

A Proposed High-intensity Focused Ultrasound Training Program in Hong Kong

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Abstract

High-intensity focused ultrasound (HIFU) surgery is a noninvasive thermal ablation treatment modality, and its clinical application is increasingly introduced into gynecological practices in China and Asia. To further strengthen the technology's standardized management, the Asia-Pacific Association for Gynecologic Endoscopy and Minimally Invasive Therapy (APAGE) collected the consensus of well-known experts in the field. They shared opinions on the management standards of the basic requirements for developing this HIFU technology in medical institutions, operators' training requirements, technical management, HIFU training program, etc., Based on the recommendations from APAGE, Hong Kong Focused Ultrasound Surgery Association developed its proposed HIFU training program for gynecologists in Hong Kong. This paper will present the training requirements and hopefully share its training and credentialing rationales with other HIFU medical institutes.

Keywords: High-intensity focused ultrasound training, Hong Kong program, stages of training, training levels

INTRODUCTION

The high-intensity focused ultrasound (HIFU) ablation surgery is a noninvasive thermal ablation procedure for treating fibroids and adenomyosis. It offers patients with safety and effectiveness.^[1-3] It is quite different from microwave and radiofrequency ablation because they involve needle puncture through the skin, with potential injury or infective morbidity. Compared to open or minimally invasive surgery, HIFU ablation benefits include no wound, no bleeding, less postoperative pain, and early recovery from surgery. With the maturity of this technology, HIFU ablation surgery will become widely used in clinical practice.

However, doctors should perform the HIFU procedures only after adequate training. The old teaching “see one, do one, teach one,” often used for surgical trainees, has long gone.

Surgical HIFU training should be properly constructed so that surgeons should learn HIFU procedures by choosing their patients and disease subjects, learning them step by step corresponding to their appropriate level of learned skills. The many surgical HIFU development and ultrasound-guided HIFU (Usg-HIFU) ablation machines and training of HIFU operators are from China. We painstakingly learned this new surgical technology.^[4] Yet, we realized that China has a different socio-medical system from other Asian and Western countries, including Hong Kong. Thus, we consider HIFU surgeons in the Asia-Pacific countries should have a set of common training programs appropriate to their countries. At the same time, China experts can provide support, share training and experience initially. The Asia-Pacific Association for Gynecologic Endoscopy and Minimally Invasive Therapy (APAGE) subcommittee of HIFU collected

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the consensus of well-known experts in China and Asia Pacific countries. They have multiple discussion meetings on the requirements of HIFU medical institutions, operators, technical management, etc., As the HIFU ablation services in gynecology began in the private sector in Hong Kong, its requirements for training and credentialing might be, at its early stage, under the Focused Ultrasound Surgery Association co. Ltd (FUSA) was formed by a group of registered medical specialists in Hong Kong. They have recommended the following requirements for HIFU services and proposed a training program for credentialing the practice. This paper suggests a proposed training program in Hong Kong; hopefully, it may form a framework to develop a common training program that can be accredited throughout Asia-Pacific.

