Sonalleve MR-HIFU therapy provides fast uterine fibroid ablation

At Samsung Medical Center, volumetric ablation proves fast and comfortable treatment

Dr. Young-sun Kim, Samsung Medical Center at the Sungkyunkwan University School of Medicine (SMC, Seoul, Korea)
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Samsung Medical Center (SMC) is one of the largest medical referral centers in Korea with 2,000 beds and about 8,500 outpatients a day. The radiology department is using Sonalleve MR-HIFU (MR-guided High Intensity Focused Ultrasound) to treat women with uterine fibroids.

Young-sun Kim, M.D., is a Radiologist and Associate Professor at the Department of Radiology and Center for Imaging Science, Samsung Medical Center, Sungkyunwan University School of Medicine, Seoul, Korea. His clinical specialty is Radiology with a focus on nonvascular interventional radiology, abdominal imaging and MR-HIFU.

Young-sun Kim, MD, is radiologist at Samsung Medical Center at the Sungkyunkwan University School of Medicine (SMC, Seoul, Korea). Through their gynecology department patients are referred to Dr. Kim for uterine fibroid treatment using MR-HIFU. “After an initial MR exam, I can decide whether a patient is a good candidate for MR-HIFU ablation with Sonalleve,” says Dr. Kim. “Patients with large intra-cavitary fibroids of 4-5 cm in diameter generally benefit the most from MR-HIFU. A small lesion can quite easily be treated by endometrial curettage. But when it is large, it takes a very long time and it can be risky, so gynecologists are often reluctant to do that.”

“Sonalleve is superior to conventional sonication methods in terms of treatment speed2. In contrast to ablation platforms using a conventional point-by-point sonication method, Sonalleve adopts a volumetric ablation technique in which the HIFU focus rotates along a trajectory of multiple concentric circles. This improves the energy efficiency and increases the treatment speed. This, in turn, expands its indication to larger fibroids. This is significant from a clinical viewpoint, although further improvement will be needed to make Sonalleve MR-HIFU a more favorable alternative to other therapeutic options.”

MR-HIFU therapy is patient-friendly, safe and effective

“The therapy procedure starts with an MR exam. After that, the patient is prepared for treatment and the QA procedure for the system is done. Patient positioning takes 10-20 minutes, and a pre-treatment MRI scan takes another 10-20 minutes. If necessary, manipulation of the bladder and/or rectum is performed1. When the patient is then ready for therapy, high intensity ultrasound waves are focused onto the target volume.

This causes localized heating and coagulation necrosis of the tissue, thus ablating the lesion without affecting nearby tissue. The process is monitored with real-time temperature sensitive MRI.”

“Sonalleve adopts a volumetric ablation technique.”
MR-HIFU ablation of 12.3 cm uterine fibroid

A 40-year-old female with complaints of urinary frequency for over a year and a growing palpable mass underwent MRI. The exam demonstrates a single large fibroid (subserosal type, 12.3 cm, type I) compressing the urinary bladder.

MR-HIFU Therapy was performed with 49 treatment cells: 1 x 8 mm, 26 x 12 mm, 22 x 16 mm. The MR room time was 3.25 hours, of which 2.42 hours was procedure time (39.5 min. sonication time). After MR-HIFU therapy the non-perfused volume (NPV) was 88.5% of the total fibroid volume; treatment speed was 179 mL/hr.

After 3 months follow-up ultrasonography was done instead of MRI due to pregnancy. The fibroid volume decreased to 42.8% of the baseline. Nocturia disappeared, no palpable mass. Successful full-term delivery via C-section.

This case shows that volumetric MR-HIFU therapy can be used to treat a huge fibroid larger than 10 cm in diameter. Also, a desire for future pregnancy does not need to be a contraindication of MR-HIFU uterine fibroid therapy. Sometimes, treatment may be beneficial.

“The Sonalleve system is capable of treating large fibroids.”
User experiences

Sonalleve is superior to conventional sonication method in terms of treatment speed.

3 Month Follow-up

MR-HIFU uterine fibroid treatment after bowel loop displacement

A 37-year-old woman had complaints of urinary frequency and a palpable mass that is growing. Initial MRI shows a single large fibroid (11.6 cm). There's no scar or interposed small bowel in planning MRI. With DCE-MR, a Ktrans of 0.0149 is found, indicative of intermediate vascularity.

On the treatment day, MRI shows a new bowel interposition (arrows). Displacement of the small bowel was achieved by a combination of urinary bladder filling (with saline), followed by rectal filling (with US gel) and urinary bladder emptying. This method is found successful in many cases with anteverted/anteverted uterus. Volumetric MR-HIFU ablation was done with one-layer strategy. Treatment time was 2.51 hours. After therapy, the NPV was 88%. After 3 months the volume reduction was 42.5% of baseline. SSS went from 24 to 11.

This case shows that interposed small bowel loops between abdominal wall and fibroid tumor could be manipulated by urinary bladder and rectal filling and/or emptying. One-layer strategy was effective in this fibroid that was not very hypervascular.
“Treatment typically takes three to four hours,” says Dr. Kim. “I fully monitor the therapy console, and intermittently see the patient. If necessary, I order an additional analgesic control. Immediately after the treatment, we perform contrast-enhanced MRI scans. Finally, the patient is observed for one hour in the recovery room and then discharged with a prescription of analgesic medication.”

**Patient feedback an important part of the learning curve**

Dr. Kim joined the first clinical trial of the Sonalleve system from August 2009 to February 2010, and has been using Sonalleve clinically since December 2010. He cites his relationship with the gynecologists as a challenging but important part of the success of the program.

“Initially, they were skeptical of the therapeutic effect of HIFU ablation therapy. I realized early on that the therapeutic effect and the safety made this method a very suitable clinical option for treating uterine fibroids, particularly because my patients gave good feedback as well. But it took a little longer before the gynecologists had confidence in this therapy. Now, the number of referrals has been increasing. Essentially, the doctors learned from the patients.”

SMC patients and physicians alike agree that non-invasiveness is a big advantage of MR-HIFU therapy. “There is no need for any skin incision, bleeding, anesthesia, long recovery time or admission,” says Dr. Kim. “This is of huge importance to many patients. As compared with uterine fibroid embolization, the lack of exposure to radiation and post-procedural pain is another big advantage. And, of course, it is good for gynecologists to have one more option to fight fibroids.”

**Future is bright for expansion of MR-HIFU**

Going forward, Dr. Kim believes that MR-HIFU will be applied to more than just uterine fibroid ablation. “The volumetric sonication method is very advantageous in achieving mild hyperthermia in specific areas in the body, and it is superior to non-volumetric HIFU sonication methods. I personally think that in the future MR-HIFU therapy may play its main role in oncologic intervention.”

Recently, SMC received approval to use MR-HIFU as an IND (investigational new device) for the treatment of painful bone metastasis to palliate bone pain. Dr. Kim and his colleagues are ready to initiate a clinical trial for treating such patients.

For centers that are considering the implementation of MR-HIFU, Dr. Kim advises, “MR-HIFU therapy does have a learning curve – do not give up. Note that good patient selection is key to successful MR-HIFU ablation of uterine fibroids. It’s important to focus on the literature regarding patient selection when starting this therapy.”

To learn more about Sonalleve MR-HIFU visit www.philips.com/sonalleve

Click [here](http://www.philips.com/sonalleve) to view video interview with Dr Kim on GetInsideHealth

Click [here](http://www.philips.com/sonalleve) to view contributions by Dr Kim on NetForum

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**References**

