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Two-year Outcomes Following Focal Laser Ablation of Localized Prostate Cancer

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Abstract

Background: There is no consensus regarding how to assess oncological control following focal ablation of prostate cancer.
Objective: To assess quality of life and in-field recurrence following focal laser ablation (FLA).
Design, setting, and participants: Of 34 men participating in a prospective outcomes study following FLA, 32 underwent prostate-specific antigen (PSA) testing and magnetic resonance imaging (MRI) at 6 mo and 2 yr. All underwent assessment of urinary and sexual function at 1 yr.
Intervention: FLA and MRI-targeted biopsy of the ablation zone.
Outcome measurements and statistical analysis: The American Urological Association Symptom Score and the Sexual Health Inventory for Men at baseline and 12 mo were compared using a two-sided Wilcoxon signed-rank test with a significance level of $p = 0.05$. The percentage of positive and negative in-field biopsies was calculated for suspicious and nonsuspicious post-ablation MRI scans.
Results and limitations: FLA was associated with no adverse impact on urinary or sexual function. For men with suspicious MRI (MRI+) findings, in-field disease recurrence of intermediate and low risk disease was detected in 75% and 25% of cases, respectively. For men with nonsuspicious MRI (MRI−) findings, in-field disease recurrence of intermediate- and low-risk disease was detected in 22.4% and 50% of cases, respectively. The change in PSA from baseline did not discriminate cases with MRI− findings with and without cancer at 2 yr.
Conclusions: MRI reliably identifies in-field recurrence of only intermediate-risk prostate cancer at 2 yr after FLA. A biopsy of the ablation zone must be performed for MRI+ findings. The decision to perform an ablation-zone biopsy for men with MRI− scans should be influenced by whether detection of low-risk disease would influence management.
Patient summary: Our study provides compelling evidence that men should undergo interval magnetic resonance imaging to assess the probability of intermediate-risk disease in the ablation zone following focal laser ablation of localized prostate cancer.

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1. Introduction

The ability of magnetic resonance imaging (MRI) to reliably detect significant prostate cancer (PCa) [1] and the availability of energy sources to selectively ablate predefined areas of the prostate has led to increasing interest in focal ablation (FA) for the management of selected cases of PCa despite the fact most PCas are multifocal at the time of radical prostatectomy [2]. Kenigsberg et al [3] recently reported that only 20% of candidates who met predefined criteria for FA and underwent radical prostatectomy were found to have any Gleason pattern 4 outside hypothetical ablation zones. The mean linear length of extrafocal Gleason pattern 4 was also <1 mm, which questions the clinical significance of untreated disease outside the ablation zone.

An international multidisciplinary consensus project concluded that ablation failure must be defined histologically as any tumor detected in the ablation field, but did not offer any recommendation on when and how to perform zone biopsies [4]. There is a paucity of studies reporting oncological control rates following FA beyond 1 yr [5]. The objective of the present study was to report our 1-yr functional outcomes and 2-yr oncological control following focal laser ablation (FLA).

2. Patients and methods

2.1. Patient cohort

Between April 2013 and February 2015, 34 men underwent in-bore FLA of localized PCa. The eligibility criteria were as follows: clinical stage T1c or T2a disease; prostate-specific antigen (PSA) <10 ng/ml; Gleason score <8; and concordance between the MRI lesion and site(s) of biopsy-proven PCa. Gleason 6 PCa outside the planned ablation zone was not an exclusion criterion.

2.2. Ablation protocol

All procedures were performed in a closed 3-T magnet (TRIO Magnetom; Siemens, Erlangen, Germany) under a periprostatic nerve block with the patient in the prone position according to a previously defined treatment protocol [6].

2.3. Follow-up

Our surveillance protocol included digital rectal examination and PSA testing every 6 mo, multiparametric MRI (mpMRI) at 6, 12, and 24 mo, and reflex four-core MRI-guided biopsy of the ablation zone at 6 and 24 mo. We previously published the MRI protocol we follow at our center [7]. PSA velocity (PSAV) was calculated for values obtained between 6 and 24 mo using the Memorial Sloan Kettering Cancer Center PCa nomogram [8]. A for-cause biopsy was occasionally performed at 12 mo because of findings in the 12-mo MRI. A positive MRI post-ablation study was based on observing contrast enhancement within or adjacent to the ablation zone. In biopsies performed using MRI/ultrasound fusion targeting, the pretreatment MRI lesion was marked on the post-ablation MRI during segmentation. Biopsies performed in-bore were targeted at the ablation zone. Four tissue cores were obtained from the segmented ablation zone. A positive biopsy at 6 or 12 mo was carried forward as a positive biopsy at 2 yr. The American Urological Association Symptom Score (AUASS) and the Sexual Health Inventory for Men (SHIM) were self-administered at baseline and at 2 wk, 3 mo, and 1 yr postoperatively.

2.4. Statistical analyses

The AUASS and SHIM score at baseline and 12 mo were compared using a two-sided Wilcoxon signed-rank test with significance set at $p = 0.05$. PSAV was also compared using a Mann-Whitney U test at the same significance level. All descriptive and comparative statistics were calculated using Microsoft Excel, v15.37 (Microsoft, Redmond, WA, USA) with the XLSTAT 2017 add-on (Addinsoft, Paris, France).

3. Results

The baseline characteristics of our study population are summarized in Table 1.

Overall, 93% of men who had not undergone secondary treatments completed the AUASS and SHIM at 1 yr. The differences between baseline and 1-yr AUASS and SHIM scores were not statistically or clinically significant (Table 2).

Oncological control was assessed via interval PSA testing, mpMRI, and MRI-guided biopsy of the ablation zone (Tables 3 and 4). Only two men refused both mpMRI and biopsy and were considered lost to oncological follow-up, although both had stable PSA values. Since our MRI follow-up was robust, we stratified oncological outcomes by positive or negative post-ablation MRI findings according to dynamic contrast enhancement sequences. Eight of the 32 MRI scans (25%) were interpreted to be highly suspicious for cancer before biopsy of the ablation zone (Table 3). MRI-guided biopsy of the ablation zone revealed that all eight

Table 1 – Patient demographics ($n = 34$)

Parameter	Result
Median age, yr (range) [IQR]	69 (52–88) [12.5]
Median pre-ablation PSA, ng/ml (range) [IQR]	5.5 (2.4–9.5) [2.9]
Race, *n* (%)	
Caucasian	30 (88)
African-American	1 (3)
Hispanic	1 (3)
Asian	1 (3)
Median maximal dimension, mm (range) [IQR]	11 (3–21) [7]
Biopsy Gleason score, *n* (%)	
≤6	
≤2 cores	10 (29)
>2 cores	6 (18)
7 (3 + 4)	16 (47)
7 (4 + 3)	2 (6)

IQR = interquartile range; PSA = prostate-specific antigen.

Table 2 – Functional outcomes over 12 mo

	Baseline	1 yr	*p* value
Median AUASS (IQR)	4.5 (3–12)	5 (4–9)	0.674
Median SHIM score (IQR)	22 (20–24)	20 (16–24)	0.153
Median pads per day, *n* (IQR)	0 (0–0)	0 (0–0)	
Incontinence, *n* (%)	0 (0)	0 (0)	

AUASS = American Urological Association Symptom Score; SHIM = Sexual Health Inventory for Men; IQR = interquartile range.

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