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Focal Laser Ablation of Prostate Cancer: Results in 120 Patients with Low to Intermediate Risk Disease

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Abstract

Purpose: Can focal laser ablation (FLA) of the prostate preserve sexual and urinary function with low morbidity in men with low to intermediate-risk prostate cancer while providing adequate oncologic outcomes?

Materials and methods: 120 patients with low to intermediate risk prostate cancer had transrectal FLA done. MRI thermometry controlled the ablation. Procedures were performed between 2013 and 2017. At 6 and 12 months, patients had clinical and MRI follow-up with biopsies of suspicious areas. Patients submitted the Sexual Health in Men (SHIM) survey to evaluate erectile function and the the International Prostate Symptom Score (IPSS) to assess urinary continence and flow.. Multivariate logistic regression identified determinants of positive imaging and biopsies. Two-sided Wilcoxon signed rank test evaluated scores and laboratory values.

Results: The median age was 64 and median PSA was 6.05 ng/mL. Eight (6.7%) of patients were African-American. The median follow up period was 34 months (from 17 to 55 months). Gleason score was 3+3 in 37 (30.8%), 3+4 in 56 (46.7%), and 4+3 in 27 (22.5%). AJCC tumor stage was T1c in 89 (74.2%), T2a in 26 (21.7%) and T2b in 5 (4.2%). Tumors were located in the peripheral zone in 108 (73%) of patients. Number of tumors treated were one in 72 (60%) of patients and 2 tumors in 47 (39.2%) of patients. One patient had 3 tumors treated. Twenty (17%) of men had additional oncologic therapy one year after FLA when biopsy confirmed cancer after an abnormal MRI. There was no difference between functional scores pre- and post-ablation.Median SHIM score at baseline was 24 vs 22 at one year ($p=0.51$) and the IPSS score was 6.5 at baseline and 6.0 at one year ($p=0.12$). The median PSA fell to 3.25 at 12 months ($p<0.001$). Tumor diameter above the median (Odds Ratio (OR), 3.36; 95% CI, 1.41–7.97) was the only significant predictor for a positive post-treatment MRI..

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Conclusions: At 1 year, FLA in selected patients has low morbidity, no significant changes in quality of life and 83% freedom of retreatment rate. Sexual and urinary function did not significantly change after FLA.

Keywords

laser ablation; prostate cancer; focal; outcomes

Introduction

Prostate cancer remains the most common solid organ tumor among U.S. men with an estimated 161,360 new cases and 26,730 deaths in 2017. [1] Curative options for prostate cancer include surgery and radiation. [2, 3] Driven by intensive PSA screening recently, prostate cancer has witnessed stage migration[4] toward a more indolent course in most new cases. [5,6,7]

Current algorithms result in over-diagnosis and over-treatment of prostate cancer. Results from the important PIVOT clinical trial assessing men with localized prostate cancer found thatsurgery or radiotherapy did not reduce prostate cancer specific or overall mortality as compared to observation.[8] Therefore,, targeted options, including FLA, are attractive, , primarily due to the negligible impact on sexual and urinary function.[9–16] Additionally, the procedure is safe and allows patients to return to work within days.[11] Most of the existing literature focuses on small phase 1 or 2 series and examines short term tumor control and safety.[9,10] This series similarly evaluates the safety and morbidity of FLA but also determines tumor control at 1 year in a large group of patients receiving FLA. With this increased focus on targeted ablation, future FLA studies will move away from safety analysis and consider long-term oncologic effectiveness due to the slow progression of low to intermediate risk disease.[17].

Materials and Methods

Study Population:

Between July 2013 and May 2017, 186 men had evaluation for prostate FLA in a prospective longitudinal outcomes investigation. The study was approved by the Institutional Review Board.

Included were men with clinical stage T1c-T2b, PSA less than 15 ng/ml, PSA density less than 0.15 ng/ml^3, Gleason score 7 or less and no metastases. In addition, eligibility included mpMRI confirmed region(s) of interest (ROI) score ≥3 using prostate imaging reporting and data system (PI-RADS) version 2, [16] and no more than 3 ROIs identified. Study exclusion criteria included men with ROIs ≥2 cm in largest diameter and MRI suspicion of extraprostatic disease and/or men with absolute contraindications to mpMRI. After applying these criteria, the final study cohort consisted of 120 consecutive patients (Figure 1). Patient demographics are summarized in Table 1.

FLA Procedure:

Of the 120 patients, 113 self-referred after discussions with their local urologist. Seven were referred by a urologist. 106 of 120 patients (88%) live outside of the institution's medical service area. All patients were healthy outpatients with ECOG performance status of 0.

All patients started oral ciprofloxacin on the day before the procedure, supplemented by intravenous ceftriaxone before the procedure For patients with a history of antibiotic allergies or antibiotic-resistant organisms evident by rectal swab, antibiotics were tailored accordingly. Patients performed saline enemas before the procedure. All FLA procedures were done in the Siemens 3T Skyra MRI unit (Siemens, Erlangen, Germany) with the patient receiving intravenous conscious sedation and lidocaine 1% injected peri-prostatically.

