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## Heart transplantation without informed consent: discussion of a case

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**Abstract** *Objective:* To discuss informed consent to heart transplantation in the case of an intensive care unit (ICU) patient: relatives' informed consent was refused by the patient himself whose cognitive ability appeared to be reasonable for the purpose.

*Setting:* ICU of a university teaching hospital.

*Patient:* a 62-year-old man who underwent myocardial revascularization had in the immediate post-operative hemodynamic instability, continuous serious arrhythmias, ventilatory support, fentanyl infusion. Heart transplantation could be the only chance for his survival.

*Intervention:* heart transplantation.

*Results:* despite patient's refusal, we

decided to hold the relative's consent as valid, and transplantation was accordingly performed, to the subsequent satisfaction of the patient.

*Conclusions:* Our decision was based on two beliefs: (1) the severity of the patient's clinical condition may have impaired his cognitive abilities; (2) the very same conditions may mask impairment and certainly make reliable assessment of cognition and judgment impossible. This being so, the preservation of life assumes priority.

**Key words** Heart transplantation · Informed consent · Decision making · Heart failure

### Introduction

Informed consent is an issue that raises complex ethical and deontologic questions, especially when intensive care unit (ICU) patients are involved. Because such patients are severely ill and because of environmental factors like stress, sleep deprivation, sedation, ventilatory dependence, they are difficult to evaluate and it is difficult to assess their competence. Consent to any kind of therapy must be informed and voluntary. This implies disclosure of information, competency and decision-making capacity. We report on a case in which informed consent to heart transplantation obtained from his wife was refused by the patient himself.

### Case report

A 62-year-old man, with a history of a previous myocardial infarction, underwent left ventricular catheterization and coronary angiogram in February 1996. Ventriculography showed massive ventricular dilatation and a severe reduction in ejection fraction (0.25); contractility was preserved only in the anteroseptal and apical segments. Mild mitral regurgitation and moderate tricuspid regurgitation were present. Coronary angiogram showed significant stenosis in the medial portion of the left anterior descending artery (LAD), occlusion of the circumflex artery, and significant stenosis of the obtuse marginal (OM) artery. The right coronary artery was hypoplastic.

On 9 April, the patient underwent a double coronary bypass (left internal mammary artery to LAD and saphenous vein to OM). Insertion of an intra-aortic balloon pump was necessary to wean the patient from cardiopulmonary bypass. Because of hemodynamic instability, amrinone and epinephrine were infused at high doses, and the sternum was left open.

On postoperative days 2, 6, and 9, the patient had several episodes of ventricular fibrillation that required electric defibrillation. On day 10, on account of both the impossibility of removing the intra-aortic balloon and the presence of continuous serious arrhythmias, the patient was listed for heart transplantation. As the patient was intubated and being treated with fentanyl infusion, informed consent was obtained from relatives. Three days later, a 59-year-old woman, who died of cerebral hemorrhage, became available as a donor. At this point, hemodynamic data were: blood pressure 90/60 mm Hg, cardiac output 4.2 l/min, cardiac index 2.6 l/min per m<sup>2</sup>, under epinephrine (0.04 µg/kg per min) and nitroglycerine infusion (4 µg/kg per min). Hematological examination showed: blood urea nitrogen 7.3 mmol/lm, creatinine 123.7 mmol/l, chloride 111 mmol/l, calcium 1.92 mmol/l, and osmolality was 290 mOsm/kg H<sub>2</sub>O.

While the retrieval team was removing the heart at a distant hospital, the patient was informed about the procedure he had to undergo, and he firmly refused heart transplantation. Despite his poor general condition and the low-dose fentanyl infusion of 0.003 µg/kg per min, he appeared to be conscious and physicians and nurses judged him to be responsive and fairly lucid. Therefore, the anesthetist thoroughly explained the situation to the patient, making it clear that this was probably his last chance of survival. Although the patient seemed to understand, he insisted on his refusal. When the retrieval team arrived at the hospital, we decided to validate the informed consent of the relatives. Accordingly, the patient was sedated and the transplantation performed.

