ETHICAL AND LEGAL ISSUES IN REPRODUCTIVE HEALTH

Legal and ethical issues in fetal surgery

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A R T I C L E   I N F O

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A B S T R A C T

Recent research in the USA has shown the advantages for children’s welfare of open fetal surgery over postnatal treatment for myelomeningocele. However, a balance must be struck between complications of premature birth risked by prenatal surgery and the long-term advantages for affected children’s health, including mobility and neurologic capacity. Risks for women are repeated surgery for intervention and delivery. The research raises legal and ethical questions about how fetal interests should influence women’s choices, and whether women may decline interventions in their pregnancies that offer their children lifelong advantages. Beyond fetal interests and women’s preferences are state interests in fetal life, which in the USA and elsewhere have been expressed in judicially authorized cesarean deliveries. Underlying issues are the nature of fetal interests; contrasting entitlements to care from their mothers of fetuses and born children; healthcare providers’ responsibilities toward fetuses; and duties of care, information, and advice to pregnant women.

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1. Introduction

Until recently, fetal surgery has been undertaken only when fetuses or infants on birth are otherwise likely to die. A decade-long US study published in February 2011 has shown, however, that fetal surgery is feasible, despite its risks, to improve the health of infants affected by a condition that is not in itself life-threatening [1]. In a study of myelomeningocele, the most common form of spina bifida, 183 women in whose fetuses the condition had been identified were randomly assigned either to standard postnatal care of their infants or to prenatal fetal surgery before 26 weeks of gestation. Comparative outcome criteria of fetal/neonatal death or the need for placement of a cerebrospinal-fluid shunt by the age of 12 months, and mental development and motor function at 30 months showed efficacy of the prenatal surgery. The trial was accordingly stopped after recruitment of 183 of the planned 200 patients, on recommendation of the independent data and safety-monitoring committee.

The study outcomes should be treated with some caution. Fetuses treated in utero were born at an average gestational age of 34.1 weeks, and 13% were delivered before 30 weeks of gestation, whereas those treated postnatally had an average of 37.3 weeks of gestation, and none was delivered before 30 weeks. One-fifth of the former showed respiratory distress syndrome, probably due to prematurity. Furthermore, all eligible cases in the USA had been funneled into 3 study centers, which developed a high level of specialized skill in the required procedures that less experienced hospitals would lack [2]. A related consideration is recognition that all women who undergo prenatal surgery face risks that indicate that all subsequent pregnancies should result in cesarean deliveries before the onset of labor [1] (p.1001).

Nevertheless, the study was taken to advance arguments for fetal surgery. One commentator summarized the study as showing that “[f]etal surgery, while increasing premature births and causing tearing at some mothers’ incisions, made babies more likely to walk and less likely to have neurological problems or need shunts to drain brain fluid” [3]. This encouraged the conclusion that the study “is likely to galvanize interest in trying to address problems before birth, including operating on serious heart defects and bladder blockages, and potentially using fetal bone marrow or stem cell transplants for sickle cell anemia and immune disorders” [4].

When women may be offered surgery—not for their own benefit or to preserve the precarious lives of the fetuses they carry, but in the hope of improving on treatments for conditions that are now treated only following birth—a number of legal and ethical issues arise. They concern, for instance, duties owed to fetuses intended to become children, fetal status in utero, therapeutic innovation, and fetal research.

2. Fetal interests

Whether fetuses have an inherent moral status or the status that societies, cultures, or individuals attribute to them is a matter of unresolved philosophic and social debate. Deception arises when a status is advocated instrumentally, particularly in order to limit women’s claims to abortion. It is unacceptable in modern law and ethics, on grounds of non-discrimination, that pregnant women should possess lesser rights to self-determination than men and non-pregnant women because they carry a fetus. Women who intend
to bear children have ethical responsibilities before birth, but are
ettled to balance those responsibilities against other responsibilities
they feel toward the wellbeing of others, such as existing dependent
children, their partners, parents, and other family members. Third
parties cannot ethically impose their priorities over women’s choices.