The prostate FLA procedure involved a transrectal approach, using one saline-cooled 17-gauge laser to create overlapping ablations through a rectal probe. The laser fiber and the rectal probe were guided to the tumors using the DynaTRIM Transrectal Interventional MRI system (Phillips®), which gives the rectal probe three planes of position adjustment to guide the laser into position (Figure 2a).

The FLA procedure involved the Visualase® thermal therapy system (Medtronic, Minneapolis, MN) composed of a workstation, a 30W 980 nm diode laser, a cooling pump, and a disposable laser applicator composed of a 600 micron fiberoptic with a diffusing tip housed within a 1.85 mm saline-cooled polycarbonate cooling catheter.[18–20] Extracted thermal data produced color-coded "thermal" and "damage" images based on an Arrhenius rate process model which are displayed on the workstation. The damage image accounts for the cumulative effects of the time-temperature history of each voxel in the image. The diffusing laser fiber tip creates a 16 to 18mm oval ablation zone and the laser can be adjusted within the cannula to "paint" an ablation zone (Figure 2b). When tumors were near the urethra a foley bladder catheter was inserted and chilled saline dripped through it to prevent thermal damage to these structures (cooled urethral saline protection or CUSP) If the targeted tumor was close to the rectal wall (i.e often the prostate capsule is directly touching or within 3mm of the rectal wall), a sheathed needle was punctured into the rectoprostatic space (also transrectal) and used to hydrodissect the rectum away from the prostate capsule (Figure 2c). Treatment duration was 3–4 minutes at 17–18W based on the intended size of the ablative zone. The cooling cannula was frequently passed through the tumor and the laser withdrawn slowly to create multiple overlapping ablations and improve the ablative margin. Target ablation temperature was a minimum of 60C.

Patient Follow-up:

At each follow up visit adverse events were graded according to National Cancer Institute (NCI) common terminology criteria, and the PSA was determined. Prostate mpMRI was performed and quality of life instruments (IPSS and SHIM surveys) were collected at the follow-up visits. If the PSA decreased by 50% and the mpMRI showed no suspicious tumors (ROI's equal or greater than PIRADS 3), mpMRI and PSA clinical follow up continued without biopsy. If any of these criteria were violated, patients underwent MRI guided biopsy of the ROI judged PI-RADS score ≥3 as well as the prior ablation zone If PSA did not

decrease by 50% and no ROI was identified then the ablation zone only was biopsied. Biopsies were performed with in-bore MRI guidance and MRI-compatible 18g InVivo core biopsy needles (Phillips®). Patients who had a positive MRI biopsy had consultation with their urologist regarding various alternative treatments, including repeat FLA, surveillance, surgery, radiation, or medical therapies. All ablations, pre- and post-procedure imaging were reviewed by one radiologist (EW) with > 20 years of experience in genitourinary radiology.

Statistical Analysis:

The 2-sided Wilcoxon signed rank test was used to evaluate changes in PSA, IPSS and SHIM scores at 6, 12 and 24 months relative to baseline. Multivariable logistic regression models determined adjusted odds ratios for likelihood of positive MRI and prostate biopsy following ablation. Goodness-of-fit was assessed using the Hosmer and Lemeshow test. The Kaplan-Meier method was used to calculate freedom from additional treatment estimates. P values less than .05 were considered statistically significant. The SAS software program version 9.4 (SAS Institute, Cary, NC) was used to perform all data management and statistical analyses.

RESULTS

At the end of the procedure, 3-plane, gadolinium-enhanced T1-weighted MR images (VIBE, Siemens AG, Erlangen, Germany) allowed assessment of the ablation zone for adequate coverage of the tumor(s). Early in this series, the tumor itself plus a 5 mm margin was the goal,[22] but, as others have noted,[10] a larger margin is preferred, particularly with Gleason score 7 tumors. The preferred method is now to “hemiablate” the involved side of the prostate assuming this can be done safely (i.e the ablation zone will not affect the nerves or rectum) (figure 2d). Hemiablation involved laser destruction of the peripheral and transitional zone on one side of the gland with avoidance of the nerve root bundle, urethra and ejaculatory ducts. Patients who were sent home with a urinary catheter with outpatient voiding trial within one week. Of the total 120 patients (median age: 64; range: 45–86) who were included in the analysis, the mean follow up period was 34 months (from 17 to 55 months). Gleason score was 3+3 in 37 (30.8%), 3+4 in 56 (46.7%), and 4+3 in 27 (22.5%) patients, respectively. The median PSA was 6.05 ng/mL (range 4.9–8.6) ng/mL) with 89 (74.2%), 26 (21.7%) and 5 (4.2%) of patients having clinical stage T1c, T2a and T2b disease, respectively. Median prostate volume was 34.0 cc^3 and maximum median biopsy cancer core length was 6 mm. Maximum median ROI diameter was 12.0 mm with the majority of ROIs located in the peripheral zone and PI-RADS score 4. Of all tumors at diagnosis, 24 (20%), 80 (66.7%), and 16 (13.3%) were graded PIRADS 3, 4 and 5, respectively.

