

Opinion

How to Avoid Medico-Legal Litigations in Performing High Intensity Focused Ultrasound Ablation for Treating Fibroids and Adenomyosis

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Abstract

High-intensity focused ultrasound (HIFU) ablation is the latest advance in surgery. It is an accepted treatment for uterine fibroids and adenomyosis in Asia. Even though it is a non-invasive surgery, with preliminary results of a very low complication rate, adverse events and complications occur. In modern medicine, patients are likely to file claims should a complication or injury occur and treatment results fall short of expectations. The increasing trend of litigations in Obstetrics and Gynaecology undoubtedly generates anxiety among gynaecologists operating with this new surgical technique. This paper is written to guide doctors performing this new HIFU treatment to reduce and steer clear of potential medico-legal problems.

Keywords: HIFU ablation; training; credentialing; medico-legal litigations; gynaecologists; fibroids; adenomyosis

1. Introduction

In the Asia Pacific region, gynaecologists increasingly embrace ultrasound-guided High Intensity Focused Ultrasound (USg-HIFU) ablation as an effective and safe treatment for fibroids and adenomyosis. Nevertheless, in HIFU ablation surgery, adverse events may arise, similar to all surgical treatments [1,2]. Patients attracted by advertising information through the Internet, promotion leaflets and sensationalised media interviews may have a certain misconstrued impression of this new technology. These patients will likely file claims if complications or injuries arise because they may feel 'cheated'.

Our medical group have painstakingly learned this new surgical technology [3] in China, which has a different legal system from western countries. Currently, no known medico-legal litigations have arisen from the early development of HIFU ablation in Hong Kong. However, the medico-legal problems are anticipated to be similar to other new surgical procedures in gynaecology [1]. The authors used information from a report "How to avoid medico-legal problems in Obstetrics and Gynaecology" written by the Medico-Legal Committee of the Royal College of Obstetricians and Gynaecologists [4], to guide doctors who practised USg-HIFU treatment in Gynaecology to reduce and steer clear of medico-legal problems.

The approach starts with the prerequisites of adequate training and supervision, consent to treatment, patient communication, adequate human and equipment resources, and investigations, followed by a safe and effective HIFU ablation treatment.

2. Subsections Relevant for the Subject

2.1 Adequate Training and Supervision

Surgical malpractice claims point to the need for addressing training. Supervision is an activity related to surgical training facilitated through observation, knowledge and skills acquisition by instruction, modelling and assessment. In the early development of robotic surgery, Lee *et al.* [5] reviewed the medico-legal liability cases in robotic surgery, and many originated from a lack of training. Jha and Rowland [6], in 2014, also pointed out the issues of education, training and clinical governance in the litigation in gynaecology. They viewed a doctor's greatest asset is their advanced training and experience.

Like laparoscopic and robotic surgery [7], HIFU training, supervision, and assessment are prerequisites for granting privileges and credentialing on the HIFU treatment [8]. Even experienced gynaecologists cannot operate HIFU treatment without proper training and supervision. There will always be a learning curve for HIFU surgery, and new trainees should be assisted or supervised, follow safety protocols, and be proctored by more experienced doctors. Commonly in litigation, the accused doctor's level of training and competency will come into question.

2.2 Consent to Treatment

Informed consent for HIFU treatment should include potential risks of HIFU ablation, such as postoperation pain, skin burn, intestinal, bladder and nerve injuries. These HIFU complications are mild; most will recover with symptomatic non-specific treatment [9–11]. Yet, doctors should also inform patients of major or minor material risks and



alternative treatment, as we learned from the *Montgomery v Lanarkshire Health Board* case [12]. Also, HIFU treatment does not remove the entire organ or excise any tissue for pathology. It is important to discuss it with patients. Persistent heavy menstrual bleeding or dysmenorrhoea after treatment for fibroid or adenomyosis may fall short of the patient's expectations. It may lead to undue angsts among patients and doctors. Another critical issue is inadequate medical documentation to substantiate the treatment options and proper counselling. In a review of 113 medico-legal files originating from laparoscopic bile duct injuries, de Reuver *et al.* [13] found documentary evidence of informed consent in only 23% of cases and details of the actual informed consent discussion in just 11.5%. At least half the cases showed either poorly documented or undocumented.

