

Focused ultrasound surgery in gynecology – a call to validate a new surgical approach

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Abstract

Ultrasound-guided HIFU (USgHIFU) ablation is now a new non-invasive surgical procedure that developed rapidly in China, with vast clinical experience accumulating in treating uterine fibroids, adenomyosis, and other gynecological diseases with great success. However, there were limited collaborative and randomized studies, except those from China. Then the success rate of this new surgery requires more validations. Therefore, to advance this new surgical approach, the paper calls for collaborative validation from reports of large randomized, multi-center studies on treating uterine fibroids, adenomyosis, and other gynecological diseases.

Keywords: FUS; HIFU; USgHIFU; uterine fibroids; adenomyosis; validation

It is uncommon for an entirely new surgical approach to become a routine gynecological practice. Focused ultrasound surgery (FUS) or high intensity focused ultrasound (HIFU) ablation for treating uterine fibroids and adenomyosis may now be considered such a development.

HIFU ablation for treating uterine fibroids and adenomyosis in women is increasingly popular in China and some Asian countries ^[1]. At present, approximately one million hysterectomies are performed in China each year ^[2]. More hysterectomies are done because of uterine fibroids and adenomyosis than any other uterine disease. When medical treatment fails to relieve their heavy bleeding and pain, women with uterine fibroids and adenomyosis are directed to surgical treatment. Despite the recent advances of minimally invasive therapy, this still implies an invasive procedure that may associate with significant physical and emotional complications. Bleeding, infection wound complications or

postoperative pain is often unwelcomed by all patients and surgeons. The surgical risks are well known, especially when hysterectomy was involved ^[3-5]. Medico-legal issues are not uncommonly distressing to all after any serious complication arising from a hysterectomy ^[6, 7]. The social and economic costs are also considered because of in-hospital expenditures and a longer recovery time after a hysterectomy ^[8, 9].

HIFU ablation treatment uses the concept of focusing high ultrasound energy on a target point at a solid tumor inside the body; the energy can generate heat up to 90 degrees without a cut wound ^[10]. Therefore, unlike the traditional surgery, wounds are made, with bleeding occurring and possible complications arising. The complications of the HIFU ablation procedure are mild, and the surrounding tissues and organs will often not be seriously damaged or injured if properly performed by well-trained, experienced doctors. Yet, at present, the minimally invasive surgery has a high success rate to remove uterine fibroids or a diseased uterus, many doctors don't believe any new surgical approach may achieve such a high success rate to the patients' satisfaction, and a new approach, other than minimally invasive surgery is likely to happen or need to change their surgical approach.

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However, ultrasound-guided HIFU (USgHIFU) ablation is now a new non-invasive surgical procedure that developed rapidly in China, with vast clinical experience accumulating in treating uterine fibroids^[11, 12], adenomyosis^[13, 14], and other gynecological diseases with great success^[15-18]. Such a non-invasive surgical procedure has reported a high success rate and has interested gynecologists searching for alternative treatment for their patients with uterine fibroids and adenomyosis. Many doctors went to China for training^[19] and established centers on their return home^[20], providing HIFU ablation service to their patients. On the other hand, MRI-guided HIFU ablation has also been increasingly used to treat uterine fibroids in Western countries. Yet, it is comparatively more complex to operate and less effective than the USgHIFU^[10]. Also, the treatment of adenomyosis with MRI-guided HIFU in western countries is still at its experimental stage.

For those centers in Asia Pacific countries where USgHIFU ablation has been established, this non-invasive HIFU treatment increases popularity among doctors and patients. However, the following issues arose when only a few collaborative studies were reported in China^[11, 12]. The success rate of this new surgery was said to be overstated and not applicable to western countries. Higher complication rates like skin burn, vaginal bleeding and pain were also reported in some studies^[21, 22]; however, these are mild and more commonly encountered with the traditional surgical treatment of fibroids^[11, 12, 23]. So far, only a few major complications or adverse events have been reported in the literature^[12, 23-25]. This new non-invasive HIFU treatment has not been validated as a useful surgical procedure because they are mainly reports from large centers from China. Skeptical judgment on this new surgical treatment hinders its recent development, especially some labeling it experimental. As a result, many private centers that have once run the treatment successfully had encountered great resistance from International Insurance Companies for reimbursement because they disputed these HIFU treatments as experimental.

The prolonged Covid-19 pandemic and trade conflicts between countries further affected the collaboration of HIFU surgical development. To advance this new surgical approach, the medical profession needs validation from reports of large randomized, multi-center studies on treating uterine fibroids, adenomyosis, and other gynecological diseases. Hopefully, with the desire to benefit their patients, medical centers should perform collaborative clinical studies to gather more data to

validate the clinical usefulness, safety, and cost-effectiveness of FUS.

CONCLUSION

This perspective paper aims to raise clinical awareness of HIFU treatment. Hopefully, randomized, collaborative multi-center clinical trials can be performed to support this surgical approach to become a routine gynecological practice.

DECLARATIONS

Authors' contributions

WS Felix Wong had made substantial contributions to the conception and writing of the paper and Lian Zhang provided advice, HIFU information and editing the paper.

Availability of data and materials

Not applicable.

Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

None.

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