FETOSCOPIC PROCEDURES TO TREAT THE FETUS IN UTERO: LEGAL CONCERNS

Ayodhya Prabhashini Rathnayake*

Faculty of Law, General Sir John Kotelawala Defence University, Sri Lanka

It is evident from the advancements in fetal medicine that, a human fetus in the womb can be subject to treatments. The technology is developed to detect fetal abnormalities and defects. Among the procedures which use for the treatment, 'fetoscopy' or the 'fetal endoscopy surgery' is of imperative concern. The surgical procedure is well used for both diagnostic and therapeutic purposes of curing foetuses. The performance of fetoscopy involves endoscopes, which are percutaneously placed in the womb through the abdominal wall of the pregnant woman. Thus, it is evident that the procedure has an impact on both the pregnant woman and the fetus in utero. Thus, it creates a collision of interests between both of the entities. The objectives of this paper are to analyse the ethical facets relevant to the pregnant woman and the fetus subject to fetoscopy while studying the aspects of medical duty of care. As the procedure is performed through the body of the pregnant woman, her autonomy is significant. In parallel to her informed consent, she has a right to refuse the treatment. In *Griswold v. Connecticut*, the court's view was that it is essential to protect the right to privacy and societal preferences for autonomy. 'Fetus' becomes a patient when the pregnant woman is presented for obstetric care. Thus, it lacks autonomy but is entitled to be treated with utmost beneficence. Thus, the health professionals who perform fetoscopic procedures are bound by the beneficence-based obligations to the fetus which create a medical duty of care to the same. The professional skill and expertise are imperative to perform fetoscopy. As the procedure has own risks to the fetus and pregnant woman, the performance is needed to comply the standards of practice. The methodology used in the paper is qualitative, and the author has analysed both primary and secondary sources of law using guidelines from the medical professionals' associations in foreign jurisdictions. As the concluding perspective, author presents that, in the process of fetoscopy the autonomy and beneficence to the pregnant woman should be balanced with the beneficence to the fetus.

Keywords: autonomy, fetus, fetoscopy, pregnant woman, law

**Corresponding Author: ayodhya.rathnayake@kdu.ac.lk*

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INTRODUCTION

'Fetal Endoscopic Surgery' is considered an emerging surgical intervention in the current world. The significance of such an intervention is that it involves the performance of surgical procedures on the fetus in utero. According to Deka et al (2012), such procedures are minimally invasive in nature, and its scope includes the use of endoscopes placed percutaneously through the abdominal wall of the pregnant mother under ultrasound guidance. Thus, the endoscopes have access to the placental surface, umbilical cord and fetus in utero. The performance of fetal endoscopic procedures (commonly known as 'fetoscopy') warrants the usage of special endoscopes with respective sheaths, cannulas and related instruments which need the special expertise of the professional who performs the surgery. It is evident that the in-utero treatment of a fetus through such procedures has currently been emerging in Sri Lanka and is famous in the field of fetal medicine. As a country which has a restrictive legal framework on the termination of pregnancy, the option of granting the pregnant woman the opportunity of in-utero treatment of the fetus is positively recommendable. However, the procedure is complicated as it involves two entities, namely the pregnant woman and the fetus. The paper discusses the significance of fetoscopic procedures, the necessity and background to impose regulations to balance the interests of parties.

The fetoscopy is an emerging medical procedure with ethical and legal implications. The main objectives of the paper are to analyze the ethical facets encompassing the pregnant woman and fetus in the scope of the procedure and to study the medical duty of care of the professionals involved in the process. Under the scope of the interests of the pregnant woman, the one patient and two patient models have been discussed. Further, the autonomy of the pregnant woman and the rights which originated from it including the informed consent law has been discussed. In the purview of fetal interests, the evolutionary technological advances and rights of the viable fetus as a patient have been elaborated. Subsequent to the discussion on the maternal - fetal aspects, the medical duty of care of the relevant professionals has taken into consideration.

METHODOLOGY

The methodology of the paper is qualitative. The author has analyzed primary and secondary sources of law. As the primary sources of law, the author has discussed guidelines issued by the professional bodies in the comparative jurisdiction: UK and the USA. Thus, the prominent focus is on the Royal College of Obstetricians and Gynecologists (RCOG), the British Medical Association (BMA) and the American College of Obstetricians and Gynecologists (ACOG). Further, case laws have been discussed in the paper. As the secondary sources of law, texts, research work on medical law and jurisprudence have been utilized.

