The use of focal therapy for the treatment of prostate cancer in Canada

Where are we, how did we get here, and where are we going?

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ABSTRACT

INTRODUCTION: Focal therapy is an emerging treatment for localized prostate cancer (PCa). The objectives of this review were to: 1) review how focal therapies are regulated and approved; 2) summarize the scope and quality of the literature regarding safety, efficacy, and side-effects; and 3) outline ongoing clinical trials of focal therapy in Canada.

METHODS: Using the PRISMA framework for scoping reviews, we searched PubMed, Embase, and Cochrane from 2021–2024, complementing Hopstaken et al's search up to 2020. We focused on studies reporting functional and oncologic outcomes. Additionally, we examined the FDA database for regulatory details and ongoing trials in Canada via *ClinicalTrials.gov*.

RESULTS: FDA approval for prostate tissue ablation was granted to high-intensity focused ultrasound (HIFU) in 2015 via the de novo pathway; other therapies followed the 510(k) route, citing equivalence to predicate devices. Most studies are in early stages, primarily single-arm, prospective cohort designs. Oncologic outcomes like cancer detection and survival rates, alongside functional data, such as adverse events and erectile function, were assessed. Recurrence-free survival at 48 months ranged from 58–92%, pad-free rates were greater than 95%, and rates of new-onset erectile dysfunction were variable, ranging from no change to 50%. Rates of serious adverse events were low, ranging from 0–14%. Three Canadian clinical trials are actively enrolling participants, and five private clinics were found offering private HIFU, irreversible electroporation, or transurethral ultrasound ablation.

CONCLUSIONS: Focal therapy technologies have gained regulatory approval for prostate tissue ablation, and aside from provincial support for cryoablation in Alberta, are available to Canadians through private payment or clinical trials. Many studies demonstrate promising cancer control and impressive functional outcomes but are limited by their short followup and lack of comparator group. Clinical trial or registry participation should be prioritized to ensure an evidence-based integration into current prostate cancer treatment approaches.

INTRODUCTION

Prostate cancer (PCa) is the most common malignancy for Canadian men, with approximately 26 000 new cases annually.[1] For men with localized PCa, which is the predominant diagnosis, traditional treatment options include active surveillance, radical prostatectomy, or radiation therapy.[1]

In patients with localized PCa randomly assigned to active monitoring, prostatectomy, or radiotherapy, there was no difference in overall or cancer-specific survival with 15-year followup.[2] Although a quarter of the actively monitored patients avoided treatment, the group had more clinical progression, metastases, and androgen-deprivation therapy initiation. Conversely, patients radically treated had more urinary incontinence, erectile dysfunction (ED), and/or fecal leakage.[2] Thus, radical therapy for intermediate-risk PCa is sometimes "overtreatment" causing unnecessary side effects, but it's difficult to predict which patient is destined to progress.

Focal therapy (FT) aims to fill this overtreatment gap by neutralizing prostate tumors while minimizing significant side effects.[3] To do so, a target within the prostate is selectively ablated with a defined margin around it, preserving the remaining tissue. Ablation approaches include treating magnetic resonance imaging (MRI)-visible lesions, location of positive biopsies (zonal ablation), or the entire ipsilateral lobe of the prostate (hemi-gland ablation). All

KEY MESSAGES

- Regulatory approval for prostate focal therapies has often been achieved through the 510(k) process in the U.S. for the generic indication of prostate tissue ablation, asserting substantial equivalence to existing products and bypassing extensive clinical trials.

- Studies to date demonstrate promising cancer control and impressive functional outcomes but are limited by their short followup, lack of comparator group, and heterogeneity with respect to inclusion criteria and outcome definition.

