Early Oncological and Functional Outcomes following MR guided Focal Laser Ablation (MRgFLA)

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Background and Introduction

Men diagnosed with localized low to intermediate risk prostate cancer and a significant life expectancy are usually offered the choice of two broad therapeutic options, either active treatment with surgery or irradiation with high risk of side effects (i.e., sexual, genitourinary, or bowel dysfunction) [1, 2], or active surveillance, with risk of disease progression and long term clinical, biochemical, and histologic observation leading to psychological pressure, and burden on patient and health care system [3].

Using its localizing strength, MRI has increased opportunities in management of prostate cancer. Additionally, MR thermometry allows real time peri-procedural monitoring to ensure selective and adequate tumor ablation.

Focal therapy (FT) for prostate cancer (PCa) reduces functional complications with promising oncological results. Magnetic resonance image (MRI)-guided Focal Laser Ablation (MRgFLA) potentially maximizes precision [4,5].

In this Phase II study, non water cooled 1064nm diode laser fibres were used for ablation.

Purpose and Aim

This study aims to determine the oncologic and functional outcomes of MRgFLA in low-intermediate-risk localized PC in the single-center series of patients treated with the 1064nm diode laser fibres.

Materials and Methods

Institutional review board approval was granted for prospective recruitment (IRB 15-9002). Interim data from an ongoing trial of 25 patients receiving MRgFLA are reported in patients with MRI visible grade group (GG) 1, 2 or 3, disease (PSA ≤ 20 ng/mL, and ≤ cT2a). All patients undergo a pre-treatment diagnostic MRI, with target lesions confirmed (Artemis, Eigen) and outlined. The laser ablation treatment is performed in the MR suite under deep sedation (IV Propofol).

Treatment is delivered via interstitial cylindrically-diffusing laser fibres (wavelength 1064 nm) inserted through a custom built multi-directional mechatronic needle-tracking device, which allows to approach the tumor along it’s long axis. After confirming catheter in the optimal location, a 1064nm diode laser fiber replaces the obturator within the catheter.

The zone of ablation, as well as surrounding tissue, is monitored simultaneously in real-time and in three dimensions by custom designed MRI thermography. Catheter/fibre number is dependent on target volume. Post-procedural coagulative necrosis volume is determined by contrast-enhanced T1-imaging.

Patients are followed for 2 years with scheduled early (6-months) and intermediate (24-months) oncologic follow-up. At 6 months following treatment, oncologic outcomes are evaluated with multiparametric MRI, PSA and 4-8 targeted biopsies from the ablation site (Artemis, Eigen). All patients undergo a pre-treatment diagnostic MRI, with target lesions confirmed (Artemis, Eigen) and outlined. The laser ablation treatment is performed in the MR suite under deep sedation (IV Propofol).

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Results and Data

At time of reporting, treatment was successfully completed in 21 patients. Intrapatient parameters are shown in Table 1. 14 patients with 15 lesions completed their 6 month follow up. No adverse events were reported. The mean age was 65 years (range 49–77), mean prostate volume 49cc (range 19–175cc) and the mean tumor volume was 1.9cc. PSA at baseline and 6 months were 6.75 ng/mL (range 2-19.4) and 3.78 ng/mL (range 0.45-12.69) respectively (Figure 1). At 6 months there was an 80% (12/15) complete pathologic tumor control rate. There were 3 patients with GG2 disease at the ablation site or margin on biopsy and all 3 patients were retreated with laser FT (repeat biopsy pending). Representative MRI images are shown in Figures 2 and 3.

The IPSS showed +27% increase between mean baseline values and at day 30, while it showed -21% decrease between baseline and at 6-months (Table 3). The sexual function domains (IIEF-5) recorded from -31% at day 30 to -21% difference at 6-month compared to mean baseline values (Table 4).

Table 1. Treatment details

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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<tbody>
<tr>
<td>Number</td>
<td>25</td>
</tr>
<tr>
<td>Day 30</td>
<td>23</td>
</tr>
<tr>
<td>Month 6</td>
<td>17</td>
</tr>
</tbody>
</table>

Table 2 and 3. IPSS, IIEF-5 scores at Baseline, one month and six months post MRgFLA

<table>
<thead>
<tr>
<th>IPSS</th>
<th>Baseline, n=25</th>
<th>Day 30, n=24</th>
<th>Month 6, n=17</th>
<th>IIEF-5</th>
<th>Baseline, n=25</th>
<th>Day 30, n=23</th>
<th>Month 6, n=17</th>
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<tr>
<td>AVG</td>
<td>7.31</td>
<td>9.33</td>
<td>5.82</td>
<td>AVG</td>
<td>20.28</td>
<td>13.91</td>
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<td>Symptoms</td>
<td>Worsening</td>
<td>↑ 27%</td>
<td>Worsening</td>
<td>↓ 31%</td>
<td>Worsening</td>
<td>↓ 21%</td>
<td>Improving</td>
</tr>
<tr>
<td>Improving</td>
<td>↓ 37%</td>
<td></td>
<td>Improving</td>
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<td>Improving</td>
<td>↑ 10%</td>
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</table>

Conclusions

MRgFLA shows encouraging short-term oncologic and functional outcomes for the treatment of low-intermediate-risk prostate cancer. However, the long-term efficacy will be determined in the coming years.

REFERENCES


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**Figure 1.** Mean PSA, ng/mL at baseline and 6 months.

**Figure 2.** Focal MRgFLA therapy of GG2 lesion in left anterior transition zone. T2-WI scan (A) and ADC map (B) show the location and size of the tumor (arrows). Immediate post treatment contrast enhanced image highlights the devascularized ablated area encompassing the site of disease. 6 month biopsy was negative.

**Figure 3.** Focal MRgFLA therapy of 2cm GG3 lesion in left transition zone. T2-WI scan (A) and ADC map (B) show 2cm GG 3 disease in left transition zone. Immediate post treatment contrast enhanced subtraction images (C, axial & D, coronal) show the devascularized ablated area of 21.2cc which required 6 different tracts for ablation.

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