

ORAL PRESENTATION

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MRI-guided transurethral ultrasound prostate ablation: midterm outcomes of a phase I clinical trial

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From Current and Future Applications of Focused Ultrasound 2014. 4th International Symposium Washington, D.C, USA. 12-16 October 2014

Background/introduction

MRI-guided transurethral ultrasound ablation (TULSA) is a new minimally-invasive modality for the treatment of prostate cancer, which aims to provide local disease control with low morbidity. A transurethral ultrasound device generates a continuous volume of thermal coagulation that is shaped precisely to the prostate using real-time MR thermometry and active temperature feedback control. The aim of this multi-center, prospective Phase I clinical study is to determine the safety and feasibility of MRI-guided TULSA, and to assess initial efficacy for treatment of localized prostate cancer.

Methods

A total of 30 patients were enrolled with biopsy-proven, low-risk, localized prostate cancer: age ≥ 65 years, clinical stage T1c/T2a, PSA ≤ 10 ng/ml, Gleason Score $\leq 3+3$ (3+4 max in Canada only). Treatment was completed under general anesthesia and drainage from a suprapubic catheter (SPC) which remains for 2 weeks. Treatment planning was performed under MRI prostate visualization, with therapeutic intent of whole-gland ablation. Treatment was delivered under continuous MR thermometry active feedback control. Primary endpoints are safety and feasibility, with follow-up to 12 months. Complete clinical monitoring is 5 years, including serial PSA, completion of quality-of-life-questionnaires and prostate biopsy at 12 months.

Results and conclusions

Median (range) prostate volume and treatment time were 47 (21-95) cc and 36 (24-61) min, respectively (n=30). MR

thermometry measurements depict a continuous region of heating with a high degree of spatial control of the ablation volume, to within 0.1 ± 1.3 mm (n=30). Median PSA reduced by 90% (60 – 99%) to 0.7 ng/ml at 1 month (n=28), remaining stable to 0.6 ng/ml at 6 months (n=20). MRI-guided TULSA was well-tolerated by all patients, with no intraoperative complications, and no reported cases of urinary incontinence, fistula or rectal injury. All complications to-date were CTCAE v4 Grade 1-3 and included: hematuria (15), urinary tract infection (10), epididymitis (1), and acute urinary retention (4) requiring prolonged or re-catheterization. Normal micturition returned after SPC removal, with return to baseline by 3 months (n=26) and improvement by 6 months (n=21): IPSS median score 9 (baseline) to 6 (6 months), and peak urinary flow 14 ml/s (baseline) to 19 ml/s (6 months). MRI-guidance enables accurate planning and real-time dosimetry and control of the thermal ablation volume. Midterm results indicate that MRI-guided TULSA is safe and clinically feasible with a well-tolerated, low side effect profile.

Acknowledgements (Funding)

This study is supported by Profound Medical Inc.

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Published: 30 June 2015

doi:10.1186/2050-5736-3-S1-O60

Cite this article as: Burtnyk et al.: MRI-guided transurethral ultrasound prostate ablation: midterm outcomes of a phase I clinical trial. *Journal of Therapeutic Ultrasound* 2015 **3**(Suppl 1):O60.

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