1. Basic requirements of HIFU medical institutions or centers
 - i. Medical institutions or centers should have the approval and be registered by the Hong Kong Government health authority for focused ultrasound ablation services
 - ii. Equipment: (a) A focused ultrasound ablation treatment system for clinical use, with complete government approval documents. (b) A multifunctional medical monitor which can monitor ECG, respiration, blood pressure, pulse, and oxygen saturation during the ablation treatment; (c) Facilities for cardio-pulmonary resuscitation include oxygen channels, manual pump, air masks, sputum aspirators, plus other first-aid equipment and medicines. (d) at least 4–5 G telecommunication systems connected to accredited HIFU centers in Hong Kong or China where online training can be provided via remote video supervision. This HIFU technology can be operated via today's telemedicine, as reported in the literature^[5]
 - iii. Staff– All medical doctors performing HIFU must be adequately trained in all technical aspects. The medical director ensures that the practicing doctors, nursing staff, and anesthetists are fully registered and qualified
 - iv. In a hospital or a medical center, the HIFU treatment theater should be designed and able to conduct the focused ultrasound ablation surgery. It has to meet a traditional hospital's operating theater requirements or newly designed HIFU theater in a clinic.^[6]
2. Basic personnel requirements for HIFU ablation
 - i. Medical doctors performing focused ultrasound ablation treatment: (1) Must have a registrable medical specialist license in Hong Kong. (2) Have a certification of training registration or completed training in HIFU ablation technology
 - ii. Other relevant health professionals: Other health professionals participating in the treatment include imaging physicians, anesthetists with clinical experience, and specially trained nurses. They must be trained and qualified in the professional system to meet the relevant conditions required for focused ultrasound ablation technology.
3. Requirements for the technical management
 - i. Strictly abide by the operation specifications and diagnosis and treatment guidelines of focused ultrasound ablation treatment technology. It is recommended to have multidisciplinary discussions before surgery among the staff and strictly follow focused ultrasound ablation treatment indications and contraindications
 - ii. The surgeon should know and apply focused ultrasound ablation treatment independently and formulate a reasonable treatment and management plan for a HIFU ablation operation
 - iii. Before implementing focused ultrasound ablation treatment, the patient and his/her family should be informed of the purpose of the operation, surgical method, alternative treatment plan, postoperative precautions, possible complications, and preventive measures, and sign an informed consent
 - iv. Establish a patient database. After each case of focused ultrasound ablation surgery, relevant patient's characteristics, indications for treatment, ablation treatment should be kept in the theatre as operative records and detailed recorded soon after treatment
 - v. Establish and improve the follow-up system with detailed documentation of any side effects or adverse events during or after HIFU ablation
 - vi. Medical institutions and their physicians regularly receive evaluations of their clinical performance and capabilities of focused ultrasound ablation technology in accordance, including case selection, treatment success rate, adverse medical events, severe complications, and deaths, etc., Follow-up visits should include postoperative patient management and patient's quality of life assessment, etc
 - vii. Other technical management requirements include regular instrument and equipment inspections, a maintenance system, a registration system, and qualified third-party insurance. The organization should conduct regular checks of the HIFU therapeutic tumor ablation system
 - viii. Establish a database to register any machine errors, breakdown, computer operating system shutdown, clinical adverse events due to machine errors during and after HIFU ablation. Correction must be promptly dealt with by appropriate personnel or mechanical engineer from the HIFU service company.
4. Training requirements.

PROPOSED TRAINING PROGRAM IN HONG KONG

HIFU surgical skills training program is an initiative by the FUSA, Hong Kong, to effectively improve training,

assessment, and credential surgeons to perform HIFU ablation treatment safely. The FUSA training program is divided into three stages. The content of the program includes (1) Lectures and acquisitions for knowledge. (2) Observation and hands-on training (3) Assessment and clinical performance.

Three stages in training are recommended:

- Stage 1: Consisted of basic HIFU knowledge and a two-day course in HIFU training [Table 2]. The introduction of HIFU is to familiarise the HIFU machine, MRI, case study, video lecture...etc., the lecture topics should be formulated and adjusted flexibly under the auspices of FUSA training centers in Hong Kong. Training centers under the APAGE-HIFU training scheme will also be available in Singapore, Hong Kong, and Taipei. More centers are to open up after the ongoing accreditation of training centers
- Stage 2: Consisted of hands-on training in China and Hong Kong. These trainings are mainly for observation and limited hands-on practice training. It is proposed that one introductory hands-on training is located at Chongqing HAIFU Medical Technology Co. Ltd or other HIFU technology companies. For Hong Kong trainees, levels 1 and 2 (see below for description) skills observation can also be arranged in other HIFU training centers in China
- Stage 3: Hong Kong trainees will be trained in China and Hong Kong under HIFU preceptors or tutors for hands-on training. Trainers in each center in Hong Kong can collaborate and communicate online with other overseas centers about training.

The above stage 3 training in China and Hong Kong requires at least 50 level-1 and level-2 skill cases [Table 1] to complete basic HIFU training in gynecology.

Level-1 skill training (a 3-6 months training program)– a minimal 20 level-1 cases is required

These cases [Figure 1] include skill training by:

- a. Level-1– observation + hands-on training in China or Hong Kong (at least study ten patients)
- b. Level-1– independently operating HIFU ablation for level-1 cases by either online telemedicine or on-site preceptor’s supervision (at least study ten patients).

After completing a minimum of 20 cases, level-1 training is completed after a clinical assessment by an independent supervisor.

