason score ≤3+4	Gleason 3+3: 82 (74%) Gleason 3+4: 29 (26%)	Clinical review and PSA at 1, 3, 6, 12, and 6-monthly thereafter. mpMRI at 6 to 12 months and targeted biopsy of suspicious areas	30.4 (Mean)	12% (5%) infield and 19 (7%) outfield positive biopsy	Retention Meatal stricture Hematuria
Tay et al.[17]	12	Sectoral	As much as two lesions <10 mm Stage <T2b Gleason 3+3 only	Gleason 3+3: 12 (100%)	Clinical review and PSA at 1, 3, 6, 12, 18, and 24 months, TMB at 6 and 24 months, mpMRI at 6 and 24 months	24	28.5% infield (21.4% CSPCa) and 42.8% outfield (7.1% CSPca)	Transient hematuria or mild LUTS (35.7%) UTI (14.2%)

(*continued*)

Table 1. (Continued)

Refs.	N	*Ablation plan*	*Inclusion criteria*	*Demographics*	*Follow-up protocol*	*Median follow-up (months)*	*Oncologic outcomes*	*Complications*
Ganzer et al.[18]	51	Hemi	Unilateral disease Stage T1c–T2a, positive biopsies <30% Gleason score ≤3 + 4, maximum core length 5 mm PSA <10	Gleason 3 + 3: 43 (84%) Gleason 3 + 4: 8 (16%)	Clinical review, PSA, and TRUS 3-monthly. Mandatory mpMRI 12-core TRUS biopsy at 12 months	17.4 (Mean)	24.6% infield (8.2% CSPca) and 36.7% outfield (2% CSPca)	UTI No Clavien grade 3 or higher Complications
Guillaumier et al.[19]	625	Focal	Concordant biopsy with mpMRI Nonmetastatic prostate cancer with Gleason score 6–9 Stage T1c: 3bN0M0 PSA ≤30	Low risk: 78 (13%) Intermediate risk: 316 (53%) High risk: 189 (32%) Missing data: 16 (2.7%)	Clinical review and PSA every 3–6 months mpMRI at 1 year and every 1–2 years Biopsy with two rises in PSA after nadir	56	Failure-free survival: 99%, 92%, 88% at 1, 3, and 5 years CSS: 100% at 5 years OS: 99% at 5 years 13% infield and 7% outfield positive biopsy	UTI (8.5%) Epididymo-orchitis (1.9%) Rectourethral fistula (0.3%) Endoscopic procedure for LUTS (9.6%)
Bass et al. [20]	166	Focal (68.1%) or Hemi (31.9%)	Unilateral disease Stage T1c-T2c	Gleason 3 + 3: 19 (11.5%) Gleason 3 + 4: 89 (53.6%) Gleason 4 + 3: 43 (25.9%) Gleason 4 + 4: 12 (7.2%) Gleason 4 + 5: 1 (0.6%) Unknown: 2 (1.2%)	Clinical review, PSA every 3 months in year 1, every 6 months thereafter Biopsy offered 1-year post-treatment	24	11% outfield CSPca, 13% infield CSPca positive biopsy	Urinary retention (13.1%) Rectourethral fistula (2.6%) UTI (2.6%) Urethral stricture (1.3%)
Stabile et al.[21]	1037	Focal (70.7%) or Hemi (29.3%)	Concordant biopsy with mpMRI	Gleason 3 + 3: 203 (19.7%) Gleason 3 + 4: 654 (63.4%) Gleason 4 + 3: 159 (15.4%) Gleason 4 + 4: 16 (1.6%)	Clinical review, PSA every 3–4 months mpMRI offered at 6 or 12 months Biopsy in patients with suspected recurrent disease based on MRI or PSA	36	OS: 99%, 99%, 97%, 97% at 12, 24, 60, 96 months, respectively. Recurrence of CSPCa: 6%, 16%, 36%, and 46% at 12, 24, 60, and 96 months Retreatment-free survival: 98%, 85%, 59%, 46% at 12, 24, 60, 96 months	Not Reported
Abreu et al.[8]	100	Hemiablation	Unilateral PCa Bilateral PCa with contralateral low volume, nondominant GG1 Stage ≤ T2	Very low: 8 (8%) Low: 20 (20%) Intermediate favorable: 50 (50%) Intermediate unfavorable: 17 (17%) High: 5 (5%)	Clinical review and PSA at 3, 6, 12, 18, and 24 months mpMRI recommended at 6–12 months Biopsy recommended at 6–12 months	20	RFS: 73% at 2 years, 92% (Phoenix) BPFS 8% infield and 10% outfield CSPCa	Neuropraxia (1%) Urinary retention (7%) Urinary tract infection (5%)