RESULTS AND DISCUSSION

Fetal endoscopic surgery

Fetal endoscopic surgery or fetoscopy is performed to evaluate and treat the congenital disorders of the fetus in utero in the second - third trimesters of pregnancy (Cleveland Clinics, Ohio, USA). Thus, the procedure can be used for both diagnostic and therapeutic purposes. As per the exposition of Lea & Luqman (2023), when diagnostic purposes are concerned, fetoscopy facilitates the direct visualization of fetal structures, including the heart, lungs, urinary system and other fetal organs. In the context of therapeutic purposes, fetoscopic procedures are used for the twin-to-twin transfusion

syndrome treatment, amniotic band syndrome release, fetal urinary tract obstruction intervention, fetal lung lesion resection, intrauterine tumour resection and related interventions. John Hopkins Health Authorities specified that such procedures are used to facilitate intrauterine blood transfusion and spina bifida repair. In the view of Ruano & Vega (2019), the fetoscopic treatments in the current world are considered technologically advanced where techniques such as fetoscopic selective laser coagulation (FSCL), fetal endoscopic tracheal occlusion and fetal cystoscopy.

Interests of two patients: a pregnant woman and fetus

In general, fetal surgery (commonly known as maternal- fetal surgery) brings forth the idea of one or two patient models. One - patient model considers the pregnant woman as the sole patient and the fetus as an entity that is dependent on the existence of the former. However, the conceptualization of the two-patient model signifies that both the pregnant woman and fetus are two patients. Begovic (2021) identified the elevated status of human fetuses and recognized them as an individual with clinical interests. Begovic (2021) quoted the ethical framework introduced by *Chervenak & McCullough*: a fetus becomes a patient when the pregnant woman is presented for obstetric care.

Hallisey (1983) recognized that the rights of a pregnant woman in the context of undergoing fetal surgery are prominently based on autonomy and bodily integrity. It is evident that the performance of fetal endoscopic surgery or fetoscopy is done through the body of the pregnant woman placing endoscopes through the abdominal wall. Thus, her natural right to make decisions is considered mandatory. As discussed in the USA Supreme Court decision, *Griswold v. Connecticut* (1965), the necessity of reinforcing the constitutional right of privacy while developing the societal preference for autonomy is upheld. Her urge for bodily integrity is interknitted with the right to be free of unwarranted bodily intrusions. In terms of *Terry v. Ohio* (1968), bodily integrity means a right entitled by 'every individual to the possession and control of his own person, free from all restraint or interference of others. .' Thus, the consent or the voluntariness of the pregnant woman for the procedures is of utmost importance. *The clinical governance advice no.6 of the Royal College of Obstetricians and Gynecologists* enshrines valid consent of pregnant women. The process of obtaining informed consent should be taken place through a shared understanding and decision-making between the patient and the clinician. Before obtaining the consent of the pregnant woman's consent, it is mandatory for the relevant professional to provide her with information and ensure that she fully understands the nature of the condition, prognosis and the consequences and risks of the proposed treatment. The right to refuse a medically recommended treatment is significant in the course of pregnancy. As per the view of ACOG (2016), a decisionally capable pregnant woman's right to refuse medical treatment is respected, and the professionals are advised to avoid exercising coercion on such decisions. ACOG further restricts the forcible interferences in the decision- making process of pregnant women, including the court-mandated interventions on unwilling patients.

Under current medical advancements, a human fetus is not a recluse anymore. Malloy (2021) stated that the imaging of a fetus through ultrasound and intrauterine videos provided the parents and medical professionals with personal and intimate knowledge about its existence. Wyatt (2002) endorsed the view that the detection of fetal movements through developed technologies convinced the medical community that the fetus has hand-face contact, startle, sucking and swallowing movements, including rapid eye movements. Lenow (2021) has identified that the current context in medicine accepts that the scientific procedures support in revealing the 'undetectable secrets about womb's tiny inhabitants'. With time, the common law started the recognition of 'fetus' as an entity deserving protection. *Attorney General's Reference* (no.3 of 1994) dealt with an instance where a man stabbed the pregnant girlfriend in the abdomen which subsequently resulted in the piercing of uterus and injuring the fetus. The fetus was born alive and died. In this instance, the man was held guilty of manslaughter. With the gradual recognition in the scope of the law, the ethical dimensions of the fetus are noteworthy. In the current context, the status of 'fetus as a patient' is frequently discussed. Chervenak & McCullough (2016) stressed that, unlike a pregnant woman, the fetus with an

insufficiently developed central nervous system cannot form a perspective on its interests. Thus, fetal autonomy is considered non-existent. However, the medical professional who deals with a fetus has a perspective on the health interests of the same. Chervenak & McCullough (2016) argued that the professional owes beneficence-based obligations to the fetus only when it becomes a patient. Chervenak & McCullough (1996) has held that the beneficence to the fetus mainly depends on the 'viability'. The 'viability' of a fetus is a matter to be considered in the light of biological and technological factors.

