Chapter

Innovation and Research in Cardiac Surgery: Bioethical Aspects

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Abstract

Significant advancements have been made in Cardiac surgery during the last decades, thanks to technological evolution. The enormous progress achieved has led to a relevant improvement in terms of surgical results, and at the same time, new ethical dilemmas have been addressed. Until the 90's ethics in cardiac surgery mainly concerned significant moral problems caused by the introduction of extremely innovative techniques. However, today's ethical issue focuses essentially on the doctor-patient relationship, other aspects of doctor's practice concern relevant ethical perspectives. Ethics affects today the activity of the surgeon and the doctor in general. It is possible to distinguish clinical ethics, an ethics of health policies, and scientific research ethics. In the following chapter, we try to analyze the main ethical aspects concerning the application of cardiac surgical procedures.

Keywords: informed consent, LVAD (left ventricle assist device), destination therapy (DT), pandemic

1. Introduction (Informed consent)

In surgery, up to the 1960s, "paternalism" was an accepted and well-regarded tradition. The surgeon chose "the best" for his patient, who had a passive role in the choices regarding the treatment of his disease. On the other hand, in modern medicine, the patient collaborates with the surgeon to pursue the ultimate good, that is, health and recovery from illness [1].

For this reason, the act of informed consent does not represent a simple proof of the patient's consent to treatment but describes the patient's awareness of the pathology and the proposed therapies. Informed consent is not obtaining a signature on a piece of paper but a complex information process made up of different parts. Three main sets of elements characterize informed consent and are the initial conditions such as capacity and voluntariness; information, characterized by explanation and related recommendations; consent including decision and authorization [2]. For preceding conditions, we mean the ability to understand information and to make decisions voluntarily. The lack of this capacity is not uncommon and often not recognized, although many tools are available to evaluate and measure it. Voluntariness is present when the patient's choices are intentional and not conditioned by coercion or external influences. Surgeons should avoid putting pressure on patients by emphasizing benefits and minimizing risks. The information

elements include a detailed explanation of the nature of the disease and the treatment options. Risks, benefits, potential consequences of the recommended therapy, and possible alternatives must be elucidated. The likelihood of success, the prognosis without treatment are other aspects to explain. The elements relating to consent conclude the informed consent process. The decision made by the patient reflects which therapeutic option among those proposed to him he considers the best based on the information obtained. The consent is signed by both parties, like a real contract [3].

As proposed by the Italian Society of Cardiac Surgery, there are five informed consents that most commonly concern the cardiac surgeon's activity:

1. Consent to coronary examination, coronary angioplasty, and interventional procedures (in collaboration with the cardiologist);

2. Consent to the processing of personal data for scientific purposes

3. Consent to cardiac surgery

4. Consent to transfusion of blood products

5. Consent of the patient's family members (in particular situations)

Before signing the consent, the patient must make autonomous decisions, without external pressure (from the doctor, the family), understand the severity of the disease, and the risk/benefit ratio of the proposed interventions.

However, the surgeon remains a point of reference for the patient, who, however, informed and aware, entrusts his or her life in the hands of another person; for this reason, the surgeon must direct and advice based on their knowledge and scientific updating. This situation, for example, emerges in cardiac surgery when the patient, who is going to undergo a valve replacement, must choose between a biological and mechanical prosthesis. It is also possible that the surgeon finds himself in a condition of "paternalism, "which means he must make the decision "for the patient" who intends to leave him the choice of the valve prosthesis to be implanted. In this case, this must be reported in the written consent. Furthermore, the surgeon has to stratify the risk for each patient based on his experience and use the most recent risk calculators (EUROScore I and II - European System for Cardiac Operative Risk Evaluation, and STS score - to help him). Society of Thoracic Surgeons score) useful for risk stratification and calculating the risk/benefit ratio [4].

2. Appropriateness of care

The theory of evaluative dynamism considers each therapeutic choice as proportionate/disproportionate; ordinary/extraordinary. The use of a means of life support is considered "proportionate" to the extent that it proves adequate to achieve a specific health goal. The proportionality of the therapeutic option is given by availability, technical possibility, and efficacy. Side effects and risks, possible therapeutic alternatives must be evaluated, and required technical and economic resources should be quantified. The extraordinary judgment correlates with a reasonably high probability of severe risks to the patient's life and health concerning his clinical condition and a low overall efficacy rate. When the effort to find the therapeutic option for life support is very high, or if the choice is linked to severe physical pain and the economic costs are too burdensome for the patient or his

relatives, a judgment of extraordinary nature and, therefore, sometimes of disproportionality is configured [5]. In clinical practice, it is mandatory to use this ethical axiom: it is the duty of the doctor to use any proportionate and ordinary means for the treatment of the disease, the use of disproportionate and ordinary methods or proportionate but extraordinary measures may be optional; while it is not ethical to use means that are disproportionate and extraordinary at the same time.

