Magnetic Resonance Imaging (MRI) – Guided transurethral ultrasound ablation of prostate cancer: Midterm outcomes of a phase I clinical trial

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Introduction: MRI-guided transurethral ultrasound ablation (TULSA) is a new minimally-invasive modality to ablate prostate tissue using real-time MRI temperature feedback control. The aim of this multi-center 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 (PCa).

Methods: Patients with low-risk PCa were enrolled: cT1c-T2a, N0, M0; PSA≤10ng/ml; GS≤6 (USA/Europe) and ≤7a (Canada). The treatment was completed under general anesthesia and suprapubic drainage. Treatment planning (whole-gland ablation) and delivery (MR thermometry feedback) were performed under MRI visualization. Primary endpoints are safety and feasibility, with follow-up to 12 months. Complete clinical monitoring is 5 years, including serial PSA, TRUS biopsy at 1 and 3 years, and QoL questionnaires.

Results: A total of 30 patients have been enrolled from March 2013 to March 2014 and have been treated with no intraoperative complications. Average treatment time was 36 (24-61) min for prostate volumes of 47 (21-95) cc. Clavien II complications included urinary tract infections (10) and epididymitis (1), resolved with antibiotics. Clavien I complications included hematuria (15), and acute urinary retention after SPC removal (4) resolving after SPC re-insertion. Median PSA was reduced by 90% (60 – 99%) to 0.7 ng/ml at 1 month (n=29) and remained stable to 0.6 ng/ml at 6 months (n=21). Normal micturition returned after SPC removal, with return to baseline by 3 months (n=26) and improvement by 6 months (n=20): IPSS mean score 9.0 (baseline) to 6.9 at 6 months, and peak urinary flow 14ml/s (baseline) to 19ml/s at 6 months.

Conclusion: MRI-guidance enables accurate planning and real-time dosimetry and control of the thermal ablation volume. Initial results indicate that MRI-guided TULSA is safe and clinically feasible with a well-tolerated, low side effect profile.

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