The only complication in the postoperative period was respiratory insufficiency, which required prolonged ventilatory support for 7 days. He was discharged on postoperative day 15 and he is doing well 15 months after transplantation.

Psychiatric evaluation was not performed prior to the patient's admission to the transplantation list because of his condition. At our center, it usually consists of a standard psychiatric interview, including a formal mental status examination by an experienced psychiatrist. However, the patient was visited by the psychiatrist before discharge. The patient was cooperative and fully lucid in all parameters. His cognition score under the Folstein Mini-Mental State Examination (MMSE) was 28 [1]; he exhibited a digit span of eight (five forward, three backward), he could say the days of the week backwards, and he was able to recall three objects after 3 min. He was well aware of the recent events; his remote memory was intact, with the exception of the days near the operation. He said he did not remember anything about it. He appeared to be satisfied with the transplant and denied he had refused consent. His mood was mildly depressed, but his affect was full and appropriate. At one year the patient was doing well, was fully aware of the heart transplantation and satisfied about the procedure carried out on him.

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## Discussion

Informed consent allows individuals to exercise autonomy in the context of medical treatment. The theoretical model of informed consent implies that doctors give all the information regarding a therapy or medical study to a competent patient who is able to understand and who voluntarily accepts or refuses the procedure or treatment proposed [2, 3].

Except in emergencies, when doctors are obliged to make independent choices, the responsibility for medi-

cal decisions has long since shifted from being physician-centered to being patient-centered [4]. At the core of this shift is the concept of the human being as a unique entity, one that unites body and psyche, and who enjoys both intelligence and responsibility for his or her own destiny. From this concept derives the imperative of respect for the individual and for his or her freedom, and thence the principle of informed consent being the only acceptable basis for medical decision making.

In the case reported here, the patient was receiving ventilatory support, had a borderline blood pressure, was receiving infusions of epinephrine and fentanyl, appeared to be conscious, responsive, and fairly lucid, and was informed that the intervention of heart transplantation could be his last chance of survival. When the collecting team arrived at the hospital there was no time to call for a psychiatric consultation and heart ischemic time was already 120 min. For this reason a mini-mental status test was not performed at the time of refusal, the patient was considered not competent, and the heart transplantation procedure was performed with the relative's consent.

In relation to the principle of informed consent, the physician's duties are at least twofold: first, not to allow his or her own views on the quality of life to prevail over, or obscure, those of the patient; second, to ensure that the patient's consent is based upon exhaustive and completely understood information [4, 5]. The first point was strongly upheld in Italy recently when the Court of Assizes in Florence ruled against a surgeon for dispensing with informed consent for surgery (performed in the course of transrectal removal of rectal polyps) that was more radical than anticipated [6]. The patient, who was an elderly woman, had died 2 months after the operation. The court's finding of manslaughter, and its assertion of the right of patients to spend their last days of life in a physically and psychologically dignified way, were subsequently confirmed both by the Court of Appeal and by the Supreme Court.

Analogously, the fourth paragraph of the European Guide to Medical Ethics [7] establishes that doctors' personal views on the quality of life cannot supersede those of the patient. The majority of commentators believe those legal standards for determining a person's competence fall into one or more of the following categories [8]: (1) communicating choices: the ability to express a choice is recognized as a form of competence; however, the stability of the choice can be examined by repeating the question and continuous reversals of intent may suggest impairment; (2) understanding relevant information; (3) appreciating the situation and its consequences; (4) rational manipulation of information. Refusal to cooperate can make it really problematic to examine a patient's competence. However, in life-

threatening situations Appelbaum and Grisso [8] believe that it can be reasonable to lower the threshold at which incompetence is evaluated. As demonstrated by a recent survey by the European Society of Intensive Care Medicine [9]: the majority of the 590 members contacted declared that a patient's refusal of surgical intervention is normally accepted, even when life itself is at stake. Interestingly, the exception to this was Catholic doctors, who proved to be more inclined to operate against the patient's wishes. Such behavior exemplifies another important ethical tenet, namely the inviolability of life itself, and the consequent duty of society in general, and the physician in particular, to preserve life. Objectors to this tenet will perhaps describe it as a point in dogma rather than in ethics.