Legal systems determine when, in law, a fetus acquires the status
of a “human being.” For instance, the position in the English Common
law system, widely followed in the many jurisdictions that apply
that system, is embedded in the Canadian Criminal Code. Section 223
(1) provides that “[a] child becomes a human being…when it has
completely proceeded, in a living state, from the body of its mother
whether or not (a) it has breathed, (b) it has an independent
circulation, or (c) the navel string is severed.” Because they are not
human beings as understood in law, including international human
rights law, fetuses do not possess human rights [5]. However, fetuses
are often recognized to have interests [6], of which they may be
availed on live birth. For instance, when individuals by will leave
gifts to their unnamed “grandchildren” and die when a daughter or
daughter-in-law is pregnant, the estate will not distribute assets until
the outcome of the pregnancy is known, in order to preserve the fetal
interest in inheritance.

Unlike a born child, a fetus is not a “patient” in a real sense, but only
by metaphor. It is analogous to a patient when the woman who carries
it, and wants care for it, is a patient. All services to her fetus will be
independent, and billed, in her name. The concept that a fetus is a patient
is usually a benign fiction, recognizing that treatment of a pregnant
woman is liable to affect her fetus. However, it would be unethical if a
care provider, without the woman’s informed consent, promoted the
interests of the fetus over those of the woman [7]. When the woman
wants care for her fetus, of course, their interests coincide.

3. Consent to fetal surgery

The background legal and ethical questions that arise once fetal
surgery is shown effective for promoting children’s general long-term
health interests are not whether pregnant women can give their
informed consent to it, but whether they can decline. Parents have
clear legal responsibilities to provide or consent to their born children’s
necessary medical care, but maternal duties to fetuses in utero are not
generally recognized. In England, the Congenital Disabilities (Civil
Liability) Act 1976 excludes children from suing their mothers for
injuries caused by mothers’ prenatal negligence (except in traffic
accidents). Some courts, such as in Canada [8], have explicitly ruled that
pregnant women owe no legally enforceable duties of care to their
fetuses, such as to drive carefully, avoid consumption of alcohol, or
submit to prenatal surgery. Legal action can be taken on behalf of
newborn children against others for prenatal infliction of injuries,
but not against their mothers. The general human rights to security
of the person and bodily integrity usually protect pregnant women
against unwanted abdominal surgery.

Fetal surgery is still considered rare but may be indicated for such
diagnosed fetal congenital conditions as diaphragmatic hernia,
heart disease, and urinary tract blockage. In open fetal surgery, a
hysterotomy is performed—comparable to a cesarean—and the fetus is
exposed and may be partially removed while remaining dependent
on the placenta. On conclusion of surgery, the fetus is replaced in the
uterus and the abdominal wall is closed for continuation of gestation.
For birth, the fetus will be surgically delivered. Less stressful for
women is minimally invasive fetal surgery, in which real-time video
imagery from fetoscopy and ultrasonography guide small surgical
instruments through little more than single needle-punctures of the
women’s abdomens.

A risk of open fetal surgery is premature labor, with all the
complications for the newborn of premature birth, as occurred in the
spina bifida research [1]. Women considering fetal surgery need to be
adequately counseled on the risks, as well as the potential benefits, of
pregnancy—as opposed to postpartum neonatal or subsequent—surgery.
Women may also need to be cautioned about the belief, sometimes
considered common among pregnant women and their partners, that
their fetuses are already “babies” and that it is necessary that they
receive immediate treatment, if possible by open fetal surgery [9].
Obstetrician–gynecologists may have to be guarded regarding
pregnant women’s vulnerability to their beliefs and anxiety regarding
their children’s potential disabilities, and also against their own
professional enthusiasms and biases in favor of open or other fetal
surgery [9].