- Healthcare providers should prioritize enrolling patients considering focal therapy in a registry or prospective observational clinical trial.

of these approaches aim to destroy the index lesion containing the highest-grade cancer hypothesized to drive disease progression.[4]

Different energy sources are used, including high-intensity focused ultrasound (HIFU), irreversible electroporation (IRE), cryotherapy, photodynamic therapy (PDT), focal laser ablation (FLA), radiofrequency ablation (RFA), transurethral ultrasound ablation (TULSA), and focal brachytherapy (Table 1). With recent advancements in prostate MRI and targeted biopsies, index lesions are better identified and targeted for ablation.[5]

Despite Health Canada and United Stated Food and Drug Administration (FDA) approval, focal therapies are not yet guideline-approved options in North America. The American Urological Association recommends, based on expert opinion, that ablation may be considered in select, appropriately informed, intermediate-risk PCa patients, with clinical trial enrollment prioritized.[6] They recognized whole-gland cryotherapy as a treatment option for localized PCa in 2008.[7] The European Association of Urology recommends that FT should only be offered within a clinical trial or prospective registry.[8] In the U.K., using certain technologies for focal therapy (e.g., HIFU, IRE) are allowed outside clinical trial provided outcomes are being collected on registry.[9] Currently, there is no Canadian Urological Association localized PCa guideline.

The objectives of this paper are to: 1) review how FTs are regulated and the pathway through which they have received regulatory approval; 2) summarize the current scope and quality of the literature, as well as the current efficacy and safety data supporting the use of FTs for the treatment of localized PCa; and 3) outline ongoing clinical trials of FT options currently available to Canadians.

Table 1. Mechanism of action of different focal therapies

Acronym	Description	Effect
HIFU	High-intensity focused ultrasound	Focuses high-energy ultrasound waves on a single location, increasing the local tissue temperature to over 80°C. This results in a discrete locus of coagulative necrosis approximately 3×3×10 mm in size.
Cryo	Cryotherapy	Induces cell death through direct cellular toxicity from disruption of the cell membrane caused by ice-ball crystals and vascular compromise from thrombosis and ischemia secondary to freezing below -30°C.
PDT	Photodynamic therapy	Uses an intravenous photosensitizing agent that distributes through prostate tissue, followed by transperineal light delivery via inserted needles. The light induces a photochemical reaction, producing reactive oxygen species that are highly toxic and cause functional and structural tissue damage, leading to cell death.
FLA	Focal laser ablation	Involves the destruction of tissue using a focused beam of electromagnetic radiation emitted from a laser fiber introduced transperineally or transrectally into the cancer focus. Tissue is destroyed through the thermal conversion of focused electromagnetic energy into heat, causing coagulative necrosis.
Brachy	Brachytherapy	A form of radiotherapy where radioactive sources are placed in or near the tumor, delivering a targeted dose of radiation to the cancerous tissue while minimizing exposure to surrounding healthy tissue.
IRE	Irreversible electroporation	Applies short bursts of high-voltage electrical pulses to create nanopores in cell membranes, leading to cell death.
TULSA	Transurethral ultrasound ablation	High-energy ultrasound waves are delivered via the urethra in a continuous sweeping directional fashion.
RFA	Radiofrequency Ablation	Uses radiofrequency energy to generate heat, leading to the destruction of targeted tissues.

METHODS

The scoping review was guided by the PRISMA extension for scoping review framework. The research questions were formulated as follows:

1. Through which pathway and based on what evidence did focal therapies receive regulatory approval?
2. What is the current scope and quality of the literature supporting FT in localized PCa?
3. What are the current efficacy and safety data supporting FT in localized PCa?
4. What clinical trials and/or for-pay FTs are currently available in Canada?

The PubMed, Embase and Cochrane databases were searched with "focal therapy," "prostate cancer," and the names of the specific technologies, such as "high-intensity focused ultrasound (HIFU)" and "irreversible electroporation." Since Hopstaken et al completed a high-quality search up to December 31, 2020, ours was limited between January 1, 2021 to January 20, 2024.[5]

Studies were included if they reported on FT as the primary treatment and one of the following two endpoints: 1) functional outcomes and/or 2) oncologic outcomes. Randomized controlled trials (RCTs), retrospective and prospective cohort studies, and single-arm studies were included. Studies concerning whole-gland treatment or with concomitant androgen deprivation therapy were excluded. Given that TULSA involves subtotal prostate ablation, this was included in the analysis. Study design, type of FT patient, and tumour characteristics were captured.

Given the expansive U.S. market, most manufacturers typically seek approval from the FDA first. The FDA is globally recognized as a best-in-class regulatory authority.[10] This review will primarily focus on the FDA, as all FDA regulatory submissions and decisions are accessible through their database, and Health Canada follows a similar regulatory pathway.

