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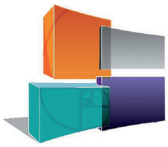

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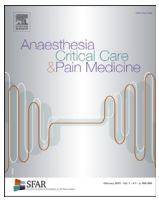

Original article

French survey of the first three-years of liver transplantation activity from uncontrolled donors deceased after cardiac death

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ABSTRACT

Objective: To assess the first three years of French activity related to liver transplantation from uncontrolled donation after cardiac death (uDCD).
Study design: Prospective and observational study in the three active centres authorized by the French Biomedicine Agency.
Patients and methods: All patients deceased between 2010 and 2012 after an uncontrolled cardiac arrest admitted to one of three centres (Pitié-Salpêtrière, Saint-Louis or Bicêtre hospitals, AP–HP, Paris, France) and potentially eligible for liver recovery were included. Abdominal normothermic oxygenated recirculation (ANOR) was used for graft preservation.
Results: One hundred twenty-six potential uDCD donors were identified as eligible for liver recovery after hospital admission. The main causes of organ recovery failure were technical failure related to ANOR (29 patients, 23%), refusal of consent (39 patients, 31% of potential uDCD donors and 40% of asked relatives) and abnormal hepatic transaminases up to 200 UI.L^{-1} during ANOR (24 patients, 19%). Finally, 11 livers were transplanted. Process efficiency was 9% [95% CI: 4–15%]. One-year recipient survival was 82%, [95% CI: 48–98%] and one-year graft survival was 64% [95% CI: 31–89%].
Conclusion: Liver transplantation from uDCD donors is achievable in France, despite low process efficiency.

1. Introduction

During last few years, despite the overall increase of transplantation procedures, the number of patients on waiting lists is still increasing, resulting in a growing mismatch between the number of available grafts and the number of patients on waiting lists. This statement is especially true for liver transplantation. In 2012 in France, 2662 patients were waiting for a liver transplantation; 1161 patients were transplanted during the year and 182 patients died before transplantation [1]. To date, the large majority (98%) of French liver transplants are from donation after brain death (DBD). To decrease mismatching, it has been proposed to enlarge the donor criteria, including donation after cardiac death (DCD) [2,3].

In France, since the decree n° 2005-949 of 2 August 2005, organ procurement from DCD donors is authorized under the control and according to protocols drafted by the French Biomedicine Agency [4]. Until today, these protocols were restricted to "uncontrolled" DCD (uDCD) donors (Maastricht classification categories I, II and IV), excluding *de facto* the organ procurement from the Maastricht classification category III ("controlled" DCD donors, i.e. dead after withdraw from life-sustaining treatment and awaiting cardiac arrest) [5]. The French kidney transplantation program from uDCD donors started in 2006 [6–8], and the liver transplantation

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program in 2010. Liver transplantation from uDCD donors requires an abdominal normothermic oxygenated recirculation (ANOR) for liver preservation [9].

The main endpoint of this survey was to describe the first three years activity of the French liver procurement procedure from uDCD donors and to calculate its efficiency. The secondary endpoint was to assess both recipient and graft one-year survivals.

2. Material and methods

2.1. Type of study

Between 2010 and 2012, we conducted a prospective observational study in the French transplantation centres authorized and active for liver transplantation from uDCD donors. This study received approval from our ethics committee (CPP Paris VI-Pitié-Salpêtrière, Paris), and was carried out in accordance with the Declaration of Helsinki.

2.2. Study population

All deceased patients after uncontrolled cardiac arrest and considered as potential donors admitted to the authorized centres for liver transplantation from uDCD donors were included in the study. Criteria for considering patients as potential donors were: age between 18 to 54 years, refractory cardiac arrest with a no flow duration < 15 min and an expected low flow duration < 120 min (or 150 minutes in case of mechanical chest compression) before cannulation.

Non-inclusion criteria were unavailability of the surgical team for cannulation and contraindication for starting a liver procurement procedure from uDCD donors. Potential contraindications were refractory cardiac arrest with a formal indication for therapeutic extracorporeal life support [10], traumatic cardiac arrest, known refusal for organ donation on hospital arrival or registration in the National Registry for organ donation refusal, opposition from a procurator in case of suspicious death, persistence of electrical cardiac activity on an electrocardiogram registered during a 5-minute no touch period after discontinuation of chest compressions (Fig. 1).

