

Review Article

Focal therapy for prostate cancer: current evidence and controversies

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ABSTRACT

Focal therapy is an organ-preserving strategy for selected patients with localized prostate cancer, aiming to eradicate clinically significant disease while preserving uninvolved prostate tissue. Advances in multiparametric magnetic resonance imaging, targeted biopsy, and ablative technologies have improved patient selection and treatment planning. Contemporary studies report encouraging short- and intermediate-term oncological control with relatively low rates of major urinary and sexual morbidity. However, the available evidence remains limited by heterogeneity in patient selection, ablative technologies, definitions of treatment failure, and follow-up protocols. The lack of mature comparative trials against radical prostatectomy or radiotherapy remains a major limitation to its adoption as standard treatment. Focal therapy is a promising option for carefully selected patients, particularly those with localized favorable intermediate-risk disease. Nevertheless, current evidence does not establish long-term oncological equivalence with radical treatments. Standardization of patient selection, treatment delivery, and surveillance, together with adequately powered comparative studies and long-term follow-up, is required to define its definitive role in prostate cancer management.

Keywords: Prostatic Neoplasms, Focal Therapy, Magnetic Resonance Imaging, High-Intensity Focused Ultrasound, Cryotherapy

INTRODUCTION

Prostate cancer is currently one of the major oncological problems in men. According to GLOBOCAN 2024 estimates, approximately 1.55 million new cases and 420,000 deaths from this disease occurred during 2024, making it the second most frequently diagnosed cancer worldwide and the fourth leading cause of cancer death in men.¹ The expansion of prostate-specific antigen (PSA) screening strategies, incorporation of multiparametric magnetic resonance imaging (mpMRI), and development of targeted biopsies have substantially changed the

evaluation of localized prostate cancer and enabled more precise disease stratification.²

Recognition of lower-volume tumors and the need to reduce overtreatment have promoted the development of strategies positioned between active surveillance and treatments directed at the entire gland. In this context, focal therapy (FT) aims to selectively eliminate clinically significant prostate cancer (csPCa), preserving as much as possible the unaffected prostate tissue and the structures responsible for urinary continence and sexual function.^{3,4} Its rationale is related to the index-lesion concept, according to which the dominant tumor focus

represents a substantial part of the biological potential of the disease. However, the presence of multifocal and clinically significant disease outside the dominant lesion constitutes a fundamental limitation of this model.³

mpMRI has transformed the identification and characterization of prostate lesions, but a negative MRI or an apparently solitary lesion does not completely exclude the presence of clinically significant cancer in other regions of the gland. Consequently, contemporary patient selection for FT requires integration of clinical, radiological, and histopathological information and, in most protocols, a combination of targeted and systematic biopsy.^{5,6}

The main technologies currently used include high-intensity focused ultrasound (HIFU), cryotherapy, and irreversible electroporation (IRE), in addition to other modalities that remain under investigation.⁷ These techniques differ in their mechanisms of action, tissue-preservation potential, and toxicity profiles. Contemporary studies have demonstrated generally favorable functional outcomes and encouraging short- and intermediate-term oncological control. However, important differences persist in patient selection, treated volume, definitions of recurrence, and follow-up protocols.^{7,8}

The most recent prospective meta-analysis included 50 studies and 4,615 patients and found csPCa-free survival of 86% at 12 months and 81% at 24 months, in addition to radical- or systemic-treatment-free survival of 82% at five years. Nevertheless, the median follow-up was only 21 months, considerably limiting interpretation of these results in the long term.⁸

Therefore, the central question is no longer merely whether FT can destroy the tumor with lower morbidity than radical treatments, but rather which patients can achieve sufficiently durable oncological control without compromising their chances of cure. The objective of this review is to critically analyze current patient selection, the main FT modalities, oncological and functional outcomes, follow-up strategies, and the controversies that currently condition its incorporation into standard treatment of localized prostate cancer.