Median procedure time was 122 minutes (range 60 to 250 minutes) and median total ablation time (laser energized) was 12.6 minutes (range 2.5 to 40 minutes). A single tumor was treated in 72 (60%) men, 2 tumors in 47 (39.2%), and 3 tumors in 1 (0.8%), respectively. In order to achieve an adequate margin around the tumor, multiple overlapping ablations were created by positioning the fiber’s diffusing tip in several locations The number of such ablations ranged from 1–10 with a median of 4 overlapping ablations.

Median IPSS score at baseline, and 6, 12 and 24 months was 6.5 (IQR 3–13), 7 (IQR 3–10), 6 (IQR 3–10) and 11.5 (IQR 8–17.5), respectively. Compared to baseline no significant IPSS changes were observed at 6, 12 and 24 months (p=0.14 to 0.06). Median SHIM score at baseline, and 6, 12 and 24 months was 24 (IQR 20–25), 22 (IQR 17–24), 22 (IQR 16–24) and 22 (IQR 16–24), respectively. Compared to baseline there were no significant changes in SHIM scores at any time point (p=0.51) as shown in Figure 3.

The median PSA in ng/mL at baseline, and at 6, 12 and 24 months was 6.05 (IQR 4.90–8.60), 5.81 (4.40–8.40), 3.25 (1.95–5.40) and 3.91 (2.36–6.46) as shown in Table 2. A significant decrease in PSA was noted at 12 and 24 months (both p<0.001), respectively.

Forty four patients (36.4%) had a positive post-ablation MRI (PI-RADS score ≥3) or persistent PSA elevation with prostate biopsy confirming insignificant (Gleason score 6 or less) in 4 patients (9% of those with positive MRI or no PSA response) and clinically significant prostate cancer (Gleason score greater than or equal to 7) in 18 (41%) of these patients Therefore, 22 patients with a suspicion of residual cancer had benign biopsies. Positive biopsies resulted in the same Gleason score except in one patient who was upgraded to Gleason 8 from Gleason 7. This case may be a true upgrade although sampling error plagues repeat prostate biopsies. Additionally, extensive FLA damage may make post-treatment Gleason scoring irrelevant similar to specimens obtained after radiation therapy to the gland. In a subset analysis of 16 patients who received hemiablation, positive post-ablation MRI and positive post-ablation biopsy was observed in 1 patient (6.2%). Of the entire 120 patient cohort, secondary therapies included reablation in 20 men (17%) comprised of 18 patients with clinically significant disease at biopsy plus 2 men who opted for reablation rather than continued surveillance for insignificant, Gleason 6 disease. Two patients (2%) went on to prostatectomy, one of which also had a reablation at 6 months and then surgery 6 months later for persistent disease

Region of interest diameter above the median (Odds Ratio (OR), 3.36; 95% CI, 1.41–7.97) was the only significant predictor for a positive post-treatment MRI with no predictors for positive post-treatment prostate biopsy identified (Supplemental Tables 1–2). There was significantly decreased freedom from needing secondary treatments up to 35 months from ablation (*log rank* p<0.001) as seen in Figure 4.

One major complication was defined as CTCAE grade III due to urinary tract infection. A total of 15 grade II complications occurred which included 2 rectourethral fistulae post FLA as shown in Supplemental Table 3. Both resolved after 4–6 weeks of continuous urinary catheterization. The most common low grade adverse event was hematuria noted in 9 (7.4%) of men. No patient experienced urinary incontinence.

DISCUSSION

In this cohort of men with low to intermediate risk prostate cancer treated by FLA, 17% required additional oncologic treatment after one year with no significant change in quality of life or urologic function. By MRI, all tumors occurred at the margins or site of prior ablation. With refined techniques, including hemiablations with larger margins, this rate of

clinically significant residual tumor 1 year after FLA fell to 6.8% although this was noted in a small group of 16 patients and will need verification with further follow up. Moreover, the size of the tumor was the only determinant for a positive post-ablation MRI which may aid in future patient selection.

This study has several important findings. First, FLA was an alternative in men considering active surveillance, surgery or radiotherapy for low to intermediate risk disease. In a recent randomized controlled trial comparing focal therapy to active surveillance, the former allowed more men to consider a tissue-preserving approach and defer or avoid radical therapy.[24] In the present study, 17% of patients underwent reablation while 2 (2%) proceeded with surgical therapy.