The FDA database was searched for regulatory submissions and approvals, and for guidance documents released on PCa FT. From each submission, regulatory pathway chosen (e.g., de novo vs. 510K vs. PMA), product classification code, preclinical evidence, and clinical evidence submitted was collected. Current clinical trials recruiting in Canada were searched using *ClinicalTrials.gov* up to August 4, 2024. Private-pay clinics offering FT for PCa by province/territory were identified with Google.

RESULTS

How did we get here?

The FDA employs different regulatory pathways for medical devices and drugs. Prostate FTs fall under the category of medical devices and are regulated by the Center for Devices and Radiologic Health (CDRH), one of the six branches of the FDA.[10] Medical devices are classified into three categories based on the level of risk they pose to patients. The risk class influences the approval process, and the evidence required to ensure device safety and efficacy. Class I devices, such as dental floss and tongue depressors, pose minimal risk and have fewer requirements for FDA approval. Class III devices, like artificial heart valves and defibrillators, sustain or support life and carry a high risk of harm should they fail. Class III devices require premarket approval, a process similar to that of new drug approval. Class II devices, which include prostate FTs, fall in between, and may not necessarily require premarket approval, thereby bypassing the need for extensive clinical testing.[10,11]

Class II devices often undergo clearance for clinical use through the 510(k) pathway, where manufacturers demonstrate to the CDRH that the device is "substantially equivalent" to a legally marketed device or predicate. The FDA deems a medical device substantially equivalent if it shares the same intended use and technological characteristics as a predicate device or has the same intended use with different technological characteristics that do not raise safety or efficacy concerns.[10]

In 2015, HIFU received FDA approval through the de novo pathway, designed for devices that do not fit existing regulatory categories and lack a valid predicate device for substantial equivalence.[12] HIFU's indication for use was the ablation of prostatic tissue, not specific to the treatment of any prostate disease. The approval was based on comprehensive data, including bench, animal, and clinical testing from the U.S. Salvage study, a multicenter, prospective, single-arm study involving 117 men with recurrent PCa after external beam radiotherapy.[12] The authors showed that whole-gland ablation with Sonablate R 450 decreased prostate volume by 11.8 cm^3 (46%), decreased prostate-specific antigen (PSA) levels in 83% of cases, and led to negative post-ablation biopsies in 61% of patients. A total of 27 serious adverse events (SAEs) were reported, consisting of urinary retention/obstruction (n=6), hematuria (n=5), rectal/urinary fistula (n=5), urinary tract infection (UTI)/urosepsis (n=5), osteomyelitis (n=3), urinary incontinence (n=1), urethral stricture (n=1), and small intestinal obstruction (n=1).[12]

All other focal therapies, except for this de novo submission, have gained approval through the 510(k) pathway, claiming substantial equivalence to a predicate device like Sonablate HIFU.[13-29] Notably, these submissions lack data on the oncologic effectiveness of the treatment. Details of FDA submission are summarized in Table 2.

Where are we now – the current state of evidence for focal therapy

Type of current evidence

The IDEAL collaboration provides a framework for evaluating surgery research.[30] Stage 1 ("idea") involves the initial use of a new procedure or proof of concept. Stage 2a ("development") refines the innovation in small groups, assessing safety. Stage 2b ("exploration") uses larger sample sizes for an initial assessment of clinical outcomes. Stage 3 ("assessment") compares the intervention's effectiveness with current standards, ideally through a RCT. Stage 4 ("long-term study") assesses long-term outcomes, typically through a registry.

A recent systematic review of 72 articles published until December 31, 2020 on PCa FT, covering eight energy sources and 5827 patients, revealed that the majority of studies to date were in the early research stages (IDEAL stages 2a and 2b).[5] Only five studies reached IDEAL stages 3 or 4, including one RCT on PDT, a feasibility RCT on HIFU, and two propensity score-matched analyses on IRE and HIFU. Most studies were single-arm, prospective cohort studies.[5] From the 15 studies included in our review since this publication, three were identified as IDEAL stage 2b and one as IDEAL stage 3.[31-34]

