The Asian perspective on HIFU

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ABSTRACT
High intensity focused ultrasound (HIFU) uses about 800 times the diagnostic ultrasound power, which converges at a focal point to deliver energy above 60 degrees Celsius resulting in cell death by means of coagulation necrosis and cavitation destruction. This article is a reflection of my journey in gynaecological surgery, from basic laparotomy to minimally invasive surgery (MIS) to virtual surgery of noninvasive technology. This work also states an opinion shared by a lot of MIS colleagues in Asia. I am indeed fortunate to witness the transformation, revolution and disruption of surgery in gynecology in my lifetime. I think HIFU has allowed us to achieve the basic tenets of surgery, one of less pain, minimal complications, optimal destruction of a diseased organ, and optimal conservation of the human body. In this article, I will focus on HIFU treatment of uterine fibroids and adenomyosis. Uterine fibroids or myomas are common benign growths of the uterus and occurs in 20% to 50% of reproductive females. Adenomyosis involves endometrial lining cells that invade into the body of the uterus, like rust into the body of a car. Both uterine fibroids and adenomyosis can cause pain, heavy menstrual bleeding, and anemia. They can compress surrounding organs as they grow, leading to urinary, bowel, vascular and obstructive complications. Fertility may also be compromised.

The rise of ultrasound-guided HIFU amongst gynaecologists in Asia

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This article is a reflection of my journey in gynaecological surgery, from basic laparotomy to minimally invasive surgery (MIS) to virtual surgery of noninvasive technology. This work also states an opinion shared by a lot of MIS colleagues in Asia. I am indeed fortunate to witness the transformation, revolution and disruption of surgery in gynecology in my lifetime. I think HIFU has allowed us to achieve the basic tenets of surgery, one of less pain, minimal complications, optimal destruction of a diseased organ, and optimal conservation of the human body. In this article, I will focus on HIFU treatment of uterine fibroids and adenomyosis.

Uterine fibroids or myomas are common benign growths of the uterus and occurs in 20% to 50% of reproductive females [1]. Adenomyosis involves endometrial lining cells that invade into the body of the uterus. These endometrial cells infiltrate into the myometrium in a small group (focal) or widespread (diffuse) manner [2]. This mixture of myometrial cells and endometrial cells gives rise to a histological spectrum visually. Hence, it’s called ‘adenomyoma’ for being more myometrial or being more glandular in nature as ‘adenomyosis’ on imaging studies.

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Surgery for fibroids and adenomyosis

Surgery for uterine fibroids (myomectomy) with uterine conservation by way of laparotomy or laparoscopy carries risk of hemorrhage. Hemorrhage that failed to be arrested can lead to conversion to hysterectomy, which is not a desired outcome for the patient. Post-operative pelvic adhesions and potential uterine rupture risk during pregnancy are concerns. Uterine rupture risk in pregnancy is generally quoted as under 2% [3,4].

In this decade, the controversy of using power morcellation for fibroids arose [5,6]. Morcellation of fibroids is a common practice to extract myoma strips through laparoscopic ports. The power morcellator (and not the justification to use it) has become the victim of a case of unintended upstaging of an undiagnosed uterine leiomyosarcoma. As a result, morcellation of fibroids after laparoscopic myomectomy had to be carried out in a bag as a standard operating procedure in...
some hospitals to prevent spread of undiagnosed uterine leiomyosarcoma.

Morcellation in a bag is a weak mitigation to prevent upstaging of undiagnosed leiomyosarcoma. The fact is the incision and the extraction of the myoma from the uterus, if the ‘myoma’ is malignant, would have already spread cancer cells and upstaged the disease before the morcellation process. Furthermore, morcellation in a bag is a tedious gymnastic exercise in the abdominal cavity. HIFU can avoid this controversy and the dilemma of morcellation.

Minimally invasive to noninvasive

Open surgery or laparotomy works to facilitate surgical removal of diseased organs. Minimally invasive surgery or laparoscopic surgery allows in selected patients the advantage of smaller scars, less painful recovery and quicker return to normal activities. In HIFU, the surgery can be performed virtually and is totally scarless unlike laparoscopy where scars are hidden or smaller. Hence, HIFU has the advantages of MIS over laparotomy and more, having shorter hospitalizations, no skin incision, no blood loss and no requirement for blood transfusions. Some centers perform HIFU as a day surgery [7].