Medical duty of care

The existence of two patients in a medical procedure creates doubts about the medical duty of care. Edozien (2012) that attitudes, communication skills, empathy, vigilance in documentation, and correct writing in prescriptions of a medical practitioner constitute the standard of practice. The role of a maternal-fetal specialist is prominent in enhancing the outcome of pregnancy. Philipson (1999) elaborated the role of a fetal medicine specialist is imperative in instances where diagnostic and therapeutic procedures are required due to the risks of fetal chromosomal abnormalities and specifically in instances where the pregnant woman is healthy, and the fetus is at a risk. 'Fetoscopy' is minimally invasive, and a considerable risk is involved. Deka et al (2012) endorsed the view that it is a safe procedure in the hands of an expert in fetal diagnostic and therapeutic techniques. Further, the performance of fetoscopic procedures requires the highest standard of skill, patience and the extensive use of ultrasound. The procedure is dependent on the use of advanced imaging technologies, which deal with a high-resolution camera attached to the fetoscope. The camera facilitates the direct visualization of the fetus (Lea, 2023). The fetoscope is introduced to the amniotic cavity under the continuous ultrasound guidance. Thus, it makes clear that a multidisciplinary team equipped with expertise is involved in the fetoscopic procedures. Deka et al (2012) identified that one of the main duties of the experts involved in the process is to minimize the risks of fetoscopy, namely preterm birth, preterm labour, premature rupture of membranes, loss of pregnancy, infection and bleeding. In the performance of the procedure, the medical professionals have to bear in mind two main concepts namely, 'fetus as a patient' and 'pregnant woman as an innocent bystander'. Thus, they face unique therapeutic and diagnostic challenges as to the intrauterine location of the fetus and the protection of the interests of the pregnant woman. In addition to the duty of care owed to the pregnant woman, the specialists owe a duty to the fetus where, at a breach, the liability for negligence arises. In the UK, the Congenital Disabilities (Civil Liability) Act 1976 imposes liabilities on medical professionals for the non-use of reasonable care, and the consequence of it creating a disability for the child. (Section 1 (5) of the Act).

Another emerging medical concept relating to fetuses is 'fetal pain'. As per the BMA (2020), the pain perception is not applicable to the fetuses under 28 weeks of gestation. However, the British medical community recommends the doctors to take effective measures to minimize the pain of fetuses throughout procedures. Such recommendations imply that there is a medical duty of care to the fetus owed by the anesthesiologists in the performance of fetoscopic procedures. In addition, the enactment of fetal pain legislation has become an emerging legal development in USA,

CONCLUSIONS/RECOMMENDATIONS

In-utero treatment of the fetus is an emerging surgical procedure in the field of fetal medicine. Among the procedures so identified, fetoscopy is of imperative concern. Fetoscopic procedures deal with the use of endoscopes with sheaths, cannulas and related tools to reach the fetus in the womb of the pregnant woman. The performance of a fetoscopy necessitates professional skills and expertise. The pregnant woman's autonomy and her ability to make voluntary, free decisions is an imperative concern. In parallel to this, the professionals involved in the procedure should respect the right to refuse medical treatments. 'Human fetus' has an evolutionary history. Before the advances in technology, the real image of the fetus was unknown to the public. However, developments in

ultrasound technologies have convinced that the fetus is entitled to the beneficence-related interests. In the treatment of the pregnant woman and the fetus, the specialist has to exercise the duty of care with high professional standards and patience. Fetoscopy, being an ultrasound-guided procedure, needs the fetal medicine specialist who performs it to have higher expertise in ultrasound. The emerging medical concept of 'fetal pain' and the duty of care of fetal anesthesiologists are of paramount importance. Thus, it is evident that in the formulation of legal and ethical guidelines, the autonomy and beneficence- based obligations to the pregnant women should be balanced with the beneficence-based obligations to the fetus.

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