Oncologic outcomes

The success of FT is challenging to determine accurately using MRI or PSA, as MRI may not detect small-volume persistent or recurrent disease, and PSA levels can remain elevated post-ablation from untreated prostate glands.[35] The surrogate outcome commonly used to estimate oncologic efficacy is the presence of clinically significant cancer (CSC) on biopsy in the treated area after 12 months of followup. Median presence of CSC post-FT is approximately 14.7% for HIFU, 8.5% for IRE, 10% for PDT, 15% for cryoablation, 17% for FLA, and 20% for RFA.[5]

Of the 72 studies included in the systematic review, only 21 reported on the detection of CSC in untreated areas (1 FLA, 10 HIFU, 4 focal brachytherapy, 3 IRE, 2 cryotherapy, 1 PDT, 1 RFA). The range of CSC detection in the untreated area for technologies with at least three studies were 2–21% for HIFU, 12.7–25% for IRE, and 0–5.9% for focal brachytherapy.[5]

Biochemical recurrence rates according to the Phoenix criteria were between 1–28% for HIFU, 7–70% for brachytherapy, and 25–71% for cryotherapy based on six, three, and four studies, respectively (median followup of 28 months, range 12–28 months). The rates of salvage therapy (radical prostatectomy, radiation, or further focal treatment) were 2–26% for HIFU (16 studies), 0–25 for IRE (seven studies), 2–14% for FLA (three studies), 11–20% for cryotherapy (five studies), 12–24% PDT (four studies), 20–50% for RFA (two studies), and 6% for brachytherapy (one study). Recurrence-free survival (RFS) was reported in three studies for HIFU, one for brachytherapy, and three for cryotherapy, and the median rates were 58% for HIFU, 92% for brachytherapy, and 56% for cryotherapy (median followup of 40 months, range 24–48 months). Lastly, overall survival (OS) was reported in eight HIFU studies, three IRE studies, two brachytherapy studies, one cryotherapy study, and three PDT studies. The median OS was 98%, 100%, 100%, 96.1%, and 100% respectively (median followup of 29 months, range 7–48 months).[5]

Following the publication of the systematic review, noteworthy studies have emerged on IRE, including a larger prospective cohort study of 411 patients and a longer-term study evaluating five-year outcomes in 229 patients.[31,32] The former reports clinically significant PCa in 24.1% of men after a median followup of 24 months, while the latter demonstrates 17% progression to radical treatment at a median of 35 months, along with RFS rates of 91% at three years, 84% at five years, and 69% at eight years, metastasis-free survival of 99.6% (228/229) at five years, and PCa-specific survival and OS of 100% at five years.

There has also been a systematic review with meta-analysis comparing IRE to HIFU. In this study, IRE patients

Table 2. Summary of FDA submissions

Technology	FDA Clearance	Indications
Focal laser ablation	510(k)	Necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy under magnetic resonance imaging guidance for multiple indications including urology, at wavelengths from 800–1064 nm.
High-intensity focused ultrasound	De novo	Class II device, high intensity ultrasound system for prostate tissue ablation.
Cryoablation	510(k)	Cryoablation of the prostate.
Radiofrequency ablation	510(k)	General use for soft tissue cutting, coagulation, and ablation by thermal coagulation. May be used to ablate tumors.
Photodynamic therapy	Advisory vote against approval	n/a
Irreversible electroporation	510(k)	The NanoKnife System with six outputs is indicated for the surgical ablation of soft tissue.
Transurethral ultrasound ablation	510(K)	The TULSA-PRO System is indicated for transurethral ultrasound ablation (TULSA) of prostate tissue.

exhibited lower mean percent PSA level reductions, higher rates of in-field negative post-treatment biopsy, and superior potency maintenance compared to HIFU patients.[33] Five-year followup outcomes from the pivotal TULSA trial were also recently reported, showing durable disease control and a favorable safety profile.[36]

Considering that a substantial number of men undergoing FT may eventually necessitate salvage therapy, it was intriguing to examine initial outcomes following salvage radical prostatectomy after IRE. Among 39 patients, there were no reported SAEs following surgery.[37] With a median followup of 17.7 (interquartile range 11.8–26.4) months, urinary continence and erectile function were maintained in 34 patients (94.4%) and 18 patients (52.9%), respectively, while overall quality of life remained consistent. Positive surgical margins (PSMs) were identified in 10 patients (25.6%), with six (15.4%) displaying significant PSMs. Three patients necessitated further therapeutic interventions following salvage radical prostatectomy.[37]