It’s ultrasound-guided HIFU and not MRI-guided HIFU

The HIFU that is designed to treat uterine fibroids and adenomyosis for gynecologists is ultrasound-guided (USg) and not MRI-guided (MRg). USgHIFU is meant to be used by any gynecologist, surgeon or trained HIFU medical officer. It operates independently of the MRI machine. Hence, USgHIFU can be housed in any day surgery or clinic [7]. On the other hand, MRgHIFU machines are operated by radiologists and they require the MRI machines accompaniment throughout the operation. USgHIFU does not need an MRI machine when in operation. The sole requirement is that the MRI images are pre-loaded into the USgHIFU station for guidance when the operation is in progress. Gynecologists have the advantage to adapt to USgHIFU because of familiarity in using bedside ultrasounds in their practice. So, the learning curve is shorter for them in HIFU surgery.

The independence from a radiologist and the independence from the MRI machine when performing HIFU serve as great turning points in the acceptance of USgHIFU by gynecologists. The gynecologist has a close understanding of his/her patient and is familiar with pelvic anatomy. If an emergency occurs during HIFU treatment, he/she can handle it urgently and appropriately. In general, a patient prefers her usual gynecologist to handle her condition than to be referred away.

The realtime ultrasound guided HIFU

USgHIFU does not need a major operating theater setup and a full surgical nursing team like conventional myomectomies. Scrubbing up and gowns are not required. All those are needed include basic cleanliness, asepsis and sterility. The USgHIFU effectiveness has improved over the years and a major advantage is its ability to ablate and destroy unwanted tissue cells with heat ranging from 70 degrees Celsius to 100 degrees Celsius. Thermal energy below 60 degrees Celsius does not achieve an effective Non Perfused Volume (NPV). This underlines the importance of the appropriate selection of various USgHIFU machines for effectiveness. It also explains the failure of MRgHIFU toward fibroid shrinkage because the NPV ratio achieved was generally below 60% [8,9]. The other distinct difference is MRgHIFU is not real-time and the ablation focus is not visible to the operator during the entire treatment process.

Below is a chart to summarize the difference of MRI guided and US guided HIFU.

| Advantage of USgHIFU | Advantage of MRgHIFU |
|----------------------|----------------------|
| No MRI machine needed | MRI machine needed |
| No anesthesia needed | General anesthesia required |
| No blood transfusions | Blood transfusions needed |
| Shorter hospital stays | Longer hospital stays |
| Quicker recovery | Longer recovery |
| Less painful recovery | More painful recovery |
| No skin incision | Skin incision |
| No requirement for blood transfusions | Requirement for blood transfusions |

HIFU advantages for physicians

HIFU offers another surgical choice for the gynecologist to advise his/her patients besides conventional surgery. No general anesthesia is required, and only conscious sedation is needed. The gynecologist does not need to scrub and gown up. The procedure allows adequate social distancing from the patient. Thus, COVID or HIV patients can receive treatment without subjecting the medical team to higher risks of infection.

In the course of HIFU training, the gynecologist will learn how to read MRI images, a skill that is not often taught in the school curriculum. This acquired experience is very useful in picking up suspicious leiomyosarcomas.

In the Chongqing HAIFU Hospital, there is a Tele-Medicine and Big Data Center that provides live audio-visual guidance and discussion for any ongoing HIFU surgery throughout China and the rest of the overseas HIFU centers. In Singapore, there is a China-Singapore International Data Channel connection. Doctors trained in HIFU can perform surgeries together with the China HIFU experts or conduct case discussions on a daily basis. The main advantage is to enable continuous practising, learning and exchange of knowledge. This is especially useful with COVID-19 restrictions imposed upon hospitals around the world at the time of writing this article.

Advantages to patient

Patients have a choice of noninvasive surgery with minimal pain, shorter hospital stays and quicker recovery to normal activities like work, travels and sports. Income loss and economic costs are lower compared to conventional surgery.

Most patients fear pain which is the main reason some avoid or delay surgery. HIFU is a good solution to allay fear of pain and surgery with a knife.