Supporters, however, will perceive the respective priorities of the inviolability of life and the individual's right to choose not as mutually exclusive but as complementary to one another. Anyway, the right of patients to forgo life-sustaining treatment has been well established in health law and medical ethics and public hospitals may not promote sectarian views and should respond affirmatively to any legal and medical wish of a patient. However, the patient should be competent or the request should be granted by a family member or legal representative [10].

In any case, physicians must not, and indeed cannot, discharge all responsibility for medical decisions onto the patient, not least because in so doing they would lose credibility in the eyes of the public [11]. This point assumes greater cogency when the patient loses the ability to understand, evaluate, and judge information received. At this point, when such loss is clearly demonstrable, should informed consent be sought from the nearest relatives? In the United States this is possible, but in Europe the situation is rather confused, varying from country to country: it is true in United Kingdom, Scandinavia, Spain, Portugal, and Greece, but not in France and Germany. In these countries relatives have to be informed, but they cannot give consent for the patient [12]. Anyway, the new proposal of the Council of Europe, through its steering committee on bioethics (July 1994, modified June 1996 and formally approved in November 1996) states: Article 8 (emergency situations) "When, because of emergency situations, the consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned" [13].

ICUs are places that especially compel this question. Serious illness, with its attendant fear, depression, and pain, may well reduce coping mechanisms and compromise judgment [14]. At the same time, precisely because ICU patients are severely ill, they are not amenable to the type of research that might deepen our understanding of their ability to apprehend and to judge. According

to recommendations of the European Society of Intensive Care Medicine, most ICU patients, due to their disease or environmental factors like stress, sedation, and sleep deprivation, are generally considered incompetent in terms of understanding a particular therapy and in decision-making capacity. In cases of emergency, in life-threatening situations, and when there is not enough time to obtain consent from the patient's legal representatives, a waiver of consent may be accepted [13]. Detailed information must later be given to the patient or to the legal representative. In the case reported, the patient received a 59-year-old woman's heart without coronary angiography. The transplanted heart was therefore outside the donor protocol parameters and was not considered by other transplant centers. Considering the situation of a limited donor pool which is not large enough for the needs of patients awaiting heart transplantation, we emphasize that this donor heart should in all likelihood have been lost and not implanted in other patients.

Our patient was affected by low output syndrome, was under ventilatory support, and was receiving catecholamine and fentanyl infusions. On the basis of a recent study [15], we believe that there are grounds to suspect that ventilatory support is particularly traumatic, and thus disorienting, to the patient's sense of judgment. Evaluating the level of agreement between clinical and formal assessment of the capacity of ICU patients to make decisions, the study admittedly demonstrated that 26 (25 %) of the 103 patients with an MMSE score of more than 19 were under ventilatory support. In the light of the MMSE grading system (0–11 = severely impaired, 12–19 = moderately impaired, 20–23 = impaired, 24–30 = unimpaired), this finding suggests that ventilatory support does not necessarily impair cognitive abilities, and the study also concludes that ventilatory support did not produce any bias in clinical assessment, i.e., clinicians did not believe that ventilatory support was necessarily prejudicial to patients' sense of judgment.

However, and significantly, 73 % of the patients with an MMSE score of 0 were receiving ventilatory support, and the authors recognize this result as indicative both of the severity of illness of the given subgroup and of the clinical difficulty of assessing mental status in such cases.

As regards the case here reported, we hold two firm beliefs: first, that the severity of the patient's condition may well have reduced his capacity to judge, and thus determined his refusal of transplantation; second, that such impairment would be neither detectable nor assessable, precisely because of the given clinical setting. Accordingly, we argue that there is a case for transplant teams to resort exclusively to the informed consent of nearest relatives when candidates for transplantation are intensive care patients. We would add that in our in-

stitution, out of 483 heart transplantations performed since November 1985, four operations have been done on precisely this basis in patients who underwent cardiac operations for heart valve replacement (three cases) and in one for ischemic heart disease; all cases were sedated before heart transplantation, and all the patients concerned were satisfied with the procedure that had been carried out on them.

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