Ethics, Legal, Social, Counselling Article

Legal Aspects of latrogenic Multiple Pregnancy

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Abstract.

During Assisted Reproductive Technology (ART) procedures, the transfer of a single embryo dramatically reduces the rate of multiple pregnancy. Proper information, therefore, should be delivered to patients before embryo transfer. In many countries, regulations limit, according to age of the patient, the number of embryos to be transferred. Selective fetal reduction should not be considered as a suitable alternative to a single embryo transfer policy. The international federation of obstetricians and gynaecologists (FIGO) recommendations on Multifetal reduction outline that the priority should be a careful planning and monitoring of infertility treatment for the reduction or avoidance of multiple pregnancy.

Keywords: Multiple Pregnancy, Iatrogenic, Fetal Reduction

Introduction

There is growing professional and public concern about the incidence of multiple pregnancy resulting from techniques of *in vitro* fertilization (IVF), and from hormonal stimulation of ovulation resulting in multiple pregnancy by natural fertilization. Even twin births are considered counter-therapeutic. This paper primarily addresses twin pregnancies, but statistics for triplet and higher pregnancies are exponentially higher. It has recently been observed that:

Multifetal pregnancies, and most notably triplet or higher-order multiple gestations, are associated with a significantly increased risk of adverse clinical outcomes, primarily owing to prematurity and its shortterm and long-term sequelae. Neonatal mortality is four times as great among twins as it is among singletons, and twins are at increased risk for long-term disability, including cerebral palsy (1).

This observation was based on a study that concluded that:

In women under 36 years of age, transferring one fresh embryo and then, if needed, one frozen-andthawed embryo dramatically reduces the rate of multiple births while achieving a rate of live births that is not substantially lower than the rate that is achievable with a double-embryo transfer (2).

The statistics showed that rates of multiple births in women who received double embryo transfer were 33.1%, and 0.8% when single embryos were transferred.

A legal aspect of evolving concern with even twin

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* Corresponding Address: Hôpital Saint Antoine, 184 rue du Faubourg Saint Antoine, 75012, Paris, France Email: j.milliez@sat.aphp.fr pregnancy resulting from medically assisted reproduction is its impact on counselling for IVF patients' informed consent. Professional, regulatory and similar IVF guidelines may limit practitioners to placement in utero of no more than three or two embryos in one menstrual cycle. Women should be advised of the prospective positive and negative effects of adhering to such guidelines, however, particularly on achieving pregnancy, the chance of multiple pregnancy, and the hazards of multiple pregnancy to fetuses, newborn children, mothers, and families, and in cases for instance of secondary infertility, families' existing children. The alternative of single-embryo transfer should be addressed, through information of its slightly reduced chance of resulting in pregnancy, its greater likelihood (but not a guarantee) to prevent twin or higher pregnancy, and its effect on the cost of treatment and the timing of treatment for repeat transfer.

Studies have long associated twin pregnancy with a series of significant changes in mothers' organ systems that, in nonpregnant women, would be considered seriously pathological (3). Commonly encountered maternal complications include elevated risk of miscarriage, covering both total miscarriage and the "vanishing twin" phenomenon discussed when first trimester ultrasound diagnosis of twin pregnancy results in singleton birth, preterm labour and delivery, anaemia, hypertension, polyhydramnios and related complications of bed rest, antepartum and postpartum haemorrhage, and



Royan Institue International Journal of Fertility and Sterility Vol 3, No 2, Aug-Sep 2009, Pages: 84-86 operative instead of natural delivery. Twin fetuses may suffer restricted development in utero and, at delivery, the physiological and neurological disadvantages of premature birth and low birth weight (4). Even when children of multiple pregnancy are born or later become normally healthy, rearing them may be disproportionately stressful and fraught with practical difficulties for parents, with impaired maternal bonding, social estrangement, marital disharmony and depressive illnesses (5).

The family-based difficulties that may arise when, due to multiple pregnancy, an infertile couple suddenly becomes responsible for an "instant family" may not be directly medical, but are central to health as understood by the WHO, namely as a state not only of physical well-being, but also of mental and social well-being. If physicians are reluctant to undertake counselling, such as on risks, causes and family responses to perinatal mortality, for which the rate in twins is nearly five times higher than that in singletons (6), they should refer patients considering IVF and hormonal stimulation to appropriate alternative counsellors or support groups. It may be challenging, however, for any counsellor to prepare an infertile couple to celebrate the birth of a wanted child while at the same time mourning the death of its twin.

Equally emotionally challenging, but a responsibility physicians may be unable to escape, may be informing patients in infertile partnerships who are considering procedures that may result in multiple pregnancy, of options of multifetal (or "selective") reduction. This is also a matter of peculiarly legal concern, on which practitioners may require advice on the criminal and non-criminal (that is, civil) laws of their jurisdiction. Termination of fetal life in utero may meet medical definitions of abortion, but not necessarily legal definitions. Where abortion is defined in law, by enacted law or judicial interpretation, as terminating a woman's pregnancy, or, in more historical language, as procuring her miscarriage, multifetal reduction may fall outside the definition, since its purpose is not to terminate pregnancy, but may indeed be, on the contrary, to promote its continuation and prevent miscarriage. Further, where abortion is lawful to preserve a pregnant woman's life or health, multifetal reduction may be so justifiable, although a practitioner undertaking or counselling a procedure on this ground may be well advised to obtain a second medical opinion on the woman's prognosis. It is widely recognized, however, that the health-protecting indication for therapeutic abortion covers both physical and mental health, so that anticipated distress due to delivery and rearing of children may be taken into account.