However, should fetal surgery come to be seen as an indicated
alternative to standard postnatal care, physicians might face legal
liability—for negligence, for instance—if they fail to inform women
of its availability whose fetuses are affected by neural tube or other
genital defects treatable in utero, at their own or other facilities
reasonably accessible to the women. They would bear a legal duty of
care to parents to inform them of all reasonable treatments from
which their children might benefit [10]. In addition, physicians might
be liable to children themselves who could have been spared
disabilities by prenatal treatment. The measure of compensation
sought would be the quantified difference between the children’s
condition and prospects in life, such as employment and marriage,
after postnatal treatment and what their condition and prospects
would probably have been following arguably superior fetal surgery.

Different legal duties that women owe to their born children and
their unborn children focus attention on when birth occurs. The
widely followed Common law provision, expressed in the Canadian
Criminal Code s.223(1), is that a child becomes born as a human being
when the child “has completely proceeded…from the body of its
mother whether or not…the navel string is severed.” If, in open fetal
surgery, a fetus was entirely removed from the uterus, in order to be
replaced after surgery for continuation of gestation, the surgical
removal might constitute a first “birth” [11]. To escape the anomaly of
a neonatal human being that is contained entirely within the uterus of
another human being, however, courts are likely to rule that
“completely proceeded…from the body” be determined not simply
by the 3 dimensions of space, but also by the fourth dimension of time.
A fetus entirely removed from the uterus only temporarily, in order to
be replaced for subsequent permanent birth, will not be considered
yet to have been born.

4. State interests in fetal life

In addition to possibly competing interests of pregnant women and
their fetuses are interests of states themselves, sometimes represented
by their governments’ legal officers. States’ interests in fetal life
acquired prominence in setting a limit to women’s constitutional
rights to abortion in the USA. States’ interests did not depend on the
fetus being a “human being” or “person” in law. In his majority
judgment in the US Supreme Court, in the historic case of Roe v. Wade,
Justice Blackmun observed that “a state may properly assert important
interests…in protecting potential [i.e. fetal] life. At some point in
pregnancy…interests become sufficiently compelling to sustain
regulation of the factors that govern the abortion decision” [12]
(p.727). He elaborated that “[w]ith respect to the state’s important and
legitimate interest in potential life, the ‘compelling’ point is at
viability…If the state is interested in protecting fetal life after viability,
it may go so far as to proscribe abortion…except when it is necessary
to preserve the life or health of the mother” [12] (p.732).

Several jurisdictions have shown their interests in fetal life, not
just passively in prohibiting abortion but actively through courts
ordering women to submit to cesarean deliveries of fetuses whose
lives were considered at risk in natural childbirth. Some lower-court
judges who have accepted contrived mental health arguments to
displace pregnant women’s power to govern their own pregnancies
when their fetuses were considered at risk have, however, been
It may be accepted that courts would not order open fetal surgery against a pregnant woman’s wishes when alternative treatment of her fetus capable of being born alive can be undertaken postnatally. The comparison with cesarean surgery is relevant because, as the full Court of Appeals of the American District of Columbia emphasized, “it would be an extraordinary case indeed in which a court might ever be justified in overriding a patient’s wishes and authorizing a major surgical procedure such as a cesarean section” [15] (p.1252).

The Court left open, however, where the line might be drawn between major and minor surgery. Minimally invasive fetal surgery might be contrasted with major surgery. If prenatal treatment of fetuses was shown to be of great benefit to born children’s health and lives to an extent that surgery postponed to the postnatal stage could not achieve, and such treatment could be undertaken by minimally invasive surgery, a court might be prepared to consider that the state’s interest would justify ordering surgery against the woman’s wishes.

This possibility may appear most likely to occur in the USA where, following the Supreme Court’s recognition of state interests in fetal life at prenatal viability [12], some states have exceptionally recognized fetal personhood at viability. Several prosecutions have been successful in trial courts for child abuse against pregnant women, though the prosecution of attempted homicide became a matter of legal uncertainty. Where postnatal care was routine, not experimental. Similarly, those treated for spinal malformation. The special feature of the study, of course, was that, according to the research protocol, and the retrospective comparative review of systematic data, which treatment offers greater advantage. Of legal authority is not necessarily ethical, and is always open to ethical challenge.

