Ethical Aspects of Fetal Heart Interventions

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The treatment of fetuses with altered cardiovascular physiology due to critical valvular stenosis or atresia is a complex clinical situation involving several ethical issues.

In contemporary clinical practice, a prenatal diagnosis of these pathological situations usually leads to the termination of pregnancy (TOP), that is offered, according to the different legal issues in different countries. It must be kept in mind and eventually discussed with the patient that, in early diagnosis, legal constraints on gestational age limit for TOP together with the development of defensive medicine may lead to an increasing number of women opting for TOP [1]. Fetal heart interventions (FHI), under these circumstances, are an alternative to TOP, offering to women the choice to continue their pregnancies and to more babies to reach birth with an acceptable outcome.

There are no laws forcing a pregnant woman to undergo invasive fetal treatment outside mainly historical legal orders of performing caesarean section for fetal distress [2]. Embarking on fetal invasive therapy or surgery is a demanding

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G. Butera et al. (eds.), *Fetal and Hybrid Procedures in Congenital Heart Diseases*, DOI 10.1007/978-3-319-40088-4_1

commitment, not only for the heaviness of the immediate treatment but also for the long-term consequences, encompassing perinatal care, postnatal management, and follow-up, including medical and social aspects, which cannot be successful without the full and active cooperation of the pregnant woman.

Given the complexity, the risks (for both woman and fetus), and the long-lasting effects of this specific interventional treatment, particular care must be paid to the practice of informed consent (IC). Moreover, it is mandatory for the ethical standard of any medical act to be aware of its shortcomings. Autonomy and human dignity are respected and promoted in the IC through accurate and complete information on the medical act, with all the benefits, side effects, and risks that it implies. The IC refers to the clinical perspective of a physician who performs his job with responsibility, fairness, and conscience, through the evidence-based medicine. The main aim has always been the patient's interest.

In order to avoid possible conflict of interests, a third person should ideally be in charge of the IC procedure. Nevertheless, when this is not possible and the information is provided by the same operator, the potential conflict must be disclosed and handled with particular care. It is also important to keep in mind that words such as child, baby, mother, and parents have important emotional impact. It must be considered if it is worthwhile to avoid them, using more neutral terms such as fetus, womb, and pregnancy, whose connotation is anatomical or functional. It is not only a linguistic choice but also an ethical one [3–4].

It is important for the IC:

1. To clarify that the aim is to increase the chances of biventricular repair [5–7], to underline fetal risks (pro and cons) either in case the FHI would be performed or in case the procedure wouldn't be performed, and to report, from most recent data, what is the clinical success rate [8–14]
2. To explain to the mother and the couple how the FHI will be held, detailing the steps of the procedure and the anesthesia for both mother and child and to deeply take into consideration both physical and psychological mother risks [15]
3. To remind that this is not a stand-alone intervention and patients will require a combination of repeated balloon aortic valvuloplasty, coarctation repair, endocardial fibroelastosis resection, and mitral or aortic valvuloplasty

The limit of the IC in this field is the paucity of data and the lack of:

(a) Data on progression of the lesions to determine whether outcome would be favorable or unfavorable. *There is a conflict of timing particularly in the diagnosis and treatment of critical aortic stenosis (AS) and intact atrial septum. On the one hand, it seems logical that earlier fetal intervention could reverse pathophysiology at least in case of AS. On the other hand, the earlier the decision is made to intervene, the less confidence the physicians have that the defect will ultimately progress to hypoplastic left heart syndrome* [16].
(b) Randomized studies on real utility of the procedure. Many argue that only a properly designed, adequately powered, and meticulously conducted

prospective trial, ideally randomized, would sufficiently overcome bias. The counteragument is that available data [8] allow to differentiate, in well selected cases, what patients were highly likely to evolve toward hypoplastic left heart syndrome and what were born with a nearly normal-sized left ventricle after fetal valvuloplasty.

Because of these reasons, women's request for treatment while refusing to enter a trial is not a rare situation. Finally, nowadays, it is preferable to take the stance of a controlled trial with possible crossover, in case of worsening of fetal conditions, being the only way to access treatment, even if TOP is then requested when treatment cannot be offered.

IC is only a part of the communication and counseling. It is very important to build a multidisciplinary team to overcome the possible difference from clinical background of different practitioners. In fact, for example, fetal cardiologists and pediatricians accord somewhat less weight to maternal decision-making than obstetrics and shift the focus of care to the fetus and perhaps privilege the interests and claims of the fetus over those of the pregnant woman [17, 18].

Ethical issues specifically related to fetal therapy articulate to a large extent around the transition between experimentation, therapeutic innovation, and standard of care. Our ability to diagnose and treat several fetal conditions has developed more rapidly than our understanding of their short-term and, even more so, long-term outcome in both treated and untreated cases.

Enthusiasm for fetal intervention must be tempered by mindfulness of the interests of the mother and her family, by careful study of the natural history of the disease in untreated human fetuses, and by willingness to abandon therapy that does not prove effective and safe, in properly performed trials.

To date, clinical results of maternal/fetal intervention for AS are based on comparisons with historical controls and address efficacy (Technè) rather than safety (Praxis) [19, 20].

In conclusion, interventional fetal cardiology is a model where ethical considerations must guide decisions, aimed to minimize damages and to increase success rate of proposed interventions. Such opportunity of applied ethics has to produce the right choice to realize the beneficence of the mother, fetus, and future child.

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