Thus, the majority of men avoided any secondary cancer treatments following FLA. Most of these patients underwent ablation of the region of interest with a 5mm margin.[21] However, after an analysis of a subset of patients who underwent more aggressive hemiablation, only 1/16 (6.2%) of patients had a positive post-ablation MRI and positive post-ablation biopsy. Hemiablation was a feasible extension of focal ablation if fluid spacing lifts the prostate away from the rectum and real-time MRI thermometry allows one to ablate next to the neurovascular bundles but no further. These patients, however, all noticed a significant drop in ejaculate volume post hemiablation. While this 3 hour procedure may seem lengthy to some, FLA is an outpatient procedure with very little recovery or pain and procedure duration is similar to other ablative or embolization procedures. As laser and MRI technology improves, this procedure time can be expected to decrease. Some are already using fusion techniques to perform FLA with transrectal ultrasound rather than using valuable in-bore MRI time [34]

Recurrences after prostatectomy vary according to publication but two large series indicate biochemical recurrences in 15–30% of patients within 5–10 years of surgery [26,27]. While focal therapies do not have this long term data, careful patient selection and improved techniques may ultimately provide similar control with an excellent safety profile and functional outcome. Additionally, surgical series report on all grades of prostate cancer while our FLA study only included Gleason 6 and 7 disease. Therefore, recurrence rates may be skewed in favor of FLA. Second, the diameter of the tumor ablated was a significant predictor for positive post-treatment MRI. This finding coincides with several studies also indicating that size was important in selecting focal therapy candidates.[28] In a recent international Delphi consensus project, focal therapy can be recommended in low to intermediate-risk cancer with tumors<1.5 ml on mpMRI or <20% of the prostate, or up to 3 ml or 25% if localized to one hemi-gland.[28] Early in our experience, the tumor itself plus a 5 mm margin was the goal, however, as others have noted,[10] a larger margin may be preferred, particularly with Gleason score 7 tumors. We give patients an option to have magnetic surveillance (yearly MRI and PSA evaluations) or focal therapy for Gleason 6 disease. Many chose treatment nevertheless, fearful after a medical professional previously proposed surgery. We also advocate surveillance after a positive, Gleason 6, post-FLA biopsy. Surveillance seems prudent for any Gleason 6 diagnosis although change in size or characteristics during surveillance will prompt treatment after repeat biopsy (even for growing Gleason 6 disease). Third, FLA was a safe procedure. The most common Grade I

complication was hematuria which resolved in all men. Two men developed rectourethral fistulae early in this FLA program and both resolved with prolonged foley catheterization. Although this was a significant complication, all of these fistulae healed spontaneously with urinary diversion and urethral rest for 4–6 weeks. These fistulae occurred in men with peripheral zone tumors and minimal rectoprostatic fat separating the two structures. Later in our series, saline/lidocaine solution was routinely injected to create a space between the rectum and prostate to minimize fistula formation.

Third, as observed in prior studies,[9–16] FLA was a safe procedure with preservation of erectile and urinary function. While demonstrating oncologic efficacy is cornerstone to evaluating treatments for any cancer, preservation of quality of life should strongly be considered when comparing treatments. Given recent data showing significant decrease in genitourinary function and quality of life up to 3 years after surgery or radiotherapy,[29,30, 31] our stability in these areas for up to 1 year post FLA compares well with other definitive treatments. There are limitations to this study. First, this was a single center prospective longitudinal outcomes study with inherent selection bias. While a majority of these men sought FLA as a treatment option, all men were counseled regarding active surveillance and other definitive treatment options. Prior level one evidence comparing focal therapy to active surveillance suggests the former as a safe, effective treatment for low-risk, localized prostate cancer.[23] These data are supported by prior FLA studies including phase I/II clinical trials.[9–16]. Second, mpMRI and targeted biopsy occurred only in patients with suspicious tumors and/or lack of PSA response to FLA. Other investigators routinely perform systematic protocol biopsy 6 months after FLA in all patients. Given the relative high negative predictive value of mpMRI for missing a significant cancer[32] mpMRI was used in addition to PSA as a guide to then target regions of interest after FLA. While there is level one evidence to suggest the utility of performing targeted without systematic biopsy in biopsy naïve men,[33] further research is needed to standardize follow-up criteria for focal therapy patients.[24,25,28] At this institution, the interventional oncology practice follows other solid tumors after focal therapy using biochemical markers and imaging findings. In these organs, 6 month protocol biopsies are not done routinely. In conclusion, data from this group of 120 patients who had FLA for prostate cancer shows promising early oncologic results without significant changes in quality of life and acceptable morbidity in men with low to intermediate risk disease.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgement

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Key of definitions

FLA	Focused laser ablation
PSA	Prostate specific antigen
mpMRI	multi-parametric magnetic resonance imaging
PIRADS	prostate imaging reporting and data system
ROI	Region of interest
IPSS	International prostate symptom score
SHIM	Sexual health in men