3. Professional self regulation

Professional self-regulation is a personal or collective process of supervision that reflects the ethical concept of responsibility for patient care and includes accountability for that care's scientific and clinical quality. The self-regulation process is best exemplified by introducing the clinical practice of critical reviews through routine meetings on mortality and morbidity [6].

4. Ethics in LVAD as DT

Left ventricular assist systems (LVAD) are widely used to treat patients with heart failure refractory to medical therapy as a bridge to heart transplantation [7]. In subjects who have severe comorbidities such as compromising their inclusion in the transplant list, LVADs can be used as definitive therapy (Destination Therapy - DT). This use implies a series of ethical aspects that include the correct selection of the patient, the patient's precise information, and the definition of a possible protocol for deactivating the LVAD [8]. There are three ethical considerations regarding the selection of patients: the inclusion and exclusion criteria must be clearly explained, justified by rational diagnostic-therapeutic paths, and frequently discussed with the patient during the evaluation phase: The medical criteria must be supported by the most current medical, scientific evidence; The assessment must be conducted based on an explicit weighting of the costs, benefits, and risks associated with the procedure to be applied. The physician is responsible for providing clear information to the patient and family members, clarifying the risks and benefits of different treatment options, including medical treatment, palliative care, and VAD as destination therapy. The patient must be informed about the treatment's goal as an innovative surgical procedure aimed at improving the quality of life. An advanced treatment plan must be presented to the patient, clarifying the patient's preferences in case of complications. It is advisable to propose different scenarios that may occur during daily life through an interview with other subjects with LVAD.

Another ethical aspect concerns the possible interruption of therapy with mechanical support [9]. According to the principle of self-determination, the patient is fully entitled to stop medical treatment so that natural death can occur. A natural death can occur as a consequence of the deactivation of an LVAD due to a dysfunction of the device, due to coexisting comorbidities, or as a consequence of the progression of the disease. There are two ways of deactivating the LVAD. A team can help the patient disconnect the device from the power supply to cause a stop of the pump. The device's interruption does not result in euthanasia since the ventricular function was already severely depressed before implanting the LVAD; the patient's death occurs from the underlying heart disease. The second option involves surgical removal, but this alternative is somewhat complicated because it could cause the patient's death and then. After all, it would contravene the goal of ensuring patient comfort [10].

5. Innovation and research, conflict of interests

Scientific research is an essential part of a heart surgeon's activity. Research must be understood as a systematic investigation aimed at a reflection, followed by scientific evaluation and analysis of the results. The scientific research results are the final product of the work and the correct analysis of the collected data. The faithful exposure of the latter is necessary to respond "ethically" to the need for health [11].

An ethical violation in the field of scientific research is present in case of falsification/fabrication of the results (failure to publish complications related to the intervention, operative mortality, causes of death during a clinical follow-up), or when it is present excessive influence of industry. In randomized clinical trials, in which patients are generally divided into two or more groups to receive a different treatment, absolute impartiality of judgment (not influenced by industry, personal interests) is required to analyze the results. For this reason, many of the studies are conducted in a "double-blind" manner, in which neither the doctor nor the patient is aware of the type of treatment received. Conflict of interest occurs when there are divergences between individual interests and the surgeon's profession's obligations [12]. Conflict of interest can arise due to problems related to the relationship between surgeon and patient and between surgeon and industry, or finally, between public and private activities. Conflict of interest is frequent and even wholly unavoidable. Therefore, the moral purpose is not to cancel it altogether - it would be impossible - but to manage it, always managing to guarantee the prevalence of the primary interest (the patient's health) over secondary interests (e.g., personal earnings and gratification, remuneration). The conflict of interest that may occur between surgeon and industry may be, for example, the choice of a prosthesis that does not give the same guarantees as other more tested prostheses (in this case, personal interest prevails).

6. Ethics in pandemic

In the event of a pandemic, the crucial role of the government, the community, and the health system is to intervene to isolate the disease and slow the spread of the infection. The health system should prepare for an epidemic peak by implementing care capabilities. If the epidemic peak exceeds the available resources necessary to cope with it, a careful resource allocation policy is indispensable. An appropriate resource allocation policy requires first identifying the decision-makers in charge of setting priorities in the distribution. Precise identification of the resources that are limited in time and require a distribution plan is essential. It is necessary to identify the subjects who can benefit most from the use of that particular resource. Finally, it is useful to determine if there is an ethical justification for giving certain groups a priority over others.

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