Preliminary clinical results: MR-HIFU Ablation of uterine fibroids with automatic volumetric ablation

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Introduction

High Intensity Focused Ultrasound (HIFU) allows non invasive treatment of uterine fibroids without anaesthesia and a fast return to normal activity [1]. For this thermo-therapy procedure, MR guidance provides anatomical images to plan treatment of the fibroid, thermal maps to quantify the HIFU heating and contrast enhanced images to measure the induced nonperfused volume. This routine clinical procedure has been optimized using an automatic temperature control combined with volumetric sonication to enlarge the ablated area. This study shows improvement of treatment safety and efficiency based on preliminary clinical trials results.

Materials and Methods

In accordance to Good Clinical Practice, 13 patients with symptomatic uterine fibroids were treated with the Philips MR-HIFU platform at St André hospital located at Bordeaux in France. The Philips MR-HIFU platform includes a phased array transducer composed of 256 channels, which allows very fast electronic displacement of the focal point. The transducer was also connected to a mechanical system that allows a large range of displacements. This HIFU system was integrated into the bed of a 1.5T Philips MRI scanner in order to acquire T2 weight anatomical images, thermal maps based on the PRF effect and T1 weighted contrast enhanced images after Dotarem injection. Several volumetric ablations were performed to cover the large fibroid volume. Each volumetric ablation was induced by steering the focal point along outwards moving concentric circles with diameters ranging from 4 to 16mm [2]. Thermal maps and thermal dose maps acquired during sonication were computed, recorded and displayed online to visually check the extent of the heating. The duration of sonication was automatically controlled as a function of the temperature or the thermal dose. The controller interrupted the sonication when thermal dose reached the threshold of 240EM over the target area or when the average temperature reached 54 to 57°C at the outer concentric circle. The exact temperature threshold was dependent on the desired thermal dose size and based on simulations to optimize total acoustic energy [3].

Results and Discussion

132 sonications were performed using similar acoustic power levels of 128±33 Watt acoustic. Figure 1 presents thermal maps measured at the end of the sonication and thermal dose maps obtained after the cooling period. The size of the ablated ellipsoid induced is characterized by a length along the beam proportional to the perpendicular diameter with a ratio close to 2. The temperature reaches 55°C in this targeted ellipsoid and decreases rapidly towards the outer border yielding a sharp ablation edge. The accuracy of the temperature control at the outer concentric circle ranges from 2.1°C to 0.6°C for the 4mm and 16mm sonication diameters, respectively. As a consequence, the ablated sonication diameter is reproducible with an accuracy of 1mm.

The larger sonication of 16mm diameter produced an ablated volume more than 100 times larger than the ablated volume produced by a sonication of 4mm diameter. Even if a larger sonication required longer sonication, 16mm diameter sonications are 35 times more efficient than the smaller sonications of 4mm diameter. As presented in figure 2, the ablation efficiency increases significantly as a function of the sonication diameter. Similarly the ablation speed without taking into account the cooling period is also increased from 0.16 ml/min to 12.3ml/min as a function of volumetric sonication size.

Contrast enhanced images acquired following the final sonication indicate a good correlation between the induced non-perfused volume and 240EM thermal dose volume. There were no serious adverse events or skin burns in this set of 13 patients treated. All patients left the hospital at the day of the treatment and they returned to normal activity after 2.4 days on average. After one month of follow up, the average symptom severity score decreased by 28.8%.

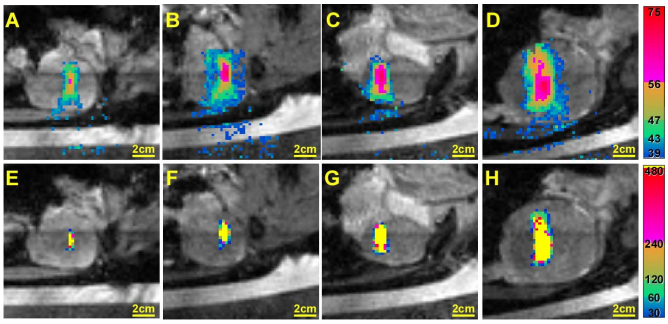

Figure 1: Thermal maps (A,B,C,D) and thermal dose maps (E,F,G,H) induced by volumetric sonications of 4mm (A,E), 8mm (B,F), 12mm (C,G) and 16mm (D,H) in diameter.

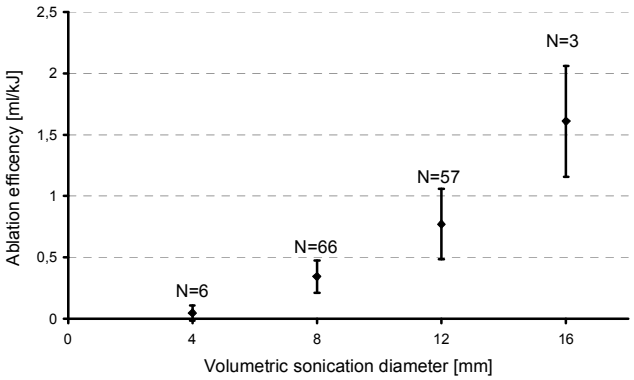

Figure 2: Thermal dose ablated volume (240EM threshold) per unit of emitted energy as a function of the diameter of the volumetric sonication.

Conclusions

The volumetric sonication method offers a large choice of ablated volumes, which significantly improves the ablation speed and efficiency. In addition, the automated temperature control improved treatment safety and ensured a reproducible ablation size which is very convenient for clinical use.

References

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