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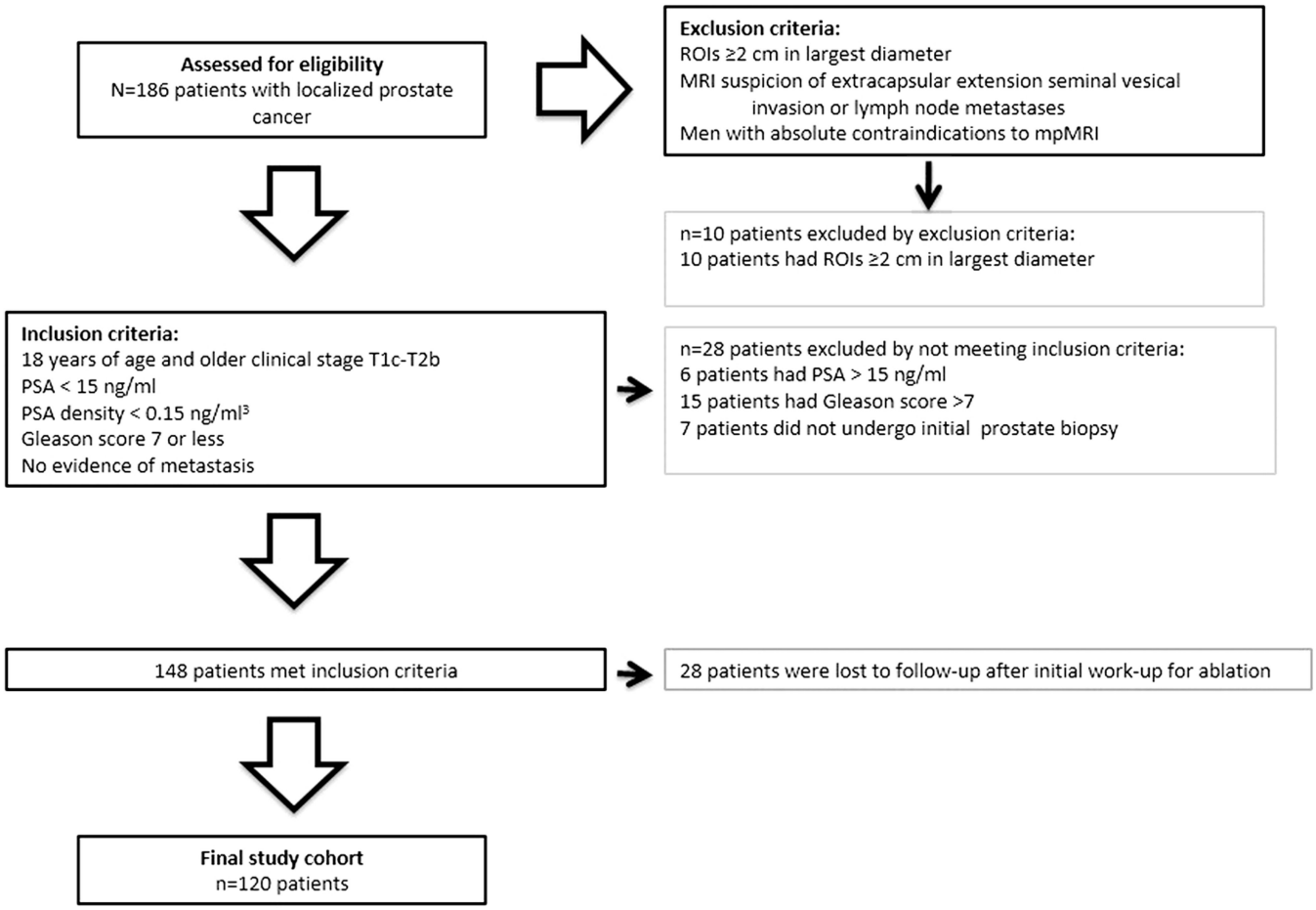

