Annales Françaises d'Anesthésie et de Réanimation 33 (2014) 138–143

Anarlf meeting

How France launched its donation after cardiac death program☆,☆☆

Interactions avec le prélèvement d'organes : la question du M3, position de l'Agence de la biomédecine

C. Antoine [a,*], F. Mourey [b], E. Prada-Bordenave [c] Steering committee on DCD program

[a] *Agence de la biomédecine, direction générale médicale et scientifique, direction prélèvement greffe organes-tissus, pôle stratégie prélèvement greffe, 1, avenue du Stade-de-France, 93212 Saint-Denis-la-Plaine cedex, France*
[b] *Agence de la biomédecine, direction générale médicale et scientifique, direction prélèvement greffe organes-tissus, SRA Sud-Est/Océan Indien, bâtiment B, 162, avenue Lacassagne, 69424 Lyon cedex 03, France*
[c] *Directrice générale, Agence de la biomédecine, 1, avenue du Stade-de-France, 93212 Saint-Denis-la-Plaine cedex, France*

ARTICLE INFO

Keywords:
Organ donation
Cardiac death donor
Circulatory death
Donor selection
Withdrawal of life-sustaining therapy

ABSTRACT

On the basis of the literature and results presented at the 6th International Conference, donation after cardio-circulatory death provides a significant, practical, additional high quality source of transplantable organs. The vast majority of DCD are 'controlled' Maastricht category III donors. In 2010, the parliamentary information mission on the revision of the bioethics laws invited the Intensive Care Societies to debate and to make recommendations to implement controlled donation after circulatory death. They came to the conclusion that such retrieval is possible in France and insisted on the medical criteria that frame it: the writing of the medical procedures, the ethical aspects and the delay. The major recommendations of the ethics committees were firstly, The WLST decision is independent of the possibility of organ donation; secondly, the strict respect of "The dead donor and organ transplantation rule" and the updated national guidance for the WLST; thirdly, the drafting of a nationally agreed protocol defining the mandatory conditions to determine death and to perform procurement and transplantation. Organ donation after WLST will be authorised only in pilot centres with a locally agreed WLST policy including external second opinion and written transcript of the WLST decision, experienced intensive care staff, a local organ procurement coordination team familiar with DBD and DCD protocols and only in hospitals authorised for organ procurement. It is important to have an optimal and standardized national guidance to limit the known risk factors of graft failure (donor and recipient choice, warm and cold ischemia time), to increase acceptance by medical community and civil society and to improve results and allow more powerful analysis.

Mots clés :
Don d'organes
Donneur décédé après arrêt cardiaque
Décès par arrêt circulatoire
Sélection du donneur
Limitation des thérapeutiques actives

RÉSUMÉ

Au vu des données de la littérature, le développement des transplantations rénales à partir de donneurs décédés après arrêt cardiaque (DDAC) fait partie des stratégies de lutte contre la pénurie d'organes car le potentiel de donneurs est important, pour des résultats comparables à ceux des greffes issues de donneurs décédés en mort encéphalique. Près de 90 % de l'activité mondiale de prélèvements sur DDAC se fait à partir de donneurs de la catégorie III et la majorité des articles concerne donc des donneurs dits contrôlés. La mission parlementaire d'information sur la révision des lois de bioéthique en 2010 s'était saisie de la question des prélèvements d'organes sur donneurs de la catégorie III de Maastricht. En 2011 et 2012, en parallèle et en interaction des comités d'éthique des sociétés savantes, le Conseil d'Orientation de l'Agence de la biomédecine a mené ses propres débats. Le Conseil a conclu à la faisabilité de tels prélèvements en France en insistant sur les critères médicaux du prélèvement, l'intentionnalité des actes médicaux, leur dimension éthique et leur délai. Les principes généraux retenus sont : premièrement, la décision de LAT est indépendante de la possibilité d'évoluer vers un don d'organes ;

☆ French NeuroAnesthesia and Intensive Care society Meeting, Paris, November 2013, 21st and 22nd: "The acutely brain-injured patient: consciousness and neuroethic".
☆☆ This article is published under the responsibility of the Scientific Committee of the "35e Journée de l'Association des neuro-anesthésistes réanimateurs de langue françaises" de la SFAR. The editorial board of the *Annales françaises d'anesthésie et de réanimation* was not involved in the conception and validation of its content.

* Corresponding author.
E-mail address: corinne.antoine@biomedecine.fr (C. Antoine).

0750-7658/$ – see front matter
http://dx.doi.org/10.1016/j.annfar.2013.11.018

deuxièmement, le respect de « la règle du donneur mort », en vertu de laquelle le processus de prélèvement ne doit en rien causer ou accélérer le décès ; troisièmement, la rédaction d'un protocole unique national précisant les modalités techniques de mise en œuvre, protocole qui est en cours de rédaction par l'Agence de la biomédecine, en lien avec les professionnels. Les centres hospitaliers qui souhaiteront s'impliquer dans ce protocole devront s'engager par écrit vis-à-vis de l'Agence de la biomédecine à en respecter les termes, à se doter des moyens nécessaires pour assurer un bon déroulement des procédures et à fournir toutes les données nécessaires à l'évaluation de ce programme.

