

Preliminary results of a phase I trial using magnetic resonance-guided focused ultrasound surgery (MRgFUS) for the treatment of patients with locally-confined low-risk prostate cancer

A. Nosov, C. Cheng, S. Kanaev, G. Gafton, V. Turkevich, A. Vorobiev
Petrov Research Institute of Oncology, St. Petersburg, Russia
National Cancer Center, Singapore General Hospital, Singapore

Introduction: The ExAblate MRgFUS system combines endorectal delivery of focused ultrasound energy with a standard GE MRI Scanner, providing anatomical guidance and real-time thermal feedback.

We present 6-month follow-up results of phase I trials conducted in 2 centers (Russia and Singapore) under local IRB approvals. Studies' aim: ExAblate feasibility and safety assessment for focal treatments of low risk prostate cancer.

Materials and Methods: Patients with low risk prostate cancer based on transperineal extended mapping biopsies were recruited and focally treated.

Follow-up included adverse events assessment; genitourinary-symptom related quality of life (measured by validated self-reported questionnaires); PSA levels; and 6-month repeated biopsies.

Results: 21 focal treatments of various extents were performed. Mean patients age; 64.4 years (49-88); mean prostate volume: 37ml (22-95); mean percentage of ablated prostate volume: 28% (9.0-78.9%);

Foley catheter was used for bladder drainage in 16 treatments; after 14 (87.5%), catheter was extracted within <24 hours. One patient was prophylactically left with catheter for a week; and another had acute urinary retention and had the Foley for 29 days.

Suprapubic catheter was used in 5 treatments that targeted the urethra. SPC's were extracted 3 days to 3 weeks after treatment.

All patients remained pad-free, leak-free continent.

One patient developed urethral stricture and bladder neck obstruction after urethral targeting.

2 epididymo-orchitis events occurred.

Out of 12 patients with baseline potency, 2 (16.7%) patients, (aged 69 and 73 years) reported 6-month erectile impairment; in both tumor locations excluded NVB sparing.

Biopsies after 15 treatments revealed no cancer in treated volumes; 6 (28.6%) had newly detected cancer foci.

PSA levels poorly reflect efficacy of focal treatments for low risk cancer: percentage of ablated prostate tissue affected PSA follow-up levels more than cancer control.

Conclusions: Focal ExAblate treatment has a promising safety profile however improved cancer localization is crucial for tumor control.

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