Figure 1.
Consort diagram

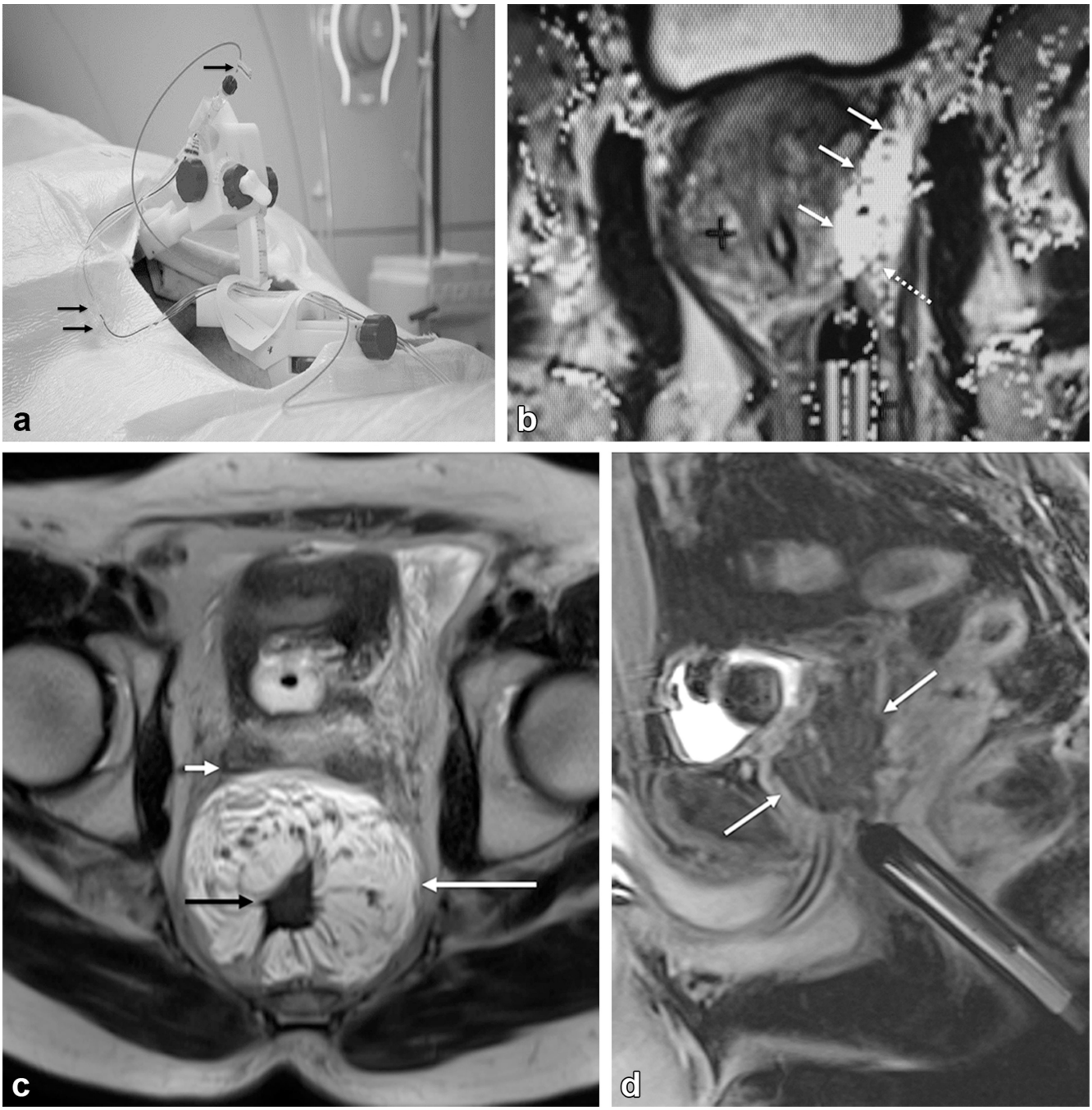

Figure 2.

Images of the Technique for Focal Laser Ablation

A. The laser fiber (arrow) and the rectal probe were guided to the targeted T2-hypointense tumors using the DynaTRIM Transrectal Interventional MRI system (Phillips®), which gives the rectal probe three planes of position adjustment to guide the laser using mpMR images in any plane. Double arrows point to the inflow and outflow tubing for cooling saline infusion.

B. The diffusing laser fiber tip creates a 16 to 18mm oval ablation zone and the laser can be advanced or withdrawn within the cooling cannula to “paint” an ablation zone (arrows point to white area—zone of tissue ablation). The dotted arrow points to the left neurovascular bundle which was monitored during the real-time procedure to avoid nerve involvement in the zone of ablation.

C. If the targeted tumor was close to the rectal wall, a sheathed needle was punctured into the rectoprostatic space (also transrectal) and used to hydrodissect the rectum (black arrow) away from the prostate capsule (small white arrow). The saline hydrodissection was bright on T2 imaging and surrounds and protects the rectum (long white arrow).

D. Hemiablation of the involved side of the prostate on sagittal T1 weighted images after intravenous gadolinium contrast administration (dark zone outlined by arrows). The dark signal represents avascular, non-viable tissue post FLA.