THEMATIC DEVELOPMENT

Patient selection and the role of magnetic resonance imaging

Patient selection is probably the main determinant of FT outcomes. Unlike radical prostatectomy, which allows histological evaluation of the entire gland, focal ablation leaves prostate tissue that may harbor disease. Therefore, the objective of preoperative assessment should not be limited to identifying a lesion, but rather to determining whether clinically significant disease is sufficiently localized to permit complete and reproducible ablation.^{5,6}

Criteria proposed by different consensus groups tend to favor patients with localized disease, an mpMRI-identifiable lesion, histological confirmation by targeted and systematic biopsy, and tumor characteristics compatible with an organ-preserving strategy.^{5,9} In terms of risk, most contemporary evidence is concentrated in low-risk and, particularly, favorable intermediate-risk patients. ISUP grade group 2 currently represents one of the settings of greatest interest for FT, particularly when the tumor is localized, limited in volume, and without evidence of significant contralateral disease.^{5,9}

In contrast, the indication in patients with ISUP grade group 1 should be interpreted cautiously. These patients may benefit from active surveillance, a strategy supported by extensive evidence and without initial exposure to the complications of ablative treatment. A study with follow-up of up to ten years compared focal cryotherapy with active surveillance in a predominantly low-risk population and found no significant oncological advantage for focal ablation, although cryotherapy prolonged the time to radical treatment.¹⁰

ISUP grade group 3 disease represents a more controversial setting. Some centers include carefully selected patients, but the evidence is considerably less extensive than for ISUP grade group 2. High-risk disease, significant extracapsular extension, seminal vesicle invasion, nodal involvement, or metastatic disease are not currently standard indications for FT with curative intent. AUA/ASTRO guidelines recommend not offering focal or whole-gland ablation to patients with high-risk prostate cancer outside a clinical trial.¹¹

The difficulty of selecting patients correctly has been demonstrated by studies comparing preoperative assessment with the prostatectomy specimen. In a multicenter cohort of 2,371 patients, only 303 (12.8%) met consensus criteria for FT, defined by a unifocal lesion, ISUP ≤ 2 , PSA ≤ 15 ng/ml, and life expectancy greater than ten years.⁵ These results show that only a relatively small proportion of patients diagnosed with prostate cancer have disease sufficiently localized for a focal strategy.

Likewise, a study comparing eligibility criteria derived from MRI/ultrasound fusion biopsy with prostatectomy findings demonstrated that 35.5% to 46.2% of patients considered candidates according to preoperative criteria would have been incorrectly selected when the complete surgical specimen was evaluated.⁶ This finding highlights a fundamental limitation: even with mpMRI and targeted biopsies, the true extent of disease may be underestimated.

For this reason, systematic biopsy retains an important role. Targeted biopsy better characterizes the visible lesion, whereas systematic biopsy may identify clinically significant disease outside the target. Combining both

strategies reduces the risk of focally treating disease that actually has a multifocal distribution.^{5,6}

Tumor anatomy also determines the feasibility of adequate ablation. Lesion location in relation to the urethra, sphincter, rectum, and neurovascular bundles may affect both tumor coverage and functional risk. The FALCON consensus has emphasized the need to individualize energy-source selection and treatment planning because the different modalities do not have identical technical characteristics.^{9,12}

Overall, the current candidate for FT should have clinically localized disease, a clearly identifiable and biopsied lesion, no clinically significant disease outside the treatable territory, and histological and anatomical characteristics that allow adequate ablation. These criteria should be understood as a selection framework rather than a universal indication, since there is still insufficient evidence to define a group in which FT has demonstrated long-term oncological equivalence to radical treatments.

Main focal therapy modalities

FT encompasses different ablative technologies that share the goal of selectively destroying tumor tissue. Differences in mechanisms of action have clinically relevant implications.

High-intensity focused ultrasound

HIFU uses concentrated ultrasound energy to produce localized thermal elevation and coagulative necrosis. It is one of the modalities with the greatest clinical experience and has been evaluated in multiple prospective and retrospective cohorts.^{7,13}

Contemporary results suggest reasonable oncological control in selected patients. A meta-analysis of visually directed focal HIFU including eight observational studies and 1,819 patients found a median follow-up of 24 months and an approximately 19.8% rate of positive biopsy for csPCa. The salvage-treatment rate was 16.2% when focal or whole-gland treatments were considered and 8.6% when only whole-gland treatment was considered.¹³ These results show that, although HIFU can provide tumor control in an important proportion of

patients, follow-up and the possibility of additional treatment remain essential components of the strategy.