Level-2 skill training (a 6-12 months training)-a minimum of 30 level-2 cases is required

These cases include skill training by:

- Level-2 cases [Figure 2] observation + on-site preceptor’s training (at least study ten patients)
- Level-2a includes: Independently operating HIFU ablation for level 2a cases by on-site supervision in Hong Kong (at least study ten patients)

Table 1: The levels of skill in the high-intensity focused ultrasound training program

HIFU Level-1 cases (expected ablation within 2 h) [Figure 1]

Fibroids

Solitary fibroid (MRI T2W hypointense)

Anterior – up to 10 cm

Posterior – up to 8 cm

Multiple fibroids – Less than three fibroids of 5-6 cm (MRI T2W hypointense)

Adenomyosis

Anterior adenomyoma or adenomyosis – localized or diffuse <8 cm,

Posterior adenomyosis or small adenomyoma <6 cm (with wall thickness at least 3 cm)

HIFU Level-2 cases (expected ablation within 3/4 h) [Figure 2]

2a cases-All fibroids and adenomyosis other than level-1 and level-2b

2b cases-MRI T2W hyperintense large fibroid >10 cm, diffuse large adenomyosis >8 cm or multiple fibroids >10-20

<In this level-2b cases, HIFU ablation risks, recurrence, and failed treatment had to be fully explained to patients >

HIFU Level-3 cases (for gynecology)

Other gynecological diseases other than fibroids or adenomyosis or high-risk patients with compromised medical conditions, for examples, placenta accreta, abdominal wall endometriosis, cesarean section scar endometriosis

Level-4 cases (for gynecology and other specialties)

Other benign nongynecologic tumors or oncologic tumors

HIFU: High intensity focused ultrasound, MRI: Magnetic resonance imaging

Table 2: Requirements for the trainee in gynecology

1) MRCOG, FHKCOG, FHKAM, or equivalent qualifications

2) Completed stage 1 and stage 2 training

For each trainee, he/she should complete the following basic requirements for training

- (a) The training materials and syllabus meet the training requirements, and the curriculum includes theoretical study and clinical practice
- (b) Ensure that the trainees complete the prescribed levels 1–2 training within the stipulated time
- (c) After the training, trainees should be tested and assessed, and a conclusion on whether they are qualified or not will be issued
- (d) Establish training, examination, and assessment files for each trainee

MRCOG: Member of royal college of obstetricians and gynaecologists, FHKCOG: Fellow of hong kong college of obstetricians and gynaecologists, FHKAM: Fellow of hong kong academy of medicine

- Level-2b includes: Independently operating HIFU ablation for level 2b cases by on-site supervision in Hong Kong (10 study patients).

After completing a minimum of 30 cases, level-2 training is considered completed.

Final Assessment x 1-2 cases by HIFU preceptor before a certificate of completed training is issued. Then, the trainee can operate on his patients independently. However, ongoing support for online supervision or on-site preceptor supervision can be arranged.