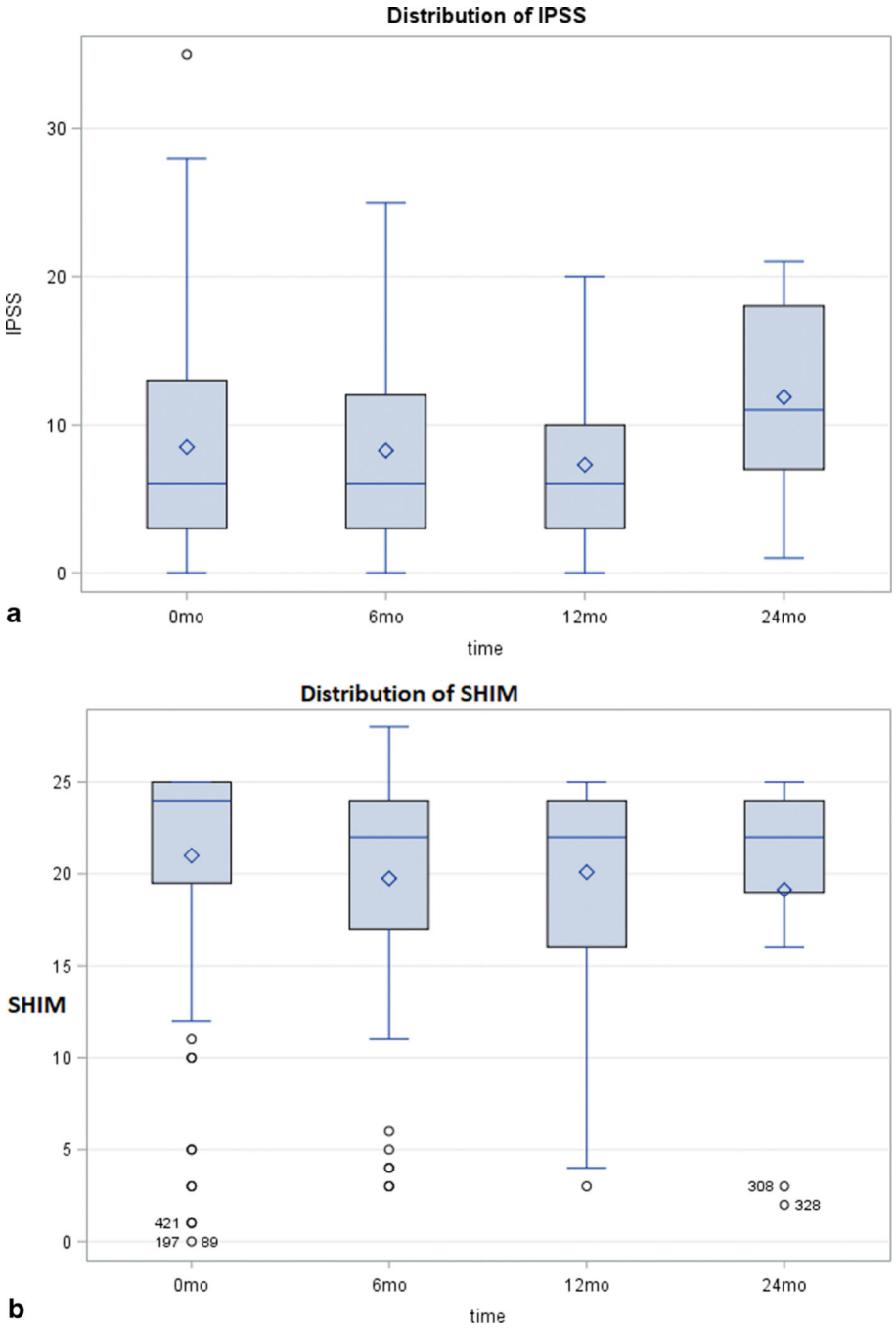

Figure 3.

Erectile and urinary function after focal laser ablation (FLA). IPSS=International prostate symptom score, SHIM=Sexual health in men score. There was no significant difference in scores before and after FLA over time. IPSS p=0.12 and SHIM p=0.51