Cryotherapy

Cryotherapy produces cellular injury through freeze-thaw cycles, with intracellular crystal formation, microvascular disruption, and tissue necrosis. Its use in FT allows monitoring of the freezing zone during the procedure, although proximity to functionally relevant structures may limit the extent of ablation.⁷

Experience with prolonged follow-up is particularly relevant. In a cohort with a median follow-up of 85 months, focal cryotherapy showed metastasis-free survival of 93.9% and overall survival of 97% at ten years. However, it did not provide a significant oncological advantage over active surveillance in predominantly low-risk patients.¹⁰ These data support the need to clearly distinguish between patients who require definitive treatment and those for whom active surveillance remains an appropriate strategy.

Irreversible electroporation

IRE uses high-intensity electrical fields to produce irreversible alterations of the cell membrane. Unlike thermal modalities, its mechanism does not primarily depend on increased temperature, generating interest because of its potential to preserve tissue and functional structures.^{7,14}

The available evidence is more recent than that for HIFU and cryotherapy. Systematic reviews show encouraging functional outcomes but considerable variability in recurrence and retreatment rates.¹⁴ The absence of mature comparative studies prevents determination of whether IRE offers clinically relevant oncological or functional advantages over other modalities.

The contemporary FT meta-analysis including cryotherapy, HIFU, and IRE found no significant differences among the three technologies in the outcomes evaluated.⁷ This suggests that, at least with the evidence currently available, patient selection and the quality of planning may be as important as the energy source used. Table 1

Table 1. Main focal therapy modalities for prostate cancer.

Modality	Mechanism of action	Potential advantages	Main limitations	Evidence status
HIFU	Thermal ablation using focused ultrasound, producing coagulative necrosis	Extensive clinical experience; image-guided planning; ability to treat focal or larger-volume lesions	Recurrence or residual disease; limitations related to tumor location and proximity to critical structures; protocol heterogeneity	Greatest clinical experience among focal modalities, although observational studies predominate
Cryotherapy	Freeze-thaw cycles producing cellular and vascular injury and	Visualization of the freezing zone; prolonged clinical	Risk of thermal injury to adjacent structures; difficulty achieving	Relatively broad clinical evidence, but predominantly non-

Continued.

Modality	Mechanism of action	Potential advantages	Main limitations	Evidence status
	tissue necrosis	experience; possibility of repeat ablation	adequate margins in certain locations; recurrence	comparative
Irreversible electroporation (IRE)	Application of high-intensity electrical fields producing irreversible alterations of the cell membrane	Potential preservation of non-tumor structures; mechanism not primarily dependent on thermal injury; ability to treat lesions near critical structures	Less experience and long-term follow-up; technical heterogeneity; need for greater comparative validation	Growing evidence, but still limited regarding long-term follow-up and oncological outcomes
Laser ablation	Application of laser energy to produce localized thermal necrosis	Precision in defining the treated volume; possibility of monitoring using imaging techniques	Smaller evidence base; protocol heterogeneity; more limited clinical experience	Emerging evidence and less extensive than for HIFU and cryotherapy

Note: Focal therapy modalities differ in mechanism of action, planning, and toxicity profile. The evidence available for all of them is mainly limited by the absence of mature comparative trials and by heterogeneity in definitions of failure and follow-up.

Oncological outcomes

Interpretation of oncological outcomes is one of the main methodological problems in the FT literature. Unlike radical prostatectomy, in which PSA should reach virtually undetectable levels, viable prostate tissue remains after partial ablation. Consequently, traditional biochemical-recurrence criteria are not directly applicable, and different studies have used heterogeneous definitions of failure.¹⁵

A systematic review of FT oncological outcomes identified wide variability in recurrence and salvage-treatment rates, in addition to multiple definitions of tumor control. The Phoenix criterion was among the most frequently used, but its applicability after FT remains debatable.¹⁵

