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Review Article

Legal Aspect of Gynaecological Ultrasound in UK Practice

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Abstract

This article summarises all aspect of Medicolegal implications in current gynaecological ultrasound practice emphasising the role of the appropriate communication and reporting. Although there are areas of ultrasound practice which risk of medico-legal debates a systematic and pertinent ultrasound examination technique protects against the above and sonographers should maintain at their best abilities high quality ultrasound performance and assure clear communication with the physician requesting the ultrasound.

Ultrasound practice in gynaecology should follow similar rules of clinical governance; respect evidence based national (and international) guidelines and re-evaluate standards of practice.

Keywords: *Ultrasound Practice; Sonographers*

Introduction

The provision of ultrasound services is a standard of modern gynaecological practice and the expected applications of ultrasound (US) in gynaecology have been increased [1,2].

The availability of US practice combined with the lower cost of US machines has increased provision of ultrasound within the gynaecological departments (portable US machines).

There is increased patient expectation of US examination during their consultation (In private sector the provision of ultrasound scanning is considered an essential service).

The advance of technology allows spectacular improvement in image creation. Digital high definition images and videos offer a clearer explanation of patho-physiology to patients and inform the appropriate therapeutic management.

A woman feel more reassured with a pelvic scan rather than with a simple digital examination and their confidence is increased in a doctor who can examine them and perform US [3].

This article discusses the legal aspects of gynaecological US practice and reflect on the challenges and the implications for contemporary practice.

Literature Review

Few reports have been published regarding medico-legal issues on gynaecological ultrasound practice (OVID research table 1 and Pub med table 2) in contrast to obstetric US (more for prenatal diagnosis medico-legal debates) [4-7].

In the *International Federation of Gynaecology and Obstetrics* [8] report on Ethical issues in obstetrics and gynaecology for the Study of Ethical Aspects of Human Reproduction and Women's Health, only issues relative to ultrasound in obstetrics were mentioned and not for gynaecological US.

Despite the increase of medico-legal litigation processes in obstetrics and gynaecology [9-11], US cases in gynaecology are not systematically reported. There is no reliable system that tracks these litigation cases and many suits are dropped before a court hearing [12]. Most claims are either settled by negotiation or mediation for whatever proportion of their full value matches the chances of success of a trial for plaintiff or defendant [13].

Although similar standards of practice should be applied in gynaecological US in comparison to other types of US examination there are differences in the medico legal potential of litigation and debates [14].