BCR = biochemical recurrence; BPFS = biochemical progression–free survival; CSPCa = clinically significant prostate cancer; CSS = cancer-specific survival; DRE = digital rectal examination; GG = Gleason grade; LUTS = lower urinary tract symptoms; mpMRI = multiparametric MRI; OS = overall survival; PI-RADS = Prostate Imaging–Reporting and Data System; PSA = prostate-specific antigen; RFS = recurrence-free survival; TRUS = transrectal ultrasonography; TMB = transperineal mapping biopsy; UTI = urinary tract infection.

A recent United States series of 100 men with very low (8%), low (20%), intermediate favorable (50%), intermediate unfavorable (17%), and high (5)% risk prostate cancer who underwent hemi-gland ablation showed a 2-year failure-free survival in 73% of patients.[8] Radical treatment was avoided in 91% of men at 2 years. Median time to PSA nadir was 3 months with a median PSA reduction of 75%. Sixty-five percent of patients underwent follow-up prostate biopsy, in which 18 patients were found to have clinically significant prostate cancer, 8 in-field and 10 out-of-field. Multiparametric MRI alone had a low sensitivity (44%) for detection of clinically significant prostate cancer recurrence after HIFU.[8] Preliminary studies show encouraging data that positron emission tomography with radiotracer ^{68}Ga-PSMA-11 targeting prostate specific membrane antigen could be used to localize recurrent disease after HIFU.[9]

Most common complications of focal HIFU ablation of the prostate include debris in the urine, dysuria, lower urinary tract symptoms, urinary tract infection, and urinary retention. A Foley catheter postoperatively helps mitigate the risk of retention due to urethral swelling. A subset of patients may experience epididymo-orchitis, hematuria, or hematospermia. Long term effects include retrograde ejaculation and anejaculation. Minimal and self-limited erectile function changes occur in 10%–20% in our experience. Rare complications include loss of erections, urinary incontinence, urethral stricture, and rectourethral fistula.

A systematic review of 13 studies and 546 patients summarized the following functional outcomes of patient undergoing focal HIFU therapy: acute urinary retention (0–24%), stricture (0–10%), incontinence (0–50%), and erectile dysfunction (0–48%).[10] Postoperative rectourethral fistula was reported in only one patient, and there were no reported deaths. Definitions of erectile dysfunction and urinary incontinence differed greatly by study.

Another systematic review of 13 studies and 346 men demonstrated that the probability of secondary local treatment was 7.8% (interquartile range [IQR]: 3.8%–10.3%).[11] Overall and disease-specific survival were both 100% (IQR: 100%–100%). Significant adverse events occurred in 1.5% of patients (IQR: 0–3.2%). Pad-free continence was demonstrated in 100% of patients (IQR: 95%–100%) and potency preservation in 88.6% of patients (IQR: 78.5%–97.5%; Table 1).

Conclusion

HIFU ablation of the prostate has emerged as an exciting new technology in focal treatment of primary intermediate risk prostate cancer and postradiation salvage treatment since FDA 510(K) clearance in 2015. Each individual patient's age, comorbidities, disease characteristics, and goals of treatment must be considered to provide appropriate counseling. Further studies are warranted to investigate long-term oncologic and functional outcomes associated with HIFU.

Patient Consent Statement

The author(s) have received and archived patient consent for video recording/publication in advance of video recording of procedure.

Author Disclosure Statement

No competing financial interests exist.

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Abbreviations Used

FDA = Food and Drug Administration
HIFU = high-intensity focused ultrasound
IQR = interquartile range
MRI = magnetic resonance imaging
mpMRI = multiparametric MRI
PSA = prostate-specific antigen
PSMA = prostate specific membrane antigen
RIM = reflectivity index monitor
RWD = rectal wall distance
TCM = tissue change monitoring
US = ultrasound