2.3. Liver transplant protocol

The protocol for liver procurement from uDCD donors is framed by the French Biomedicine Agency [11]. When the potential uDCD donor arrived at a hospital with refractory cardiac arrest, the prehospital time frame (Fig. 1), eligibility criteria and potential contraindications for the liver procedure were quickly checked. Then, a 5-minute no touch period with discontinuation of mechanical ventilation and chest compressions was performed during which a continuous electrocardiogram was registered. In absence of signs of life and electrical cardiac activity (i.e. asystole or agonic rhythm), death was declared according to French law [4]. At the same time, the French registry for organ donation refusal was consulted and next-of-kin (if present at this time) were asked about consent for organ donation. In absence of exclusion criteria and after declaration of death, mechanical chest compressions and ventilation were resumed and implantation of ANOR was performed. ANOR was implanted through the femoral vessels after groin surgical opening. Both the femoral vein and artery were cannulated and connected to an extracorporeal circuit. The extracorporeal circuit consisted of a centrifugal pump, an oxygenation membrane, an air-oxygen mixer and a monitoring consol. Depending on the temperature of the body, a heat exchanger was connected to the ANOR. An aortic balloon catheter was inserted in the contralateral femoral artery and inflated in the supradiaphragmatic-descending aorta, in order to limit blood-oxygenated circulation to the abdominal floor. After successful ANOR implantation, liver viability was assessed via repeated blood transaminase level measurements. The procedure was discontinued if blood transaminase levels were above 200 UI.L^{-1} on two successive measurements after the start of ANOR. ANOR was discontinued if the potential donor's next-of-kin reported a patient refusal for organ donation. Liver recovery was performed if no refusal and no contraindication were found during the ANOR phase. Maximal authorized duration of the ANOR phase until *in situ* liver cooling was 240 min (Fig. 1). In absence of contraindications from the specific kidney protocol from uDCD donors, kidney retrieval was also performed. During liver recovery phase, a meticulous exploration of the abdominal cavity was performed, in order to check contraindications for liver procurement. Hepatic biopsies were systematically performed. The liver recovery procedure was stopped in case of macroscopic abdominal contraindications or extended steatosis (>15 to 20%) or hepatic fibrosis observed during extemporaneous examination. Grafts from uDCD donors were attributed in priority to the local centre. Potential receivers were previously selected and specifically informed about the uDCD graft origin. Inclusion criteria for liver uDCD recipients were patients under 65 years and waiting for a first liver transplantation due to a liver tumour with a MELD score under 20 [12], absence of major surgical history and absence of portal venous thrombosis.

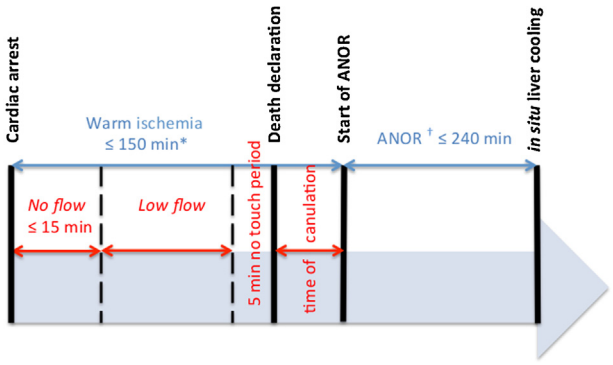

Fig. 1. Time frames during the uncontrolled donation after cardiac death procedure. *120 min without mechanical chest compression device. †ANOR: abdominal normothermic oxygenated recirculation.

2.4. Collected and analysed data

During the study period, data about potential uDCD donors were prospectively collected. Data about recipients were retrospectively collected. Blood transaminase levels during the ANOR phase were analysed between T_0 (start of ANOR) and T_{final} (last blood measurement during the ANOR phase). Efficiency of the liver transplantation procedure from uDCD donors was defined as the ratio between the number of effectively transplanted grafts and the number of identified potential uDCD donors for liver recovery after hospital admission.

2.5. Statistical analysis

Continuous variables are reported as means ± standard deviations (SD) or medians [25th–75th percentiles], as appropriate. Because of small sample size, no statistical tests were carried out and we preferred to use a strictly descriptive statistic approach. All calculations were performed with GraphPad Prism® v5.0 (GraphPad Software, San Diego, Californie, USA).