1. Introduction

At the beginning of transplantation era, cadaveric organs were recovered from deceased donors after cessation of cardiac activity. Donation after cardiac death (DCD) was the method of reference in France and in the world. Progress in resuscitation led to international guidelines with a shared scientific, medical and legal definition of brain death.

DCD donors have been classified into categories after a Consensus meeting held in Maastricht in 1995 [1], recently modified during the 6th International Conference on Organ Donation after Circulatory Death organized in Paris in February 2013 (Table 1).

Although France stopped donation after CD, many others countries kept on doing it, either by choice, or because of cultural or religious difficulties with the concept of brain death. In the meantime improvement in the performance of technology has led to significantly improved outcomes with kidneys donated after cardiac death. A decrease of primary non-function (PNF) rate and an improvement of long-term graft survival has been observed, which now appears to be the same for DCD and DBD, in spite of high rates of delayed graft function (DGF) [2–4]. Recently, Dominguez et al. published the current situation of donation after circulatory death (DCD) in the Council of Europe Member States [5]. From 2000 to 2008, 5004 organs were transplanted from DCD, including 4261 kidneys, 505 livers and 157 lungs. Controlled DCD represented 89.2% of kidney transplantation activity with donation after cardiac death. In spite of 5% PNF and 50.2% DGF, 1 year kidney graft survival was 85.9% [5].

These improvements were obtained due to a more precise selection of donors and recipients, the respect of cold and warm ischemia time limits and to several major therapeutic innovations, specifically: machine perfusion preservation [6,7] or extracorporeal perfusion [8–10].

In the light of what is observed outside France, it seems likely that a DCD programme would help decrease organ shortages: There were only 3044 kidney transplants in France in 2012 (46.5 pmh), the access rate to renal transplantation is 22.8%. From 2002 to 2012 the median waiting time increased from 16.6 to 23.2 months [11].

2. The French DCD programme

Procurement from donors after cardiac death was re-examined in France in 2003–2004, taking into account the feasibility, results and ethical and legal consequences. The terms of the law were changed to authorize donation after cardiac death, but only for a limited number of pilot centres with a single national medical protocol issued by the Agence de la biomédecine [12]. Initially, this programme was only applicable to donors in Maastricht category I (donors are dead on arrival) and II (donors are those who die after unsuccessful resuscitation). From January 2007 to August 2013, 432 renal transplantations and 12 liver transplantations from DCD were performed in France. The 1-year kidney graft survival rate was 87.2% without censured deaths and 90.4% with censured deaths [13]. Several reports, mostly from Spain and United Kingdom, describe comparable results of transplantations from uncontrolled DCD [14,15].

In France, the end of life law, which had only just been passed in 2005, ruled out Maastricht class III at the start of the programme. In 2010, the parliamentary information mission on the revision of the bioethics law invited the Intensive Care Societies to debate and make recommendations for controlled donation after circulatory death [16,17]. According to these proposals, the major recommendations of the Agence de la biomédecine ethics committee were:

- three guiding principles:
  - the decision to withdraw life-sustaining treatment (WLST) must be independent of the possibility of organ donation. The family will not be approached about organ donation until the decision to withdraw life-sustaining treatment has been made and independently agreed, and the family has been involved in the decision and had accepted it,
  - "the dead donor rule and organ transplantation" must be strictly respected. This states that patients must be declared dead before any organs are removed and that interventions after WLST do not accelerate death [18],
  - if a patient had agreed to donate organs after their death, these patients should be offered the possibility to donate their organs in the case of planned end of life;

Table 1
Modified European Maastricht categories of donation after cardiac death (DCD) – Paris 2013 classification [30]: same skeleton as classification published in 1995 by Koostra et al. [1].

Category I	Unwitnessed circulatory arrest	Sudden-unexpected CA, no attempt of resuscitation by a medical team
Uncontrolled	I A – In-hospital	WIT to be considered according national recommendations in place
	I B – Out-of-hospital	In- or out-of-hospital setting
Category II	Witnessed circulatory arrest	Sudden-unexpected-irreversible CA, unsuccessful resuscitation by a medical team
Uncontrolled	II A – In-hospital	In- or out-of-hospital setting
	II B – Out-of-hospital	
Category III	Awaiting circulatory death	Planned, expected CA, withdrawal of life-sustaining treatment
Controlled		Euthanasia excluded
Category IV	Circulatory arrest while brain dead	Sudden or planned CA during or after brain death diagnosis process but before retrieval
Uncontrolled and controlled		