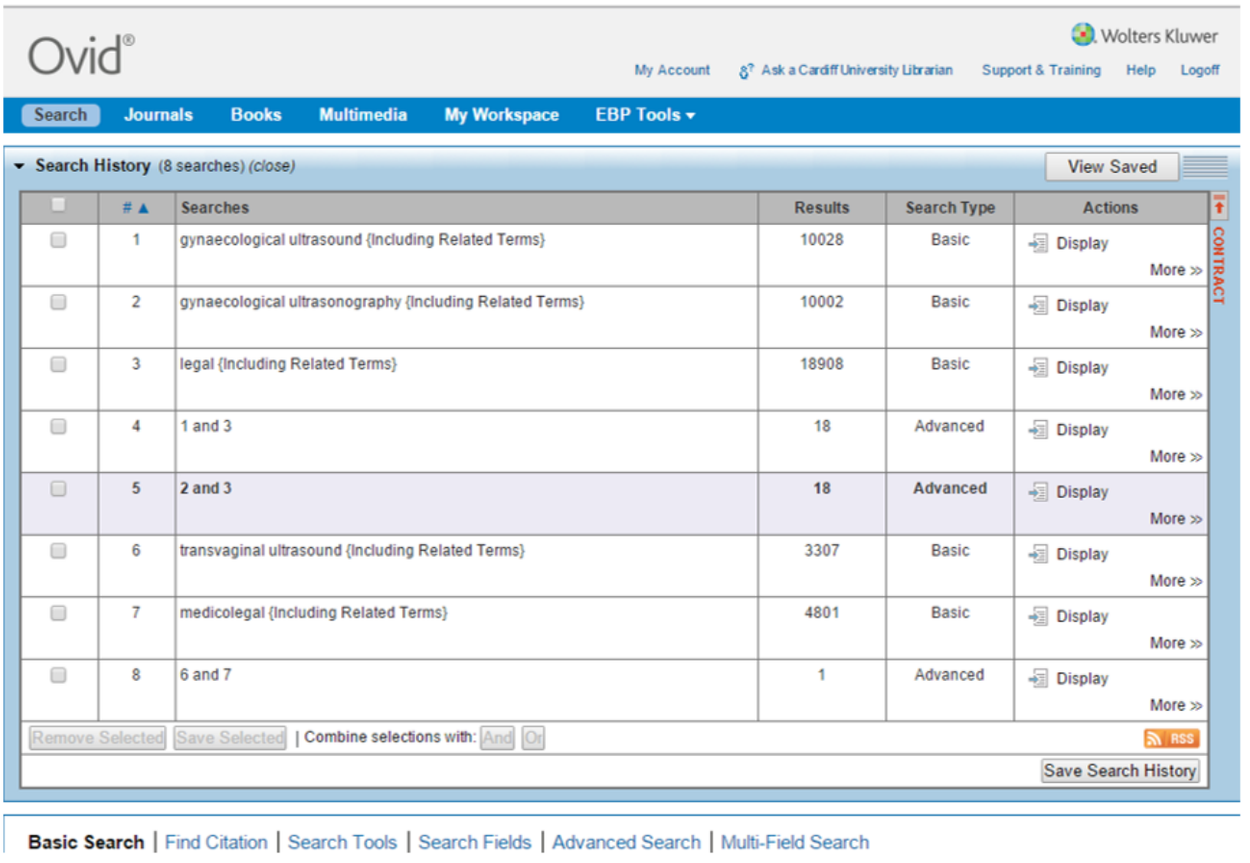

Table 1: *Example of Ovid® literature research using relevant key words.*

Pub med literature research using key words such as:
Legal aspect gynaecological ultrasound: two articles, one relevant. Transvaginal (TVS) ultrasound litigation: eight articles and one relevant Transvaginal ultrasound legal: thirteen articles and one only relevant.

Table 2: *Pub med literature research.*

Gynaecological US applied exclusively to women. Transvaginal ultrasound scan may be perceived as an invasive technique (violation or sexual harassment claims using the transvaginal ultrasound probe).

The US study report has variable impact on patients depending on the indication and context of the US study. The potential for litigation varies if, for example, the US is performed for fertility assessment [15] or to exclude gynaecological cancer; whether US is used in an emergency situation [16,17] excluding an ectopic pregnancy, or pre-operatively.

An erroneous report may or may not lead to a litigation claim. Depending on patient stress and expectations, perception about ultrasound diagnostic power and agreed consent determines whether there will be a claim or not.

However it is not only the patient experiences who will challenge the US practice of the sonographer (or specialist) but there other sources of medico-legal debates mainly due to suboptimal practice (non-respect to clinical standards, non-respect of National Health System (NHS)/hospital regulations and potential breach of patient confidentiality).

Discussion

Ultrasound examination as a medical act is regulated under the national standards of patient care by the United Kingdom Association of Sonographers [18] the British Medical Ultrasound Society [19], The Society and College of Radiographers [20] and The Royal College of Radiologist 2015 [21,22]. Appropriate training and reliable performance is mandatory [23]. Table 3 depicts areas of legal debates within gynaecological practice.

The principles of effective diagnostic ultrasound procedures
Potential benefits patient management conservative/operative
Potential injuries (psychological anxiety, technical safety aspect)
Practitioners' qualifications (Up to date, registration)
Equipment requirements (safety issues, maintenance, accuracy)
Equipping the workplace (adequate machine and settings)
Hygiene
Examination procedure (technique)
Findings (experience)
Documentation (complete report imaging back up)
Communication (clear report and differential diagnosis)

Table 3: *Ultrasound practice and potential source of legal risks.*

Therefore there are many areas where the sonographer may be at "fault". From documentation, rigorous images or videos in the data basis which support the ultrasound report, the summary and the full report level of explanations and communication of the results to the patient and doctor. Consent issues may be arising in some ultrasound examinations where the standard of privacy - appropriate place to examine is not respected.

Accordingly complaints can be raised with one or more of the above parts of gynaecological US practice (Table 2) contributing to allegations of:

Negligence

Medical negligence occurs when there is a breach of a legal duty of care owed by a doctor to a patient that results in damage (s). Negligence actions are preferred by the courts in the United Kingdom when pursuing a cause of action, both because medical intent is not an issue, and because defendants are liable to pay financial damages to compensate for the actual damage caused by negligence.