Functional outcomes

Rates of SAEs were generally low, ranging from 0–14% across 19 HIFU studies, with a median of 2%.[5] SAEs included a myocardial infarction (IRE), rectourethral fistula (FLA), UTI, and gross hematuria. In a recent large, retrospective review, strictures developed in 133/1290 patients (10.3%) and urinary fistulas developed in 16/1240 (1.3%) of patients following HIFU.[38]

Most studies used patient-reported outcomes to monitor pad-free rates post-treatment. All modalities reported >95% median pad-free rates post-treatment, with many showing no change from baseline.[5]

Data on erectile function is more variable. Most studies show no significant decline in patient-reported measures of erectile function (such as International Index of Erectile Function or Sexual Health Inventory for Men) after treatment. Multiple focal brachytherapy studies did show a decline in erectile function after treatment, with new-onset ED rates as high as 50%. ED rates after HIFU were estimated at 20%, with up to a 17% increased use of PDE5 inhibitors. Six studies of IRE showed a decline in erectile function after treatment, although a propensity score-matched analysis of IRE vs. robotic prostatectomy did show a statistically significant difference favoring IRE.[5]

A comparative trial of IRE vs. HIFU showed the proportion of patients experiencing a severe AE (≥grade III) ranged from 0–8%, and that both modalities were associated with positive functional outcomes, as well as maintenance of quality of life after treatment.[33]

Ghoreifi et al recently demonstrated that after a median followup of 43 months, 19.6% of patients treated with FT regretted their decision. Higher PSA at nadir, presence of cancer on followup biopsy, bothersome postoperative urinary symptoms, and ED were independent predictors of treatment decision regret.[39]

Canadian involvement

It is noteworthy that Canada has been at the forefront of advancing evidence-based FT. Two prostate cryoablation programs initiated in Canada in the 1990s have yielded over 50 peer-reviewed publications.[40] Canadian researchers published foundational preclinical and phase 1 clinical trials over a decade ago for focal laser ablation and MRI-guided transurethral ultrasound therapy of the prostate gland.[41-43] Canadian sites also contributed patients to early studies of TOOKAD® Soluble photodynamic therapy.[44] More recently, Canada led phase 1 and 2 trials of MRI-guided focused ultrasound ablation for PCa.[44-48] A Canadian group has also revealed the importance of systematic control biopsies when assessing the response to FT, regardless of PSA kinetics or MRI results.[35]

Where are we going

Currently, there are five clinical trials in Canada focused on energy-based ablation of PCa actively seeking participants for enrollment (Table 3). The CAPTAIN trial is a RCT comparing radical prostatectomy to TULSA (subtotal) for treating localized, intermediate-risk PCa.[49] The HDR Focal Study is exploring the feasibility of using focal HDR brachytherapy for well-defined multiparametric MRI visible disease.[50] There is a single-arm, prospective study of in bore MRI-guided focal laser ablation (MRgFLA) in patients with early-stage PCa.[51] There is a phase 2, multicenter, RCT assessing whether prostate-specific membrane antigen-positron emission tomography (PSMA-PET) can improve diagnostic accuracy for the primary staging of PCa for patients undergoing FT, thereby reducing residual and recurrence disease.[52] Lastly, the WIRED trial is a pan-Canadian, investigator-initiated, non-randomized clinical trial examining the oncologic benefit and safety of IRE for intermediate-risk PCa.[53]

In the U.S., there are several ongoing trails. The PRESERVE trial, a pivotal study investigating irreversible electroporation for ablating prostate tissue in intermediate-risk PCa patients, has successfully reached its enrollment target.[54] Preliminary results show a 67.6% (52.3–82.2%) reduction in PSA at six months, 8.3% rate of grade 3 AEs, and no grade ≥4 AEs. Final results