The meta-analysis by Tay and colleagues included 49 cohorts corresponding to 21 cryotherapy studies, 20 HIFU studies, and 8 IRE studies. Pooled overall survival was 98%, cancer-specific survival was 99.3%, and metastasis-free survival was 98.5%. The pooled rate of csPCa detected by biopsy after treatment was 22.2%, with 8.9% of disease within the treated field and 12.3% outside the field. The need for a second FT was 5%, while 10.5% of patients required radical treatment.⁷

These results are encouraging but should be interpreted in the context of heterogeneous median follow-up ranging from 6 to 63 months. In addition, post-treatment biopsy was mandatory within the first 24 months in 73.5% of cohorts.⁷ Therefore, the absence of protocol-mandated biopsy in a proportion of studies may lead to underestimation of residual disease.

The prospective-studies meta-analysis published in 2025 included 50 studies and 4,615 patients. csPCa-free survival was 86% at 12 months and 81% at 24 months, while radical- or systemic-treatment-free survival at five

years was 82%. The pooled incidence of grade ≥ 3 adverse events were 3%, urinary incontinence requiring a pad increased by approximately 3%, and new erectile dysfunction was observed in 11% of patients.⁸ However, the median follow-up was 21 months, constituting the main limitation for establishing oncological durability.

Therefore, current data allow us to state that FT offers reasonable initial and intermediate-term control in selected patients, but do not allow the conclusion that it is equivalent to radical prostatectomy or radiotherapy in terms of long-term oncological control.

Functional outcomes

The main potential advantage of FT over treatments directed at the entire gland is functional preservation. By limiting the treated volume, the goal is to reduce damage to the sphincters, urethra, rectum, and neurovascular bundles. Contemporary studies generally show a low incidence of severe urinary incontinence and less functional impairment than that described after radical treatments.^{7,8}

In the meta-analysis by Tay and colleagues, most cohorts evaluating urinary function reported low impact. Among studies evaluating sexual function, approximately 46% reported low impact, 49% moderate impact, and 6% severe impact.⁷ The 2025 prospective meta-analysis found an incidence of new erectile dysfunction of approximately 11%.⁸

However, these results should be interpreted cautiously. Studies do not uniformly use functional questionnaires, assessment time points, or definitions of dysfunction. In addition, baseline function may vary considerably among populations, and patient selection may favor men with better baseline function.

Functional preservation should also not be considered independently of oncological control. A reduction in toxicity represents a net clinical benefit only when accompanied by adequate tumor control. The fundamental challenge of FT is precisely to achieve a balance between sufficient ablation and functional preservation.

FOLLOW-UP AND DETECTION OF RESIDUAL DISEASE

Follow-up is one of the least standardized aspects of FT. Because viable prostate tissue persists, PSA cannot be used as the sole marker of response. Ablation-related changes also make interpretation of mpMRI difficult during the first months.^{16,17}

A contemporary review published in 2024 concluded that post-FT assessment should integrate PSA, mpMRI, and prostate biopsy. The first mpMRI is usually recommended between six and twelve months, avoiding very early imaging because of inflammatory and structural changes associated with treatment.¹⁶

Biopsy remains fundamental. The contemporary review recommends a protocol biopsy at approximately 12 months, combining targeted and systematic samples to evaluate both the treated area and the presence of disease in untreated regions.¹⁶ Surveillance based exclusively on MRI may be insufficient, because absence of a radiologically suspicious lesion does not completely exclude residual disease.