Liability for most of the clinical negligence claims is under the Law of Negligence. Where it is the patient pathway of care, how general practice (GP) services refer and finally treat the patient before or after an action into the hospital or whether a specialist intervention occurred or not.

There are four important elements to a negligence lawsuit that must be proven:

1. The defendant owed a duty, either to the plaintiff or to the general public
2. The defendant violated that duty
3. The defendant's violation of the duty resulted in harm to the plaintiff
4. The plaintiff's injury was foreseeable by a reasonable person.

Breach of duty of care

Duty of care imposes an obligation to exercise reasonable care to avoid acts or omissions which can be reasonably foreseen to be likely causes of physical harm to patient [24]. Non-malfeasance means that health personnel should prevent causing harm and is best understood as expressing the limits of beneficence, known as 'primum non nocere' or "first to do no harm".

The sonographer relationship gives rise to the normal duty of care to exercise reasonable care skill and judgement. The legal duty of care is a single duty encompassing a moral and ethical duty to see, diagnose treat or refer the patient. The legal duty is owed, irrespectively of the experience if the doctor or it may be directly owed by the doctor to a third party (private practice).

Where there is no duty to exercise care then there is no legal consequence. Duty towards to the patient is arising from professional obligation. As the General Medical Council (GMC) regulates and licenses the practice of doctors in UK, under the provision of the medical Practice Act 1983, the GMC sets professionally led medical regulation by setting out the principles of Good Medical Practice [25]. From the professional contract/implementation of example the Primary care Trust in the past or NHS obligations NHS contract 2015/2016 [26]. In case of private practice 'breach of contract' can lead to a legal action up to six years in a breach of contract claim and up to three years in a negligence claim.

Duty towards the patient is implied by general Legislation for instance the Goods and Services Act 1982 [27], Consumer Protection Act 197 [28], European Convention on Human Rights (ECHR) 1988 Human rights Act 1988 [29], where article 2 of the ECHR is the likely area of a claim example not receiving a medical treatment (after ultrasound scan result) or not receiving different or/and probably more expensive treatment example IVF.

Fiduciary duty is applicable for ultrasound examination where a patient has placed a confidence in another person (sonographer/doctor) and this confidential relationship is breached, in particular regarding confidentiality of the US examination or unnecessary repetitions of US examinations.

Breach of duty can be detected in cases of conflict of interest where for example ultrasound examinations are exaggerated in order to create more medical consumption/increasing the fees or payments towards to NHS or private clinics, where the number or type of ultrasound is not absolutely necessary. Other areas of medico legal issue could be conferences, gifts, sponsorships for example a multinational company influence doctors who will influence other less experienced doctors to buy the promoted product.

Another breach of duty case could be the intentional fraud where the US report is altered purposely. An example could be when a patient requests an "altered report" in order to justify the US session to the insurance company claim (US for private IVF treatment but written as polycystic ovarian syndrome (PCOS) request scan through NHS services). Other case of breach of duty could be a procured related litigation case when agents such as foam or other contrast medium are used for hysterosalpingo-foam-sonography (HYFOSY) without the appropriate licence. The usage of non-licensed products versus licensed should be part of the informed consent towards the patient/or within research project. Third party injuries to patient, example infection risk during examination an extremely rare possibility, are cases of direct harm and therefore cases of breach of duty.

Breach of duty to foetus/embryo

The duty to protect the embryos and not harm them is stipulated by the Congenital Disabilities (Civil Liability) act 1976 [30]. Though the foetus/embryo lack legal status, the law still provides protection from harm especially in the usage of medical treatments [31]. Where the ultrasound findings will determine continuation or not of the pregnancy, locate abnormal locations of pregnancy [32,33] or determine with other prenatal screening systems to proceed in an invasive prenatal test example chorionic villous sampling or amniocentesis [34]. Misdiagnosis of miscarriage or ectopic pregnancy can be a source of complaints and serious causation cases [35,36]. Difficulty to detect rare cases of heterotopic pregnancy [37] and misdiagnosis is another difficult situation which needs pertinent US assessment and senior clinical input.

If anything of the patient deviates from the above may be a source of complaints, litigation claims and court prosecution. Ultrasound skills must be demonstrated, whether the studies are being handled by a radiologist, obstetrician/gynaecologist, maternal-foetal medicine physician, or an emergency room physician [38]. Of ultrasound liability cases, obstetric cases contribute 75%, gynaecological and abdominal each produce 10%, and breast studies produce 5% of cases. In the cases that have been closed, 90% involve issues such as failure to perform the examination, faulty performance of a scan, "invented" lesions, a missed diagnosis, lack of communication, and informed consent [39].