2.3 Patient Communication

Canadian Medical Protective Association (CMPA), reported a rapid 85% increase in complaints from 1983 in 2007 to 3387 in 2016. The CMPA's data showed that communication is a key issue in most cases [14]. It recommended patient-targeted communication and behaviour to reduce patients' complaints. For a HIFU surgeon, not only should one inform the patients of the benefits of HIFU treatment, but other alternative treatments. One of the plaintiff's common claims was a lack of other treatment options and a comparison of these options.

2.4 Adequate Human and Equipment Resources

A shortage of nurses, doctor's supervision, and well-maintained medical equipment may adversely impact the medico-legal decision. Medical product liability is especially important for HIFU treatment. As HIFU technology depends on the accurate targeting of solid tumours, a reliable computer and clear real-time ultrasound images during the ablation will improve the safety and efficacy of treatment. The mechanical manipulation of the HIFU and imaging ultrasound transducers during the procedure and the temperature control of water in the ultrasonic chamber must function smoothly, properly and reliably to avoid inflicting injury to patients. Regular maintenance of the HIFU machine is paramount. The case law "*Greenman v Yuba Power Products, Inc*" in 1963 clearly defined product liability that "a manufacturer is strictly liable in tort law when a product was to be used without inspection for defects, proved to have a defect that causes injury to a human being" [15,16].

2.5 Investigations Relating to HIFU Treatment

Magnetic resonance imaging (MRI) scan of the pelvis is mandatory for HIFU treatment. It is for a pre-op assessment of the pathology and as the actual guide during the HIFU procedure. Blood tests such as complete blood pictures, liver function tests, renal function tests, and coagulation profiles can assess a patient's health condition

before the procedure. However, patients should not undergo unnecessary investigations and invasive procedures [6]. As HIFU ablation does not give a pathological diagnosis, doctors performing HIFU need to be aware of this, especially with rapid growing uterine tumours that might suggest the risks of malignancy or uterine sarcoma. MRI images and serum Lactate dehydrogenase (LDH) might help, but a definitive diagnosis of uterine sarcoma or atypical leiomyoma might be difficult [17].

2.6 Safe and Effective HIFU Procedure

Non-adherence to surgical safety protocols and poor clinical decision-making will lead to intraoperative surgical complications. For example, a prolonged ablation without intermittent rest periods may cause skin burns. A surgeon who fails to define the anatomy and locate the lesion can injure the endometrium or surrounding organs. Therefore, carelessness in performing the procedure, not following the standard treatment protocols, and not recognising the risks of HIFU thermal spread may breach the duty of care to patients.

3. Discussion

As HIFU ablation treatment has only recently been used in gynaecology, medico-legal issues relating specifically to it have not been recognised. Doctors performing HIFU treatment should adhere strictly to the principles of good professional care and anticipate specific medico-legal issues that might arise in various stages and aspects of HIFU treatment of gynaecological conditions. Retrospective wisdom in this area can be learned from studying medico-legal matters which occurred in the early development of laparoscopic and robotic surgery.

Doctors performing HIFU treatment should learn an updated diagnostic knowledge of MRI interpretation. They should also practice HIFU diligently and learn to avoid and handle complications. For the time being, postgraduate training in this new technology for gynaecologists in practice is non-existent. Therefore, gynaecologists with insufficient training who perform HIFU surgery may potentially be at risk for liability. The litigation complexity is similar to robotic surgery's early development [5,18]. Therefore, international surgical associations should collaborate on this new development to set up training requirements and credentials for HIFU ablation treatment.

Finally, in a medico-legal situation, a claim's verdict depends on the expert witness arguing the balance of negligence probabilities. If a claim arises in HIFU ablation in any country, expert witnesses called upon will be retired or out of tune with this new HIFU technology. They will spend their time examining records in detail, giving opinions on any breach of the basic duty, e.g., a lack of detailed HIFU information, lack of adequate informed consent, delayed diagnosis of complications, and failure to repair the damage early. Thus, doctors performing HIFU on patients

should be aware of these considerations. Regardless of how advanced and complicated a HIFU procedure is, the basic principles under which the medical profession must observe should never be compromised.

To conclude, to avoid medico-legal litigations — one of the essential things is good communication with patients. Informed consent forms should be correctly filled in and signed by patients before a witness. All medical records should be dated and recorded at consultations before and after HIFU treatment. HIFU doctors should work under all three “adequacy”, i.e., adequate training, skills, and documentation. A better understanding of the importance of seeking assistance from proctors or experienced supervisor early in HIFU training is likely beneficial.

Author Contributions

FW and TL designed and wrote the paper. PHW revised and gave advice to some of on medico-legal aspects in the papers. All contributed to editorial changes and approved the final manuscript.

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