Table 2: Selection and follow-up of patients undergoing focal therapy

Serial no.	Stage	Recommended assessment	Clinical objective
1.	Diagnostic confirmation	PSA, clinical examination, mpMRI, and prostate biopsy	Confirm cancer and determine the initial extent of disease
2	Histopathological characterization	Biopsy targeted to the lesion identified on mpMRI + systematic biopsy	Confirm tumor grade and detect clinically significant disease outside the index lesion
3.	Risk stratification	ISUP grade group, PSA, clinical stage, tumor volume, and lesion characteristics on mpMRI	Identify patients with localized disease potentially amenable to focal treatment
4.	Anatomical assessment	Location, size, and extent of the lesion; relationship to urethra, sphincter, rectum, and neurovascular bundles	Determine whether adequate ablation is technically feasible while preserving functional structures
5.	Candidate selection	Localized disease, identifiable and treatable lesion, absence of clinically significant disease outside the ablation volume, and sufficient life expectancy	Select patients in whom the potential functional-preservation benefit justifies oncological uncertainty
6.	Focal treatment	HIFU, cryotherapy, IRE, or another modality according to location and tumor characteristics	Complete ablation of the tumor volume with a safety margin and maximal preservation of functional tissue
7.	Initial post-treatment assessment	Serial PSA and clinical/functional assessment	Establish initial response and detect clinical or biochemical changes suggestive of residual disease
8.	Follow-up mpMRI	Generally, around 6–12 months	Evaluate the ablation bed and detect suspicious residual or 9. recurrent lesions
9.	Control biopsy	Targeted biopsy of the treated area + systematic biopsy, usually around 12 months	Detect residual or recurrent disease within or outside the treated field
10,	Long-term surveillance	PSA, functional assessment, mpMRI, and biopsy according to risk and clinical/radiological findings	Detect recurrence, progression, or new clinically significant disease
11.	Residual/recurrent disease	Review with mpMRI and biopsy when indicated	Determine whether a second ablation is possible or whether whole-gland treatment is required
12.	Salvage treatment	New focal therapy, radical prostatectomy, or radiotherapy according to location, extent, and patient characteristics	Achieve definitive oncological control in persistent or recurrent disease

Note: Selection and follow-up should be individualized. Persistence of viable prostate tissue after ablation prevents the use of PSA as the sole response marker; therefore, surveillance should integrate clinical, biochemical, radiological, and histopathological parameters. Targeted and systematic biopsy remains important for detecting residual or extrafocal disease.

This limitation was illustrated in a study of patients undergoing focal cryotherapy in which 12 patients had residual or recurrent ISUP ≥ 2 disease. Of these, 11 had follow-up MRI classified as PI-RADS 1–3, demonstrating that an apparently reassuring MRI can coexist with clinically significant disease.¹⁷

The PI-FAB and TARGET systems have been developed to improve standardization of MRI interpretation after FT.^{16,18} However, these systems require further validation and still do not replace histological assessment when there is clinical or radiological suspicion.

Follow-up should also incorporate functional assessment. Erectile function, urinary symptoms, continence, and quality of life should be measured using validated instruments, particularly during the first year, when most functional recovery occurs.¹⁶ (Table 2.)

Recurrence and salvage treatment

Recurrence after FT can conceptually be classified as disease within the treated field or outside the field. Intralesional disease may indicate incomplete ablation or an underestimated lesion, whereas extralesional recurrence may reflect initially unrecognized multifocality or subsequent development of a new clinically significant lesion.^{7,16}

This distinction has therapeutic implications. In patients with localized residual disease and favorable anatomy, a second ablation may be considered. Conversely, multifocal disease, grade progression, extracapsular extension, or clinical progression may require whole-gland treatment with radical prostatectomy or radiotherapy.

The possibility of salvage treatment is an important feature of FT and should be part of the information provided to the patient before the procedure. In Tay's meta-analysis, approximately 10.5% of patients required radical treatment after FT and 5% received a second FT.⁷

Therefore, FT should not be conceptualized as a necessarily definitive procedure for all patients, but rather as a strategy requiring a structured surveillance program and maintaining the possibility of salvage treatment when there is evidence of persistent or recurrent disease.

Position relative to active surveillance, prostatectomy, and radiotherapy

Comparison with active surveillance is particularly relevant in low-risk patients. In this group, focal treatment may represent overtreatment, since active surveillance allows treatment to be deferred without necessarily compromising oncological prognosis. Long-term follow-up results of focal cryotherapy did not demonstrate a significant oncological advantage over

active surveillance in a predominantly low-risk population.¹⁰

In patients with favorable intermediate risk, the situation is different. These patients may require definitive treatment and currently represent one of the main groups of interest for FT. However, the choice should be individualized, considering that prostatectomy and radiotherapy have a considerably more mature evidence base.