What is the question that US examination tries to answer?

Patients should be counselled about the limitations of the US study, other differential diagnosis or potential diagnostic errors in imaging technique [40] and the importance of communication if their clinical condition change or deteriorates. The information provided by the US may determine the therapeutical management and therefore its consequence varies if US is performed for screening, ongoing chronic disease (endometriosis) or fast development condition (ovarian cyst, neoplasia or uterine sarcoma).

Depending on the suggested US diagnosis a surgical versus a conservative approach will be discussed with the patient. In some conditions the ultrasound will not indicate whether an operation has to be done but with which way this surgical procedure can be done (laparoscopy versus vaginal or abdominal surgery) and therefore a pertinent US study can assist the clinician to propose the less invasive technique without decreasing the effectiveness of the surgery. A patient follow up with US examinations may detect changes of pathology in time (especially for chronic conditions such as endometriosis or leiomyomas). However if a follow up is arranged and the quality of the US study is suboptimal, the discriminative power of US detection (normal to abnormal structure or new pathology) is altered and therefore the patient is in risk of a delayed treatment or to suffer from an aggravating condition (large ovarian cyst which changes in time to a cyst containing a borderline tumour).

Causation and damages

Patient may claim damages in two ways. First, if the US did misdiagnose (false positive) a condition with subsequent unnecessary operations or if a condition was not detected (despite enough imaging support) where there is a false negative result and by consequence an early intervention was not proposed. For example an enlarged uterine leiomyoma which was not followed up and become sarcoma in 6 months post ultrasound scan or an enlarged ovarian cyst which became bigger ending with an acute adnexal torsion which needed an urgent oophorectomy or in case of misdiagnosis of adenomyosis delaying patient treatment [41].

How a patient uses the information from US depends on the consequences to their personal life. Therefore a suboptimal quality US examination should be recognised and a second follow up US should be arranged. Overall the ultrasound examination in gynaecology has not the same legal consequences depending on what we search to find with the examination: If the ultrasound scan is used as screening test [34] (example ovarian cancer screening program ongoing research) with a prediction about the development or not of a condition, If another imaging technique is compared to the US standard practice (Three-dimensional 3D-US other MRI or CT scan) where the new technique may be or not be superior so the US examination back up the final medical decision for management and finally the usage of the US information in preoperative assessment for instance, if the uterus is too large a laparoscopic hysterectomy may be potentially more risky procedure for complications rather a standard total abdominal hysterectomy. Another example which could illustrate the above is when an adnexal mass evaluation change the surgical approach from laparotomy to laparoscopy [42,43].

Some examples of diagnostic errors leading to causation and damages are:

- Misinterpreted US study appears when an abnormality is seen but unfortunately is incorrectly described for instance a benign lesion is called malignant or vice-versa or a corpus luteum described as neoplasia which can lead to an unnecessary surgery. If there is a differential proposal within the report this can be defendable if the case go to jury verdict (at least the clinician could think about another way of management).

- An example of invented lesion can be illustrated in early pregnancy with a corpus luteum seen as an ectopic pregnancy and if it is treated with methotrexate an adverse outcome is produced.

- Incomplete US study may lead to legal complaints example if not all part of the uterus is seen or commented, therefore a missed lesion or pathology may not be detected.

- Product liability where the US machine used for the examination is not regularly maintained and it does not comply with safety standards and acceptable imaging accuracy [18,19]. This liability is very rarely a problem in NHS as there is an existing program of clinical governance responsibility for ultrasound practice [44]. However in private practice it is difficult to always assure this (regular service and maintenance).

It is estimated that 80% of cases are lost if they go to jury verdict, therefore many layers regarding an error in perception or missed diagnosis are settled before court trial. Sonographers should be aware that they are legally accountable for their professional actions, including the reporting of ultrasound examinations, in all circumstances.

Radiological or ultrasonographic dependant medical acts can be a source of medico legal claims if misplaced devices have not been detected for example a missing or migrated intrauterine coil could jeopardise the contraception effect or create intra-peritoneal adhesions and infections [45].

Medico-legal problems may arise if communication from the sonographer to the doctor ordering the US examination fails. The time delay from acknowledgement of the report until surgical decision may be detrimental for the patient's life/care.