Table 3. Current clinical trials recruiting in Canada

Title	Energy	Phase	Canadian sites	Status
A comparison of TULSA procedure vs. radical prostatectomy in participants with localized prostate cancer (CAPTAIN)	TULSA vs. radical prostatectomy	Multicenter, randomized control trial	London Health Sciences Center & Sunnybrook Research Institute	Recruiting
HDR monotherapy for prostate cancer: A Feasibility study of focal radiotherapy yields	High-dose rate brachytherapy	Single-arm feasibility study	University Health Network, Toronto	Recruiting
MRI-guided focal laser ablation of prostate cancer (MRgFLA)	Focal laser ablation	Single-arm prospective study	University Health Network, Toronto	Recruiting
PSMA-guided ablation of the prostate (P-GAP)	Focal therapy (unspecified)	Phase 2, multicenter, randomized controlled trial	University of Alberta	Recruiting
A pan-Canadian, investigator initiated clinical trial with focal ire directed to intermediate-risk prostate cancer (WIRED)	Irreversible electroporation	Single-arm, prospective study	University Health Network, Toronto	Recruiting

assessing oncologic, functional, and safety outcomes are expected in late 2025.[55]

Several novel FT options are in development and on the horizon. The VAPOR 1 study demonstrated promising outcomes for transurethral vapor ablation in men with intermediate-risk PCa, with a larger, multi-institutional pivotal trial involving 235 patients currently underway.[56,57] Laser-excited gold-silica nanoshells (GSNs) have exhibited the ability to selectively ablate low-intermediate-grade tumors within the prostate, with a multi-institutional study completing enrollment in November 2021.[58] PSMA-targeted PDT agents have been developed, offering potential for image-guided prostate tumor resection and subsequent PDT to eliminate unresectable or remaining disease.[59] Histotripsy, a magnetic-guided, non-invasive, non-thermal focused ultrasound therapy, has been explored in the preclinical setting for PCa60 Subtotal surgical therapy (precision prostatectomy) has also been shown to have promising early results in a pilot study of 25 patients.[61]

Ongoing research is also dedicated to refining imaging capabilities. Currently, MRI only identifies approximately 66% of all tumors and significantly underestimates tumor size.[62] Researchers are working on a 7T MRI, promising improved signal-to-noise ratio compared to 3T systems.[63] Initial studies have shown better resolution, faster acquisition, and the identification of 83% of index lesions in ex-vivo prostates; however, further work is required before clinical implementation.[64] MicroUltrasound (MicroUS) is a novel imaging technology developed by Exact Imaging (Toronto, ON, Canada), which has obtained regulatory approval in Canada for visualizing and biopsying the prostate. With a resolution of 70 microns — matching the diameter of a typical prostatic duct — MicroUS offers a significant improvement over transrectal ultrasound (TRUS), which typically provides resolutions of 200 microns or more.[65] This enhancement translates to a threefold improvement in spatial resolution compared to conventional-frequency TRUS. Given its precise and real-time visualization capabilities, particularly in the peripheral zone, MicroUS holds promise as a guiding tool for FT. A pilot study to evaluate MicroUS-guided focal laser ablation is launching at the University of Toronto.[66]

Canada has also seen an increase in the number of private clinics offering FT for PCa over the years. Based on a non-systematic Google search, there are currently five clinics in Canada offering this service (four in Ontario and one in Quebec). Treatments currently offered privately include HIFU, IRE, or TULSA.

DISCUSSION

The Canadian healthcare system operates on public funding and is administered at the provincial and territorial levels, with each having their own procedure for assessing and financing medical devices. This results in variations between provinces. For instance, while prostate cryotherapy is publicly funded in Alberta, it is not covered in any other province or territory. The decision to fund a particular device involves a health technology assessment that evaluates both its clinical effectiveness and cost-effectiveness. Following this assessment, health authorities at the provincial or territorial level engage in negotiations with manufacturers regarding pricing, reimbursement rates, and the terms of coverage.

For numerous reasons, including sparse RCT data, cost, and knowledge translation, in many provinces and territories, public funding for PCa FT has encountered obstacles. Regulatory approval for prostate FTs has often been achieved through the 510(k) process, asserting substantial equivalence to existing products and bypassing extensive clinical trials. While this approach accelerates device introduction and encourages innovation, it shifts the responsibility of generating level 1 evidence from manufacturers to academic institutions. The challenge lies in funding and executing clinical trials after the fact, especially when well-intentioned providers who believe in the devices' superiority begin offering the treatment off-trial.