AUA/ASTRO guidelines state that patients with high-risk prostate cancer should not receive focal or whole-gland ablation outside a clinical trial. For patients with intermediate-risk disease, FT may be considered in selected contexts, whereas patients with low-risk disease may be candidates for surveillance.¹¹

The fundamental problem is the lack of long-term comparative evidence. Available FT studies are predominantly single-arm prospective cohorts, retrospective studies, and meta-analyses of heterogeneous populations.^{7,8} Although functional outcomes are attractive, there is still insufficient evidence to determine whether a potential reduction in toxicity is accompanied by tumor control equivalent to that of radical treatments.

This uncertainty should be explicitly communicated to the patient. International consensus on FT has indicated that equivalence between focal ablation and standard treatments has not been demonstrated and that FT continues to require prospective investigation.^{9,12}

DISCUSSION AND FUTURE PERSPECTIVES

FT has evolved considerably over the past decade. The combination of mpMRI, targeted biopsies, new ablative technologies, and more structured surveillance systems has allowed it to move from a predominantly experimental strategy to a clinically available option in selected centers. However, this technological development has been faster than the generation of long-term comparative evidence.

The main challenge remains accurately identifying the patient whose disease can be controlled through partial ablation. The index lesion is a useful concept for understanding prostate cancer biology, but it cannot be interpreted as synonymous with exclusively unifocal disease. Available evidence demonstrates that a proportion of patients considered candidates according to mpMRI and biopsy may have additional disease or greater extent on the prostatectomy specimen.^{5,6}

The second challenge is the heterogeneity of technologies. HIFU, cryotherapy, and IRE use different mechanisms and do not necessarily produce equivalent lesions. However, current meta-analyses have not demonstrated clear differences among these modalities.⁷ This may reflect either comparable efficacy or the

difficulty of comparing populations, protocols, and different success criteria.

The third challenge concerns the definition of failure. The absence of a universal definition of recurrence after FT makes comparisons among studies difficult and may produce apparently contradictory results.¹⁵ Standardization of outcomes should be a priority for future trials.

The fourth challenge is follow-up. There is currently increasing consensus around the combined use of PSA, mpMRI, and biopsy, but differences remain regarding the exact timing of each assessment.¹⁶ Contemporary practice favors a protocol biopsy during the first year followed by risk-adapted surveillance. mpMRI plays a central role, although its limitations after ablation require its findings to be interpreted together with clinical and pathological findings.

New diagnostic tools could improve this situation. Incorporation of PSMA-PET, artificial intelligence applied to MRI, micro-ultrasound, and molecular biomarkers represents a promising research direction. However, these tools must be specifically validated in the post-ablation setting before being incorporated as substitutes for biopsy or established follow-up methods.

Finally, the future of FT will depend on comparative trials with sufficiently prolonged follow-up. Studies should evaluate not only biochemical recurrence, but also biopsy-confirmed clinically significant disease, metastasis-free survival, need for salvage treatment, cancer-specific survival, urinary function, sexual function, and quality of life.

In this context, FT should currently be considered an organ-preserving strategy for carefully selected patients treated within structured surveillance protocols. The available evidence allows it to be considered a promising option, but does not yet justify presenting it as equivalent to established radical treatments.

CONCLUSIONS

Focal therapy is a promising strategy for selected patients with localized prostate cancer and may provide an attractive balance between tumor control and functional preservation. Contemporary evidence shows favorable short- and intermediate-term oncological outcomes and a relatively low incidence of severe functional toxicity.

However, the multifocal nature of prostate cancer, the possibility of underestimating tumor extent, heterogeneity of ablative technologies, and the lack of uniform definitions of failure continue to limit interpretation of the results. Selection should integrate mpMRI, targeted and systematic biopsy, histopathological characteristics, and anatomical distribution of disease.

Currently, FT appears to have the greatest utility in carefully selected patients with localized favorable intermediate-risk disease. It should not be considered an established alternative for high-risk patients or an automatic substitute for active surveillance in low-risk patients.

The main uncertainty remains the durability of oncological control. Until comparative studies with prolonged follow-up become available, FT should be presented as an organ-preserving strategy with encouraging initial results, but with uncertainty regarding its equivalence to radical prostatectomy and radiotherapy. Standardization of selection, treatment, and follow-up, together with prospective comparative studies, will be fundamental to determining its definitive role in prostate cancer treatment.

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