Late marriages and single ladies are common in this generation. HIFU gives them an alternative to treat their fibroids or adenomyosis without surgical incisions and avoids damage to their uterus or losing their womb. If HIFU fails to control the growth of fibroids or adenomyosis then the choice of conventional surgery can always be the next resort.
My personal opinion

I am very convinced after practising gynecology for 38 years that when you ask a patient with fibroids or adenomyosis if she prefers to have a surgical cut or surgery without a skin wound, the answer is obvious.

The first action of HIFU is to stop the growth of the tumor and then to wait for the uterus to gradually absorb the tumor or expel it. By ensuring adequate HIFU power delivery and ablation of selected tumors, shrinkage of around 70% to 90% can be achieved in 12 months [10,11].

With advantages including its ability to deal with difficult uterine fibroids and challenging uterine adenomyosis, it’s only a matter of time that this new technology will be accepted by the rest of Asia, in particular South-East Asia. The doctors are eager to explore new technologies, especially as their populace becomes better educated and more affluent than before.

HIFU will not replace conventional surgery because there are limitations for HIFU in gynecology. However, HIFU certainly is a good alternative to preserve reproductive potential and femininity.

Pride and prejudice

China is the birthplace of USgHIFU. One wonders why it took so long for USgHIFU to be introduced outside of China.

China after her cultural revolution is still a conservative society. China had been humbled for a long period and prefers to hide her strength and bide her time. It was only in the last 30 years that China opened up to the outside world.

The Western world having enjoyed much of the industrial revolution and progress in science, technology and standard of living, will find it hard to believe innovations and inventions from Asia can be an acceptable match. It is the pride of the more developed Western countries. USgHIFU is an Asian invention and furthermore it’s from China. Thus, the suspicion of poor quality and substandard Chinese products which are ingrained from past experiences by some developed countries, will find it difficult to overcome the prejudice.

The USgHIFU was approved by Chinese authority for clinical treatment in the year 2000. Gradually, it was accepted by Taiwan and Korea for treatment of fibroids and adenomyosis. Singapore is a population mainly educated with English because of its colonial past. Hence, the medical universities and colleges are aligned with English-speaking countries, e.g. UK, Europe, Australia and USA. Usghifu was passed over initially and MRgHIFU was first accepted. It was only in 2018 that a hospital in Singapore finally agreed to install the USgHIFU. Now there is a lineup of doctors, especially gynecologists, waiting to be trained.

It was also in 2018, that a powerful gynaecological endoscopic society of Asia called APAGE (Asia Pacific Association of Gynaecological Endoscopists) accepted HIFU for treatment of fibroids and adenomyosis into their scientific programme.

In 2019, with push from NICE (National Institute for Health and Care Excellence) of UK and support from an USgHIFU research partner, Oxford University, that UK finally accepted USgHIFU for treatment of uterine fibroids [12]. This is a landmark in the history of USgHIFU – a Chinese invention was acknowledged by the hall of medical science.

Another reason for the slow progression and acceptance of HIFU is the learning curve for the procedure is relatively long compared to conventional surgery. Having patience and abiding to guidelines are of paramount importance. It will take a month of training at a HIFU center and a completion of 50 to 100 cases for one to be competent or certified. This applies to gynecologists with ultrasound imaging skills in their practice. In China, for total beginners that have no pelvic ultrasound experience, the duration of learning HIFU takes about 6 months.

Ignorance and departmental politics are also often the hindrance of adopting new proven medical devices.

Conclusion

In conclusion, USgHIFU is revolutionary to the practice of gynecology. Standard textbooks will be revised to include HIFU as an alternative modality for the treatment of uterine fibroids and adenomyosis. HIFU has a ‘green movement’ effect in being less reliant on disposable surgical equipments and less dependent on major operating theater setups. The cost of surgery and manpower requirement will decrease.

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HIFU is not an arcade game. Neither is it a bowl of water with ultrasound. It is acquiring a smart, virtual therapeutic system that comes with research, teaching, learning and management. It is a whole new world of surgery that demands undivided attention that comprises focus, judgment and skill. The sound of HIFU is ringing in Asia.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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