If ultrasound, optic fibre visualization (fetoscopy), or other reliable prenatal diagnosis shows one fetus to be severely compromised or abnormal, selective reduction to remove it may also be justified where a legal abortion indication of severe fetal handicap or gross disfigurement is recognized. Where law provides, as, for instance, in Britain, that abortion is lawful when account is taken of prospective injury to the health of "existing children" of the mother's family (Abortion Act 1967, s. 1(1) (a)), it may be straining language too far to claim that this can justify selective reduction of one of two or more normally healthy fetuses contemporaneously in utero. However, current data and attitudes seem no longer to support professional refusal to reduce a healthy twin to a singleton pregnancy. Practitioners refusing their patients' requests for selective medically indicated twin to singleton reduction have a legal duty to refer their patients to other practitioners known not to object.

Discussion of practitioners' legal duties to inform patients of risks of induced multiple pregnancy, and of options for its management and reduction, supposes legal liability for failure to discharge such duties to the satisfaction of legal standards. Liability may arise for breach of contract when practitioners are paid, by patients or third parties on their behalf, on a fee-for-service basis. Salaried staff-members may be employed by clinics that charge patients fees, so that contracts will be between clinics and patients, clinics bearing vicarious liability for their employees' misconduct. Independently of contractual liability, defaulting practitioners may also be liable for breach of fiduciary duty, where that legal concept is recognized and considered applicable. The key issue, however, is potential liability for negligence. In many significant legal systems, liability for the tort, or delict, of negligence is based on:

i. A legal duty by a defendant to the complaining party;

ii. Breach of that duty, often shown by the defendant's failure to perform in compliance with the legally-determined standard of care

iii. Legally recognized injury or damage

iv. Evidence that the injury or damage was caused by this breach of the duty of care.

Courts have been resistant to finding that birth of a baby is a form of legal injury or damage. Reflecting cultures that historically approached the births of babies as a blessing or divinely shaped gift, and reluctant to stigmatize children at the beginning of their lives as injuries or damage to their parents and families, judges have been unpersuaded to award compensation for negligently-performed sterilization procedures, and might remain conservative regarding claims of negligently-induced multiple pregnancy. Where modern legal systems have "burst the blessing balloon," they may be willing to award only modest damages. If children are born with predictable genetic or congenital injuries, however, courts finding negligent practices or counselling resulting in conception might award financial compensation based on the difference in costs of rearing the impaired as opposed to unimpaired children.

This is an area of the law in which courts in westernized countries often have developed their own distinctive jurisprudence, sometimes in deliberate comparison with and/or contrast to the law in other countries. Approaches range from maintaining a "no recovery" rule, reflecting birth as an unlimited blessing, to, though very exceptionally, regarding birth as an injury that entitles parents to compensation for the costs of rearing the child from birth to adulthoood. Most legal systems are more willing to find the birth of predictably handicapped children more compensable than birth of healthy children, and if they allow recovery for birth of a healthy child, they are likely to offset the quantified benefits a child brings to parents against the costs of upbringing, including to a point of extinguishing parental recovery entirely. There is widespread, although not uniform, agreement that births are not to be approached as legally actionable injuries to the children themselves, and that women should not be legally expected to mitigate their injury by termination of pregnancy, or even by multifetal reduction.

From the perspective of practitioners at risk of being found negligent or otherwise legally liable for treatment that results in multiple pregnancy, and for any of the compensable injuries to which it leads, it is worthwhile to observe that their legal liability is an insurable interest. If risks of having to compensate injured patients are not covered by membership of a medical professional self-protection association or union, practitioners may seek the financial protection of commercial insurance policies, reflecting costs of the premiums in patients' fees. Such insurance contracts, in contrast to any for criminal legal liability, are not contrary to public policy. Patients may also be advised to seek their own insurance coverage for any injuries they suffer due to multiple pregnancy, but this does not reduced practitioners' potential liability since patients' insurers may exercise rights to require parents to press legal claims against practitioners for recovery of compensation entitlements, from which patients' insurers can be reimbursed for payments they have made.

FIGO recommendations on Multifetal reductions (7)

Recommendations:

1. Multiple pregnancy of an order of magnitude higher than twins involves great danger for the woman's health and also for her foetuses which are likely to be delivered prematurely with a high risk of either dying or suffering damage.

2. Clinical priority should be by way of careful planning and monitoring of infertility treatment for the reduction or avoidance of multiple pregnancies. However where such pregnancies arise it may be considered ethically preferable to reduce the number of foetuses rather than to do nothing.

3. Multifetal reduction is not medically considered as terminating that pregnancy but rather as a procedure to secure its best outcome.

4. Information provided must include the risks to mothers and foetuses with and without foetal reduction including miscarriage. Whether the couple decides to maintain or to reduce high order multiple pregnancies they should be assured that they will receive the best available medical care.

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