Discussion of the law and ethics of fetal and pediatric research requires scrutiny of what elements of the spina bifida study constituted research. Randomization of the treatment of the 183 eligible women who agreed to enter the study was research, in that their treatment was governed not by a clinical judgment of what was in the best interests of each individual woman and her prospective child, but by the research system of random allocation. However, the actual treatment of the women and children allocated to standard postnatal care was routine, not experimental. Similarly, those allocated to prenatal fetal surgery received treatment that was indicated by the conditions shown on exposure of the fetuses. This treatment was not experimental in itself but may have been seen as somewhat novel therapy, or therapeutic innovation.

What was new in this research was the concentration of all of the cases within the 3 medical centers afforded exclusive control of all instances of fetal surgery for spina bifida in the USA between February 2003 and December 2010, the systematic follow-up testing of the 158 children who remained accessible to the investigators, and the retrospective comparison and contrast of the follow-up data of how the children were able to function—for instance, regarding their mobility and neurologic capacity. That is, the research component of the study was not in the prenatal surgical and/or postnatal management of each child, but in the systematic control of each case according to the research protocol, and the retrospective comparative review of all of the outcome data. The new knowledge came from rigorously scientific evidence of the comparative effects over time of fetal surgery in contrast to standard postnatal care of children born with spina bifida, to replace anecdotal evidence and presumptions from unrelated instances.

An issue on which leading US ethicists are divided [3] concerns the concentration of all cases eligible for the study into only 3 hospitals. The medical community believed that, if the surgery was available elsewhere, few women would agree to participate in a definitive study. Accordingly, for almost 8 years, physicians in all but the 3 US hospitals conducting the study agreed not to offer open prenatal surgery for spina bifida cases. Some ethicists believe that physicians in other hospitals who believed—correctly, as it turned out—that prenatal surgery was preferable for children wronged their patients who did not want to be referred to 1 of the 3 study hospitals by declining to offer it, and denied the chance of significant lifelong benefits to their children.

However, others consider it of redeeming benefit to all future parents and children affected by spina bifida to know, by independent review of systematic data, which treatment offers greater advantage. This benefit justified conduct of the study in a way that ensured that the surgical techniques and follow-up measures would be reliably controlled, standardized, and monitored. Physicians outside the study centers might not have applied the surgical techniques and follow-up measures developed at the 3 study hospitals sufficiently consistently to achieve confidence in the outcome. This confidence persuaded the independent data-monitoring board to end the study prematurely, in order not to preclude the offer of its benefits from women and their children whose randomization might deny them access.
6. Conclusion

The study of open fetal surgery for spina bifida has shown the advantage that this procedure offers children diagnosed in utero to be affected by this condition. Had the study shown that the procedure was no better or of less benefit than postnatal treatment, however, it would still have been beneficial for the information of women offered a choice of prenatal intervention. Studies do not have to prove superiority of the procedures under investigation in order to be ethically justified. Studies that disprove false beliefs are as ethically justifiable, and as valuable, as those that allow a hypothesis of superiority to be created or sustained.

In future diagnoses of fetal spina bifida, women in the USA and elsewhere where open fetal surgery is available will have to be informed of this treatment option. Information must be given not only of its advantages for the child’s future but also of its implications for the woman, including cesarean delivery at the end of this and perhaps any subsequent pregnancy. The woman will then exercise her own judgment on whether to take the disadvantages of the procedure for her and her child, such as possible premature birth, for the sake of its advantages. The woman’s choice should not be open to challenge on legal or ethical grounds. Fetal life itself is not at stake, and state agents and courts would egregiously violate a woman’s human rights in seeking to overturn her decision to decline prenatal surgery, or to accept it where it is available.

References


[15] In Re AC (1990), 573 Atlantic Reporter (2d) 1235 (District of Columbia Court of Appeals, en banc).