The generation of robust evidence for these technologies is further hindered by the approval granted for the broad indication of prostate tissue ablation. While

Table 4. FALCON consensus on the use of focal therapies for the treatment of prostate cancer

FALCON consensus	Statements
Patient selection criteria	
Life expectancy	Life expectancy should be a determinant of focal therapy. Age should not be a determinant.
Voiding symptoms	Voiding symptoms do not contraindicate focal therapy.
Genetics	Genomic test results might influence the decision to offer focal therapy. Patients with BRCA gene mutation should not be offered focal therapy. Tissue genomic tests should not be offered to all patients prior to focal therapy.
PSA	PSA should be considered as an inclusion or exclusion criterion for focal therapy.
Histopathology	Focal therapy should not be offered to patients with localized ISUP 1 prostate cancer if they agree with active surveillance. Focal therapy should be offered to patients with localized ISUP 2 (percentage of pattern 4 <10%) prostate cancer even if they agree with active surveillance. If cribriform pattern is present, focal therapy should be considered overactive surveillance. Focal therapy should be offered to patients with localized ISUP 2 (percentage of pattern 4 >10%) prostate cancer. Focal therapy should be offered to patients with localized ISUP 3 prostate cancers. During the final discussion, there was an 89% agreement that focal therapy should be offered to these patients with localized ISUP 3 disease. Focal therapy should not be offered to patients with localized >ISUP 3 prostate cancer.
Lesions	All lesions can be treated with focal therapy with favorable oncological and functional outcomes regardless of their location if the lesion can be reached safely by the chosen energy. Prostate volume does not matter if the lesion can be reached.
MRI and biopsy	Local clinical stage should be based on MRI. Focal therapy should not be offered in cases of extracapsular extension on MRI if highly likely. ≥3–4 targeted + ≥10–12 systematic biopsies should be performed. MRI in-bore or MRI/ultrasound fusion biopsies or cognitive fusion biopsies are permissible. Focal therapy should not be offered in case of negative MRI and positive biopsies. Focal therapy should not be offered if MRI is not available or if the quality is low. PSMA-PET/CT is not considered a suitable replacement for MRI in patient selection for focal therapy. The presence of positive biopsies outside the lesion detected on MRI does not contraindicate focal therapy. Focal therapy may be offered to patients with multifocal MRI lesions. If positive biopsies are found in one of multiple MRI-detected lesions, focal therapy should treat the confirmed lesion.
Treatment approach	
Treatment extension	The minimal margin when treating the lesion is 5 mm. A minimum safety margin of 10 mm would be unnecessary. Hemiablation should not be considered the minimal extent of a focal treatment.
Energy selection	No energy can be recommended over others in terms of effectiveness and safety. Energy selection should be mainly based on the location of the tumor and operator's experience.
Margin	Focal therapy may be performed if the lesion is <5 mm from the rectum. A minimum safety margin of 10 mm from the rectum would be unnecessary. Focal therapy should not be performed if the lesion is <5 mm from the sphincter. A minimum safety margin of 10 mm from the sphincter would be unnecessary.
Followup	
Followup	Patients should be followed up to 10 years by the urologist. Patients may be offered more than one salvage focal therapy after the failure of the initial focal therapy.
Functional outcomes	Functional outcomes must be assessed every 3 months for 1 year, then yearly until stability. Functional outcomes should be assessed exclusively by validated questionnaires (such as EPIC, IPSS, and IIEF).
Oncologic outcomes	PSA should be done 3-monthly for the first year, then 6-monthly. There is no consensus on PSA failure definition after focal therapy. MRI should be performed every 6–12 months initially, and subsequently on an annual basis. ≥10–12 systematic plus ≥3–4 target biopsies should be done within 12 months post-treatment.

IIEF: International Index of Erectile Function; IPSS: International Prostate Symptom Score; ISUP: International Society of Urological Pathology; EPIC: Expanded Prostate Cancer Index Composite; MRI: magnetic resonance imaging; PSA: prostate-specific antigen; PSMA-PET: prostate-specific membrane antigen-positron emission tomography.

the FDA accepts certain surrogate endpoints, such as lowering of PSA, prostate volume, and increased negative biopsies, these are not traditional oncologic endpoints. This complicates the application of data to PCa patients.