Responsibilities are often at an advanced clinical level (consultant responsible of the patient care or superintendent sonographer) and consequently higher demands are placed upon the professionals, not least in terms of clinical updating, competence to practice and also legal liability [18].

Sharing cases, information lacking cases from which allied health professionals (e.g. sonographers) can gain valuable information (multidisciplinary approach and case discussion with clinical feedback of the final diagnosis); thus, a decreased potential of patients harm (direct/indirect) and medico-legal claims.

In particular the respect of national standards to base US practice on evidence and peer practice; the need to keep detailed records (protocols) of such practice; the need to know when the limit of US ability is reached; and as such when to ask for advice from a medical practitioner/radiologist is mandatory in order to decrease the risks of misdiagnosis leading to causation and patient damages.

It is inappropriate and unethical to "force" a transvaginal ultrasound examination for example in a woman that does not want it or did not understand it. Sometimes misunderstandings can occur if the set-up of the examination is not adequate (no respect of patient privacy or absence of a chaperon). The patient may feel vulnerable and decline to go through it.

Therefore patient information for the purpose of obtaining consent plays a significant role avoiding unnecessary misunderstanding and thus claims. Ideally it should be verbal and the refereeing doctor should prepare the patient by explaining what an US examination is how the US is done and what should be expected about tolerance and patient experience. Why a US examination is needed should be explained at the first instance and how important the expected information gained from this US examination will be.

So a consent needs to be established prior to the examination including what is asked by the doctor (patient needs to know if the general practitioner asked for transvaginal scan or not) and if a pelvic gynaecological US is not of good quality the need to proceed with a transvaginal ultrasound imaging. Areas of individual practice influence the relations with the sonographer - doctor and patient. Are the limitations of the US examination explained to the patient? Did the practitioner show the images to the patient or blindly concluded with a report? There is the clinical opinion (not evidenced based yet) that if the gynaecologist/sonographer shows to the patient the US study in real time and explain what he/she measures and why then the patient has full confidence about the US examination and confirms that the sonographer has done the best to achieve the best images thus the most of the accuracy for the diagnosis. Perhaps with this way a decrease of complaints may happen. Inappropriate time "rushing" to complete the US examination is linked with omissions and danger of inaccurate diagnosis. The US practice in gynaecology should follow the recommendations of GMC patient confidentiality [46] before, during and after the examination.

Patient has the right to complain and there is an established process to be followed through NHS Trust rules, Clinical Negligence Scheme for Trusts (CNST) [13]. The Duty of Candour [47] is a legal duty on hospital, community and mental health trusts to inform and apologise to patients if there have been mistakes in their care that have led to significant harm. Through this process few cases end up to court.

Local Research, multi-centred research and ethics committee should take into consideration the medico-legal pitfalls within the proposed ultrasound research projects in order to protect the patients and the organisations from litigation issues. The complaints about professional misconduct follow the same rules of the GMC [25] and Royal College of Radiologist (RCR) UK recommendations [48].

Cases related to sonographers are unusual because usually the reporting physician is considered responsible for the interpretation of the study. Whereby the doctor, requesting the ultrasound, should have the knowledge how to interpret (profound ideally) the ultrasound image and what are its limitations. Consequently a clinical judgment based only on the summary of an ultrasound report is potentially dangerous without seen the images by each self. Data protection and digitalised systems such as the PACS (Picture Archiving and Communication System) [49] facilitate the pertinent study of the images and quick access to the reports. Respect to the patient confidentiality in any part of the ultrasound examination and communication of the report is ruled by GMC recommendations [46], RCR recommendations [50].

In future more medico-legal claims will arise and professional insurance should be considered from the early stages of US practice. Public awareness of medical errors and increased publicity of layer groups specialising in medico-legal claims will source litigation in sonography within the NHS and private practice. This phenomenon about US practice in the UK, is not yet accentuated as within the United States [12,51].

Conclusion

For the aforementioned reasons and reflection, modern US practice following regulatory body guidelines and standard recommendation should decrease the legal risk but it is unlikely to eliminate completely the possibility of missed diagnosis, pathology detection in retrospect and unrealistic patient expectations. Although there are areas of US practice which risk of medico-legal debates a systematic and pertinent US examination technique protects against the above and sonographers should maintain at their best abilities high quality US performance and assure clear communication with the physician requesting the US.US practice in gynaecology should follow similar rules of clinical governance; respect evidence based national (and international) guidelines and re-evaluate standards of practice.

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