Final report for "Accelerated Focused Ultrasound Ablation of Uterine Fibroids with MR guided Vascular Targeting—a Pilot Study

Background

Magnetic resonance-guided focused ultrasound surgery (MRgFUS) is a FDA approved noninvasive treatment option for symptomatic uterine fibroids. While the technology has been demonstrated to be safe and effective, the procedure takes several hours to cause coagulative necrosis of the uterine fibroids. At times, the procedure can last 3-5 hours, while the patient lies in the prone position, under moderate sedation. Because of the lengthy nature of the MRgFUS procedure, methods to decrease treatment time can be extremely useful in the clinical setting

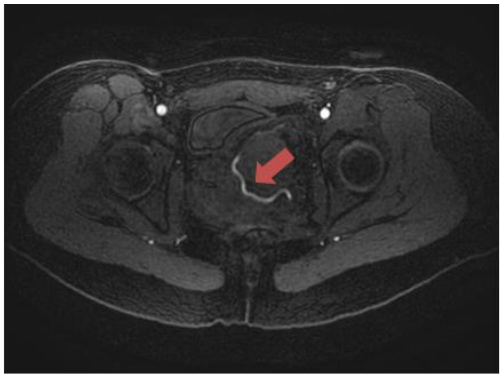
One method to potentially decrease treatment time is targeted vascular ablation. The purpose of our clinical trial was to evaluate if targeting the vascular pedicles of the fibroid would result in the treatment of the entire fibroid volume, thereby reducing procedural time.

Patient recruitment

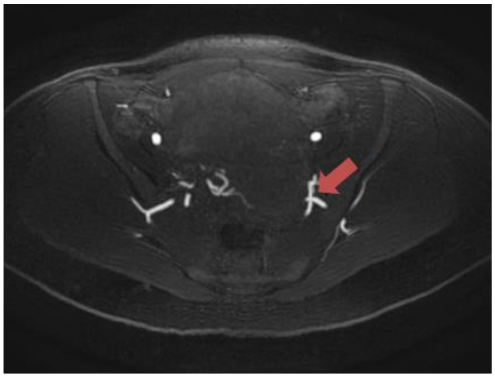
We had intended to recruit 6 patients who met criteria to undergo treatment with MRgFUS. We were able to recruit only 4 patients for the study. The biggest challenges to recruitment were identifying patients with the appropriate fibroid characteristics which would be amenable to treatment and patients who were willing to undergo repeated imaging prior to treatment.

Pre-procedure imaging

Prior to the procedure, each patient was seen and examined by the treating physician and consented for the procedure and the treatment. Prior to the procedure, the patients underwent an MRI of the pelvis with Ablavar (FDA approved blood pool MR imaging agent). Ablavar was used to obtain high resolution arterial and blood pool phase images of the fibroid vasculature. Based on pre-procedural imaging, regions of fibroid with inflow vascular pedicles were identified to target on the procedural day.



T1-weighted post contrast with fat saturation sequence following the administration of Ablavar. Note the left uterine artery coursing through the fibroid (red arrow).



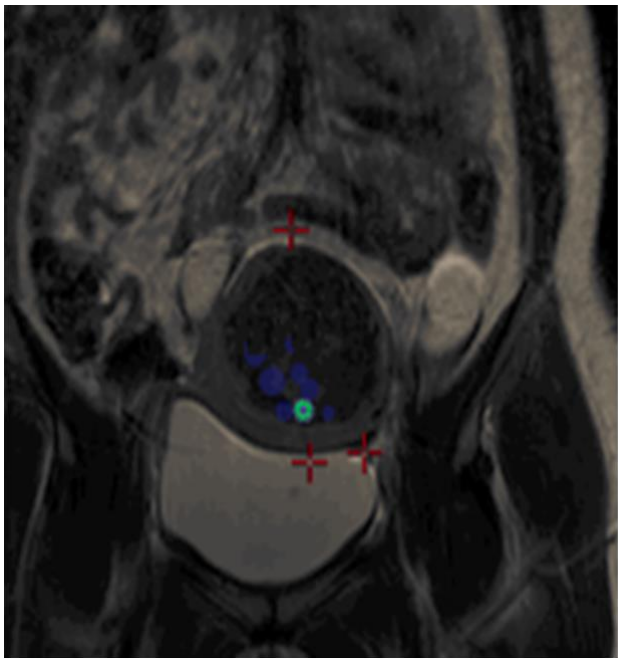
T1-weighted post contrast with fat saturation sequence following the administration of Ablavar. Note the branches of the right uterine artery coursing through the fibroid (red arrow).

MRgFUS procedure

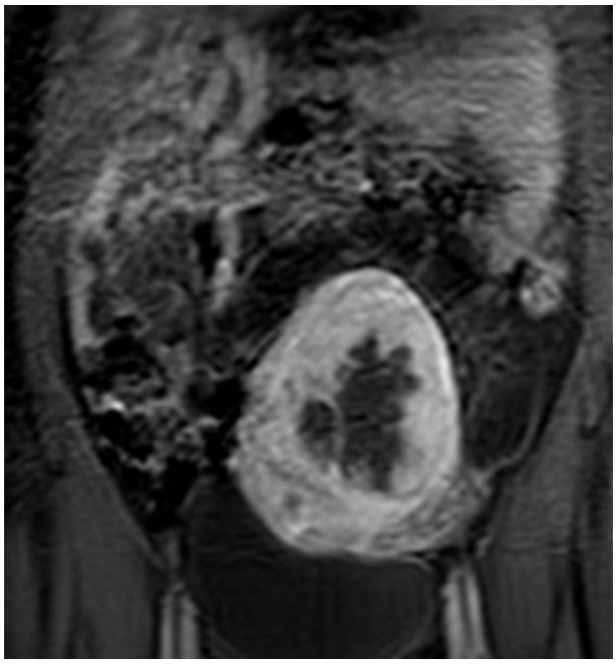
On the treatment day, following the standard patient preparation, the sonications were targeted to the fibroid region identified as containing the uterine vessels. Post treatment T1-weighted contrast-enhanced magnetic resonance images were obtained to calculate the non-perfused volume (NPV).

Patient follow-up

Four patients were treated with the vascular targeted ablation protocol during MRgFUS. The procedural time for all patients was 1 hour. All patients had greater than expected fibroid devascularization, with NPV to total fibroid volume ratios of 73%, 68%, 65%, and 55%. Three months following the procedure, fibroid-related symptoms had reduced and quality of life had improved in all patients.



Coronal T2 image from vascular targeting treatment. Notice blue regions representing treated regions of the fibroid.



Coronal T1-weighted post-contrast image with fat saturating demonstarting greater than expected nonperfused volume.

Three of the four patients opted for repeat MRgFUS to completely ablate the remaining fibroid tissues. The remaining one patient underwent a myomectomy 1-year following MRgFUS for persistent symptoms.

Conclusion:

We are very grateful to the Focused Ultrasound Foundation for the support that enabled this pilot study. This study demonstrates that vascular targeting during MRgFUS may result in shorter procedural time and greater-than expected fibroid devascularization ultimately resulting in symptom improvement. Further research is necessary to evaluate for the appropriate amount of devascularization necessary to result in extremely high NPVs and alleviating symptoms, preventing the need for additional treatments.

Sincerely,

Maureen P. Kohi, MD

Principal Investigator