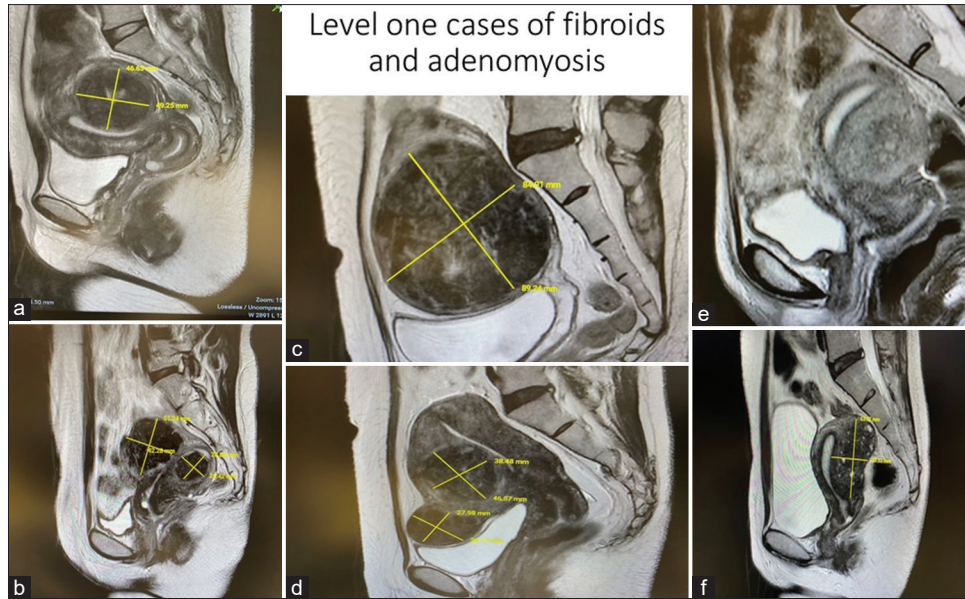


Figure 1: Magnetic resonance images of fibroids and adenomyosis that are suitable for level 1 skill training (a) T2-weighted image hypointense fibroid 6.7 cm × 5.1 cm, (b) Two T2 weighted image hypointense fibroid 5.1 cm × 4.2 cm and 2.8 cm × 2.6 cm, (c) T2-weighted image hypointense fibroid 8.2 cm × 8.9 cm, (d) Two T2-weighted image hypointense fibroid 3.8 cm × 4.6 cm and 2.8 cm × 3.6 cm, (e) Small adenomyoma in the posterior uterine wall, (f) Small posterior adenomyosis 6.3 cm × 3.7 cm

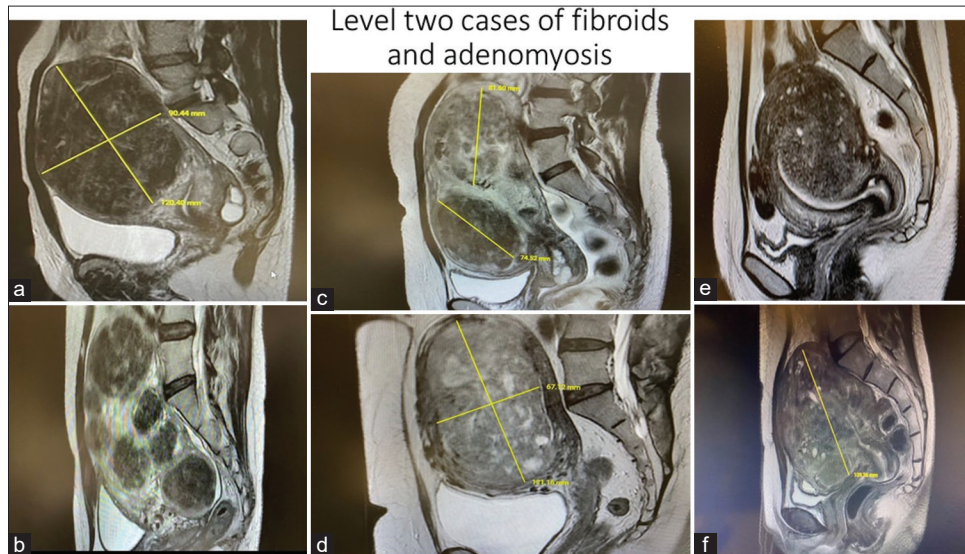


Figure 2: Magnetic resonance images of fibroids and adenomyosis that are suitable for level 2a and 2b skill training (a) T2-weighted image hypointense fibroid 9.0 cm × 12 cm, (b) Multiple T2WI hypointense fibroids (>10) ranging from 2 cm to 7 cm, (c) T2-weighted image hypointense and isointense fibroids measuring 7.5 cm and 8.2 cm, respectively, (d) T2-weighted image hyperintense fibroid 12 cm × 5.7 cm, (e) Large adenomyosis in the posterior uterine wall, (f) Large adenomyosis in the anterior uterine wall

Level-3 and level-4 skill training need advanced learning and accreditation by FUSA or Hong Kong Medical Colleges in Hong Kong

The requirements of a training center are listed in Table 3.

DISCUSSION

Before the widespread acceptance of the HIFU technology, the community must recognize its safety, effectiveness, and

training accreditation. Ultrasound-guided HIFU ablation is an effective and noninvasive treatment for fibroids and adenomyosis, which was developed and endorsed in China. However, there has not been any training program overseas because it was not introduced widely outside China. This paper aims to present the training program in Hong Kong for this new procedural technology. It focuses on teaching technical knowledge, hands-on training, and supervised training at different skill level procedures.

