Volumetric MR-guided high-intensity focused ultrasound with direct skin cooling for the treatment of symptomatic uterine fibroids: proof of concept study

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Background/introduction
To prospectively assess the safety and technical feasibility of volumetric magnetic resonance-guided high-intensity focused ultrasound (MR-HIFU) ablation with direct skin cooling (DISC) during treatment of uterine fibroids.

Methods
In this proof-of-concept study, eight patients were selected for clinical MR-HIFU ablation of uterine fibroids with use of an additional DISC device to maintain a constant temperature (T=20°C) at the interface between the HIFU table-top and the patients' skin (Figure 1). Technical feasibility was determined by verification of successful completion of MR-HIFU ablation. Contrast-enhanced T1-weighted MRI was used to measure the treatment effect (non-perfused volume (NPV) ratio). Safety was evaluated by recording of adverse events (AEs) and their relation to the investigational DISC device within 30 days' follow-up.

Figure 1
Results and conclusions

Results: All MR-HIFU treatments were successfully completed in an outpatient setting. The median NPV-ratio was 0.56 (IQR[0.27-0.72]). Immediately after treatment, two patients experienced coldness related discomfort which resolved the same day. No serious AEs were reported within 30-days' follow-up. No skin burns, cold injuries or subcutaneous edema were observed in patients treated with the DISC device. Conclusion: This study showed that it is technically feasible and safe to complete a volumetric MR-HIFU ablation with DISC. This technique may further reduce the risk of thermal injury to the abdominal wall during MR-HIFU ablation of uterine fibroids.

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