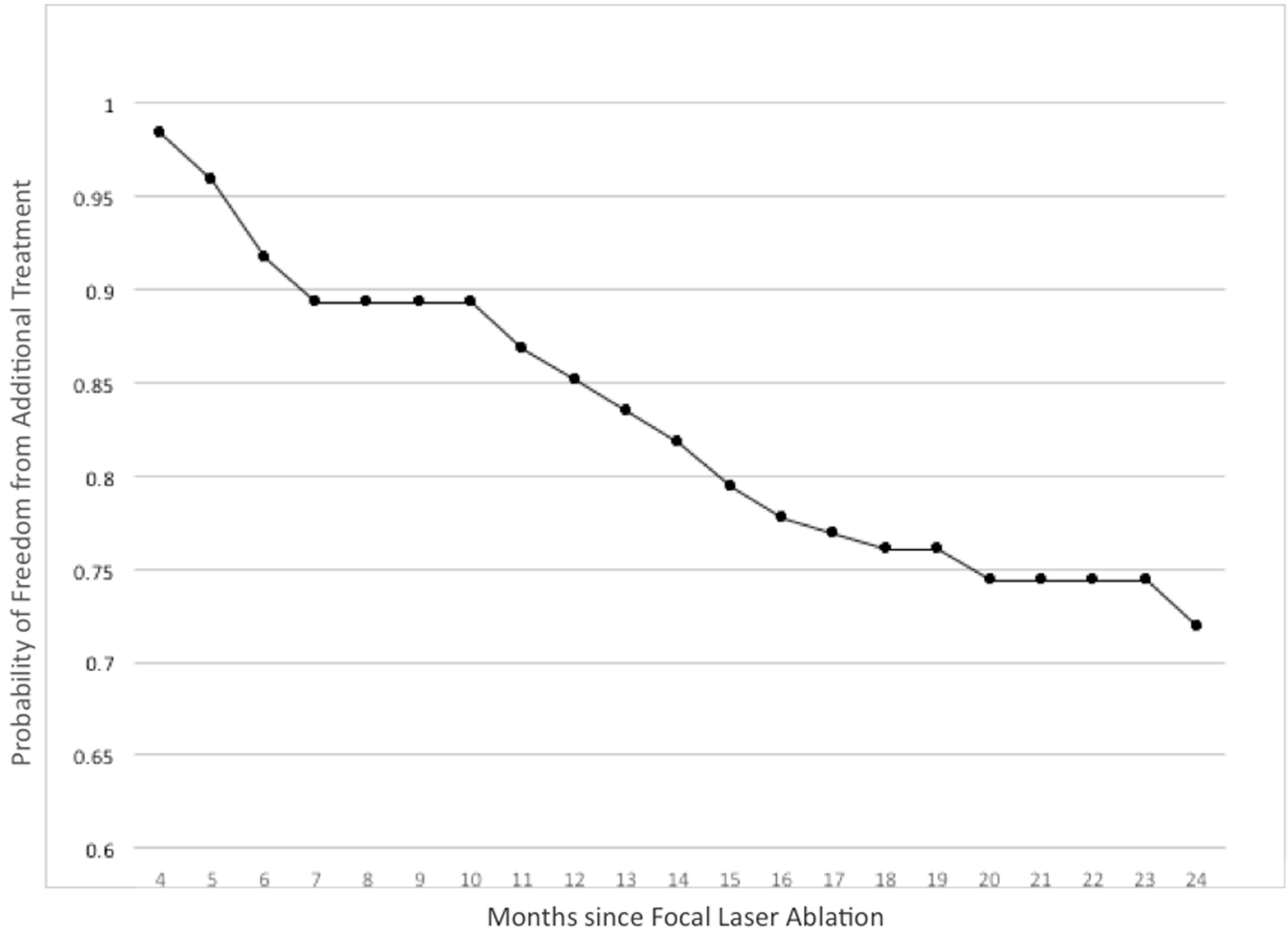

Figure 4.

Freedom from needing secondary treatments up to 24 months from ablation (*log rank* $p<0.001$).

Table 1.

Characteristics of Patients and Tumor Characteristics at Baseline for the 120 Men in the Study Cohort

Patient Demographic or clinical characteristic	Laser Ablation No. (%)
Pretreatment PSA level, ng/mL	17 (14.2%)
< or equal 4	
4–10	88 (73.3%)
>10–20	15 (12.5%)
Median	6.05
IQR	(5.0–8.7)
PSA Density, median	0.18
Gleason score	
6	37 (30.8%)
3+4	56 (46.7%)
4+3	27 (22.5%)
2002 AJCC T category	
T1c	89 (74.2%)
T2a	26 (21.7%)
T2b	5 (4.2%)
Age, years	
< or equal 50	2 (1.7%)
51–60	33 (27.5%)
61–70	65 (54.2%)
>70	20 (16.7%)
Median	64
IQR	59.5–69
Race/ethnicity	
White	111 (92.5%)
Black	8 (6.7%)
Hispanic	1 (0.8%)
Year of Ablation	
2013	12 (10.0%)
2014	52 (43.3%)
2015	39 (32.5%)
2016	17 (14.2%)
Prostate volume (MRI, cc), median	34.0
Max ROI Diameter (MRI, mm), median	12.0
Lesion Location	
Anterior	16 (10.8%)
Central	8 (5.4%)
Transition	16 (10.8%)
Peripheral	108 (73.0%)

Patient Demographic or clinical characteristic	Laser Ablation No. (%)
Number of lesions	
1	72 (60%)
2	47 (39.2%)
3	1 (0.8%)
MRI Grade *	
3	24 (20.0%)
4	80 (66.7%)
5	16 (13.3%)
Max Ca Core Length (mm), median	6

Note: Percentages may not sum to 100% due to rounding.

Abbreviations: AJCC, American Joint Committee on Cancer; T: Tumor; PSA, prostate specific antigen; IQR, interquartile range

* PIRADS v2 classification

Table 2.

Oncologic Outcomes

PSA ng/ml	Baseline	6 mo	12 mo	24 mo
Median (IQR)	6.05 (4.90–8.60)	5.81 (4.40–8.40)	3.25 (1.955.40)	3.91 (2.366.46)
p-value		0.11	<0.001	<0.001
Parameter			**Laser Ablation No. (%)**	
Positive biopsy post FLA (any disease)			22/120 (18.3%)	
Positive biopsy post FLA (clinically significant disease)			18/120 (15%)	
Reablation performed			20/120 (17%)	
Need for other definitive therapy			2/120 (2%)	

Abbreviations: FLA, Focal laser ablation; PSA, prostate specific antigen; IQR, interquartile range