Table 3: Requirements for a training center

- 1) A medical unit that meets the technical management requirements of focused ultrasound ablation treatment
- 2) Relevant training center needs to carry out the HIFU ablation services for more than three years, no less than 300 cases within three years before applying to be a training center. One of the criteria for a successful application is a low incidence of <1% severe complications
- 3) The training center director should be a registered medical practitioner and a HIFU specialist of good character and vast experience. The center should also have at least 3 HIFU specialists as trainers and supervisors

HIFU: High-intensity focused ultrasound

In Hong Kong, the HIFU ablation service was set up in a private clinic by a small group of gynecologists after intensive HIFU training in China. There is little guidance for other practicing gynecologists in Hong Kong to learn and practice this new technology. China is the only place where USg-HIFU is popular and widely practiced. The Chinese HIFU manufacturers are also keen to provide clinical training in their headquarters and related HIFU training centers in China hospitals. The Chinese OandG Association in Mainland China also sets up a well-established. Expert consensus group to regulate the HIFU training and applications.^[7]

Then, who should be responsible for the safe introduction of new surgical technology in Hong Kong? Unlike minimally invasive surgery, this HIFU technology does not have training platforms similar to MIS, such as virtual reality (VR) training, bench model simulations, cadaver, and live animal model surgery. Besides, MIS training is readily available in many medical institutes or private hospitals. Like the da Vinci robotic surgery, HIFU ablation is heavily involved in the smooth operation and application of a machine. There is a consensus that we should be wary of training standards promoted by machine manufacturing companies. In 2017, the Washington State Supreme Court ruling in a case of medical litigation implied that surgeons learning a new surgical technology promoted by companies was clearly insufficient.^[8] Training requirements might be better designated by doctors with related surgical experience in practice. In Hong Kong, it is almost by default that the teaching, inspiring, and training of other doctors in this new technology lie flatly in the hands of the few gynecologists who had set up the first specialized HIFU surgical center 1½ years ago.^[4] They also set up the FUSA, which developed this training program based on their HIFU learning experience, guided and supported by some HIFU groups and centers from China and Asia Pacific countries. Hopefully, it can provide a training program to ensure structured teaching of this new technology in Hong Kong.

Based on our understanding, for our training program to be successful, several training components are important,^[9] including (1) a knowledge component, (2) observation

and hand-on practicing component, and subsequent (3) a supervised training component in a clinical setting. Our program provides the above features as tabled before in the text. Learning surgical techniques requires surgical trainees to engage in more clinical activities, such as stages 2 and 3 in our training program. “See one, do one, teach one” is not the best way to teach complex technical procedures. “See many, do many, teach many” should now be appropriate for our surgeons to perform complex operations.

Nonetheless, there would be challenges and difficulties in implementing our proposed HIFU training program in Hong Kong.

1. Private doctors might not readily take up training opportunities as they might be otherwise occupied in their practices. Finding a balance between patients’ safety and doctors’ training will require a more structured and well-organized approach. With limited resources in a HIFU center in the private sector, we would need to identify candidates with commitment and a special interest in the technology for recruitment into the training programs
2. The exposure to new technical procedures is based on suitable patients and opportunities rather than structured theoretical objectives. In Hong Kong, HIFU ablation is not well established and set up in the university, and teaching units are not available; the responsibility in introducing and teaching this new technology to doctors in HK lies in the hands of the few gynecologists in the private sector. They have amassed a wealth of experience in treating women with benign soft-tissue tumors of the uterus this year and a half. Trainees in the private practice are encouraged to bring their patients in for treatment and their training at the same time. Moreover, trainees are also invited to be either observers or surgical assistants whenever an opportunity arises
3. There is a learning curve to master any new surgical technology. Okada *et al.* reported the impact of the learning curve of MRgFUS treatment could safely achieve a larger nonperfusion volume ratio and clinical outcome.^[10] However, there are very few other references or information to discuss HIFU ablation surgery’s learning curve. More studies on this issue would be helpful to develop an appropriate HIFU training program
4. As the setting up of the HIFU ablation system and the machine is expensive, not many hospitals, private or public, will be readily eager to set up a HIFU service. Fortunately, the future development of VR into this area can be translated into clinical practice. This computerized HIFU VR surgery can hopefully be an effective prepatient HIFU training program for trainees.

Our training program is primarily for HIFU ablation of fibroids and adenomyosis in gynecology. Our pilot training program stresses the importance of acquiring the right skills for HIFU procedures of various difficulties and complexities

and teaches them to gynecologists. A group decision based on surgical difficulties and safety represents the “expert consensus” on this new HIFU technology. Leading communities worldwide would benefit from standardizing and validating our training program for its effectiveness in teaching surgical competence, minimizing wasted time in learning, and focusing on the breadth of skills needed for a new HIFU surgery.

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Conflicts of interest

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