Predictors of Success in MRI-Guided Focused Ultrasound Therapy of Uterine Leiomyomas

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Introduction: Focused ultrasound is a non-invasive thermoablative technique, which has been in use since 1942 (Lynn et al). However its acceptance has been limited in the past, due to lack of target definition and difficulty in obtaining feedback about thermal dosimetry. MR-guided Focused Ultrasound Surgery (MRg-FUS) overcomes these limitations, and is an FDA-approved treatment to reduce symptoms of uterine fibroids. The short-term (3 and 6 month) decrease of fibroid volume and symptom after MRg-FUS have already been demostrated (Hindley et al, 2004). The aim of the present study was to determine the predictors of success of MRg-FUS on volume reduction and symptom relief at 12 months post-treatment.

Methods: This is a single center retrospective analysis of MRg-FUS in 71 fibroids (66 patients) with symptomatic leiomyomas. Therapeutical thermal ablation sonications were delivered with an MRg-FUS system (ExAblate 2000, InSightec, Haifa, Israel). Real-time temperature-sensitive MR-imaging was performed for sonication localization and direct temperature monitoring. MR images were obtained using a 1.5 T magnet (GE Medical System). Using 3D software (3D Slicer, Brigham & Women's Hospital, Boston, USA), fibroid non-enhancing volume (NEV) and total volume (TV) were calculated prior to, immediately post, and 12 months post MRg-FUS. Uterine fibroid signal intensity (SI) on pre-treatment non-enhanced T2-weighted images were categorized as hyperintense or hypointense compared to skeletal muscle. The total score of patient-reported Symptom Severity Score (SSS) of the Uterine Fibroid Symptoms and Quality of Life Questionnaire was also obtained prior to and 12 months post treatment. Treatment sonications were defined as sonications within 10% of peak power. Temperature of sonication was the average of 3x3 voxel ROI around the hottest value. Data were analyzed statistically by one-way repeated measure of Anova and two-way Anova with post hoc Tukey test, and by simple linear regression. Data were expressed as Mean±1SEM.

Results: Mean TV before MRg-FUS was 255.5±23.9 mm^3. NEV after MRg-FUS was 43.0±6.4 mm^3, which represents 16.3±1.6 % of TV ($NEV_{MRg\text{-}FUS}$). 12 months post MRg-FUS both TV and SSS was reduced by 9.3±2.9 % and 37.4±3.6 %, respectively, compared to pre-treatment data ($p<0.001$). We found that both SI and $NEV_{MRg\text{-}FUS}$ had an independent effect on 12-month volume reduction ($p=0.028$ and $p=0.033$, respectively). 95.6 % of fibroids with $NEV_{MRg\text{-}FUS}>20\%$ decreased in size 12 months after sonication, while this value was only 62.5 % in those with $NEV_{MRg\text{-}FUS}<20\%$. In fibroids with $NEV_{MRg\text{-}FUS}<20\%$, low T2W signal fibroids showed 13.2% volume reduction, while high T2W signal fibroids remained unchanged. However, in fibroids with $NEV_{MRg\text{-}FUS}>20\%$ both high and low signal fibroids demonstrated a decrease in volume. Patients with greater $NEV_{MRg\text{-}FUS}$ had greater reduction in SSS ($p=0.020$), however, SI had no effect on SSS reduction. Number and power of sonication, treatment temperature and initial fibroid volume had no effect on either TV, or SSS reduction in the present study.

Conclusion: MRg-FUS of uterine leiomyomas results in moderate volume and considerable symptom score reduction at one-year post-treatment, however, the extent of change in both volume and symptom score varies hugely among the patients. Fibroid signal intensity on T2 weighted images and nonperfused volume immediately post treatment are predictors of success of MRg-FUS therapy: 1) volume reduction is greater in low T2W signal fibroids compared to high signal ones at 12-month follow-up; 2) a nonperfused area of at least 20% after MRg-FUS appears to be necessary to reliably achieve fibroid shrinkage one year post MRg-FUS. These findings may serve as guidelines for patient selection and for predicting outcomes for MRg-FUS treatment of uterine fibroids.