**Focused Ultrasound Surgery in Gynaecology – 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.

Passwords: FUS, HIFU, uterine fibroids, adenomyosis, validation

**Introduction**

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 popular in China and some Asian countries (1). Approximately one million hysterectomies are performed in China each year (2). More hysterectomies are done because of uterine fibroids and adenomyosis than any other problem of the uterus. 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. Not uncommonly, medico-legal issues are so distressing to all after a serious complication. The social and economic costs are considerable for the significantly prolonged stay in the hospital and a long recovery time.

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 (3). Therefore, unlike the traditional surgery, in which wounds are made, with bleeding occurring and possible complications arising. The surrounding tissues and organs of the tumor will not be damaged or injured. Because 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 the surgical approach.

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 (4, 5), adenomyosis (6, 7), and other gynecological diseases with great success (8-11). 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 (12) and established centers on their return home (13), 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 (3). 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 treatment increases in popularity among doctors and patients. The issues arise when only limited collaborative studies exist, except those in China (4). Then the success rate of this new surgery was said to be overstated and not applicable to western countries. It had also been reported to have higher mild complications like skin burn, vaginal bleeding, and pain in its early studies (3-5). Although only a few major complications or adverse events are reported in the literature, the 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. The medical profession needs validation from reports of large randomized, multi-center studies on treating uterine fibroids, adenomyosis, and other gynecological diseases to advance this new surgical approach. 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.

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