

TRANSRECTALLY DELIVERED, OUTPATIENT MRI-GUIDED LASER FOCAL THERAPY OF PROSTATE CANCER: NINE YEAR INTERIM RESULTS OF NCT #02243033

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INTRODUCTION AND OVERALL GOAL

In the United States alone, new prostate cancer cases for 2018 were estimated at 164,960 and deaths at 29,430 according to the Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov/statfacts/html/prost.html) SEER Stat Database: Cancer Stat Facts: Prostate Cancer Statistics at a Glance, Estimated New Cases in 2018 and Estimated Deaths in 2018. Focal therapies for low risk and intermediate risk localized prostate cancer and salvage treatment are increasingly being explored.

SPECIFIC AIMS

Our objective is to investigate the efficacy of using MR-guided laser focal therapy for MR visible prostate cancer utilizing a transrectal approach in an outpatient setting.

RATIONALE AND BACKGROUND

Lasers have been used for soft tissue necrotization for decades¹. A commercially available MR-guided biopsy system allows insertion of a laser fiber for insertion into biopsy proven cancerous lesions facilitating ablation of MR-visible tumor with real-time thermometry.

METHODS AND MATERIALS

We used a 1.5 Tesla Philips Achieva XR MRI system (Philips Healthcare, Best, The Netherlands) for both image acquisition and real-time thermometry. DynaCAD and DynaLOC (Invivo, Orlando, FL, USA) software were used for image analysis and laser fiber placement into the area of biopsy-confirmed tumor. Laser focal therapy was delivered using a Visualase (Medtronic, Minneapolis, MN, USA) 15W, 980 nm diode laser and cooled Visualase or non-cooled Tranberg (CLS, Farmington MA, USA) laser fiber introduced transrectally using the DynaTRIM (Invivo, Orlando, FL, USA). MR imaging was used to monitor energy deposition, irreversible damage estimates and coagulation necrosis.

RESULTS

Under IRB-approved, HIPAA-compliant protocol, 146 men were treated. 228 cancer foci were treated. Total procedure time was between 1.5 and four hours. No serious adverse events or morbidity were reported. Of the 6 mo. post-procedure biopsies, 20% were positive for csPCa in-field, consistent with residual or recurrent cancer. 3% of biopsies positive for csPCa performed at 6 mos. post therapy were out-of-field. We observed a 37% decrease in mean PSA at 12 months post therapy and no statistically significant change in International Prostate Symptom Score (IPSS) and Sexual Health Inventory for Men (SHIM) scores.

DISCUSSION AND CONCLUSION

Our data indicate that outpatient, transrectally delivered MRI-guided laser focal therapy for prostate cancer is both safe and feasible. In the current climate of cost-reduction and emphasis on minimally-invasive treatment of cancer, focal treatment of prostate cancer may be an attractive option. The precision and controllability achieved under MRI-guidance may have favorable results for cost effectiveness and quality of life without eliminating the possibility of whole-gland treatment in the patient's future. We will continue to follow these men for twenty years as part of an IRB-approved clinical trial (NCT# 02243033)².

REFERENCES

1. Miller JC. Brief history of laser ablation. AIP Conference Proceedings 288, 619 (1993); doi: <http://dx.doi.org/10.1063/1.44865>.
2. Phase II Laser Focal Therapy of Prostate Cancer (LITT or FLA). <https://clinicaltrials.gov/ct2/show/NCT02243033?term=02243033&rank=1>, accessed 5/29/2019.