Furthermore, designing trials for the cancer-specific use of these devices raises uncertainties regarding patient inclusion criteria (low-risk vs. intermediate-risk), the choice of comparator (active surveillance vs. radical treatment), and the tracking of outcomes. For instance, there is no universally agreed-upon definition for biochemical recurrence after FT, unlike after radical prostatectomy or radiation therapy.

There have been many attempts by groups of experienced clinicians and their associations to address these challenges. One such example is the Falcon project that conducted a comprehensive survey involving a broad panel of international stakeholders to achieve consensus on various aspects of PCa FT.[67-69] Their publication reports consensus statements on ideal patient selection, treatment approach, and followup for patients undergoing FT for PCa. Additionally, they identify topics where consensus could not be reached, providing guidance for future research in the field. Key consensus statements are outlined in Table 4 (reproduced with permission).

In the absence of robust clinical data, post-market surveillance becomes crucial. This allows regulatory bodies to monitor emerging public health issues associated with new devices after regulatory approval. The FDA's Manufacturer and User Facility Device Experience (MAUDE) database and Health Canada's medical device incident database mandate the reporting of complications leading to "death and serious injury" by manufacturers, importers, and device user facilities.[70,71] These reports are accessible to the public. Since 2015, the MAUDE database has recorded 16 reports of complications for prostate tissue ablation devices regulated under product code PLP, with the most common complication being the development of a fistula.

Until reforms in the regulatory process take place or ongoing clinical trials help define the role of FT, it is advisable for healthcare providers to prioritize enrolling patients in a registry or prospective observational study. This ensures that data on efficacy and safety can continue to be collected. An example of this is the International Focal Therapy Outcomes Registry, overseen by the Focal Therapy Society (FTS). This registry tracks the clinical outcomes of various ablative treatments for partial prostate gland therapy. The FTS supports multicenter, international clinical trials and serves as an excellent platform for accessing the most recent developments in FT and establishing direct connections with experts in the field.

CONCLUSIONS

FT technologies have gained regulatory approval for prostate tissue ablation and, aside from provincial support for cryoablation in Alberta, are available to Canadians through private payment or clinical trials. Many studies demonstrate promising cancer control and impressive functional outcomes but are limited by their short followup and lack of comparator group. Clinical trial or registry participation should be prioritized to ensure an evidence-based integration into current PCa treatment approaches.

COMPETING INTERESTS. Dr. Kumar has received speaker honoraria from Knight Therapeutics Inc. Dr. Ghai has participated I clinical trials supported by Clinical Laserthermia Systems (CLS) Inc, Exact Imaging, and Insihtec Ltd. Dr. Klotz has received research support and honoraria for speaking engagements from Debiobiopharm, Exact Imaging, and Profound Medical; has participated in clinical trials supported by Exact Imaging, Profound Medical, and Sumotomi Pharma; and is President of KVR Pharmaceuticals. Dr. Mannas has been an advisory board member for Photocure, TerSera, and Tolmar; has received speaker honoraria from AbbVie, Astellas, Bayer, Janssen, and TerSera, and a research grant from TerSera; and is a senior advisory board member for Hexamer Therapeutics. Dr. Bhindi is an advisory board member for Bayer, EMD Serono, Ferring, Janssen, and Verity; has received speaker honoraria from Bayer, Merck, and Pfizer; and has participated in clinical trials supported by Bayer, Elypta AB, and Janssen. Dr. Inman has been an advisory board member for AbbVie, Combat Medical, Johnson & Johnson, Seattle Genetics, and TerSera; has received honoraria from National Institutes of Health, Department of Defense, TerSera, and Tolmar; and has participated in clinical trials supported by CG Oncology, FKD Therapies, Genentech-Roche, Janssen, Medtronic, Profound Medical, Seattle Genetics, and Theralase. Dr. Perlis has received honoraria for advisory board attendance, educational events, and consultation from AbbVie, Focal Healthcare, Knight, Spectracure, TerSera, and Tolmar. The remaining authors do not report any competing personal or financial interests related to this work.

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