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ASTS Recommended Practice Guidelines for Controlled Donation after Cardiac Death Organ Procurement and Transplantation

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The American Society of Transplant Surgeons (ASTS) champions efforts to increase organ donation. Controlled donation after cardiac death (DCD) offers the family and the patient with a hopeless prognosis the option to donate when brain death criteria will not be met. Although DCD is increasing, this endeavor is still in the midst of development. DCD protocols, recovery techniques and organ acceptance criteria vary among organ procurement organizations and transplant centers. Growing enthusiasm for DCD has been tempered by the decreased yield of transplantable organs and less favorable posttransplant outcomes compared with donation after brain death. Logistics and ethics relevant to DCD engender discussion and debate among lay and medical communities. Regulatory oversight of the mandate to increase DCD and a recent lawsuit involving professional behavior during an attempted DCD have fueled scrutiny of this activity. Within this setting, the ASTS Council sought best-practice guidelines for controlled DCD organ donation and transplantation. The proposed guidelines are evidence based when possible. They cover many aspects of DCD kidney, liver and pancreas transplantation, including donor characteristics, consent, withdrawal of ventilatory support, operative technique, ischemia times, machine perfusion, recipient considerations and biliary issues. DCD organ transplantation involves unique challenges that these recommendations seek to address.

Key words: Expanded criteria donors, extended donor criteria, extended donor pool

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Introduction

The American Society of Transplant Surgeons (ASTS) champions efforts to increase the number of organs that are available for critically needed transplants. One important effort involves transplantation of donation after cardiac death (DCD) organs and improving outcomes of these transplants. This goal is particularly relevant because DCD donors have been shown to be a potential source of transplantable organs that has yet to be fully utilized (1,2). Cardiac death is defined as 'irreversible cessation of circulatory and respiratory function' (1–5). Controlled DCD involves planned withdrawal of ventilatory and organ-perfusion support in the face of catastrophic illness (Maastricht III), whereas uncontrolled DCD involves unexpected cardiopulmonary arrest and/or unsuccessful resuscitation (Maastricht I, II, IV) (1–6). Controlled DCD offers the patient and the family the opportunity to donate when criteria for brain death declaration will not have been met prior to cardiac death. It should be emphasized that whether or not organ donation is to be pursued, such patients' legal decision maker(s) elect to withdraw ventilatory support because of a hopeless prognosis. The transplant community has no say in whether or when support will be withdrawn. Furthermore, it must be recognized that the patient who is considered for DCD is not dead and not a donor unless and until he or she should die.

Growing enthusiasm about the option of DCD organ procurement ought to be tempered by the realization that both

the yield of transplantable organs from DCDs and the outcomes after DCD organ transplantation are not generally as favorable as those with donation after brain death (DBD) organs (7–19). DCD shall not be viewed as an equally acceptable alternative to DBD because DCD on average yields fewer organs and the organs probably have more risk than organs recovered from DBD donors (7–12,14–19). The relative risks and benefits of DCD organ transplantation are being established. The safety of various DCD protocols and organ procurement and transplant techniques is being evaluated. DCD should be considered only when the DCD option might genuinely expand the organ donor pool because DBD organ procurement will not be possible. Regulatory oversight of the mandate to increase DCD (20) and a recent, highly publicized lawsuit involving professional behavior during an attempted DCD (21) have fueled scrutiny of this activity. The following recommendations regarding controlled DCD of abdominal organs and their transplantation represent expert opinion and are evidence based when possible (Table 1). They are practice guidelines that can be adopted by transplant surgeons and centers and can be individualized as needed. It is the expectation of the ASTS that these recommendations may require modification in the future, as innovations designed to improve outcomes are explored and implemented.

Methods

The ASTS Council requested that the Standards on Organ Transplantation Committee propose best-practice guidelines for controlled DCD abdominal organ procurement and transplantation. A work group composed of committee members and additional experts in DCD prepared a list of topics that the recommendations should cover, performed a computerized search of the National Library of Medicine for English language citations from 1990 through 2008 using the words 'donation after cardiac death' and 'non-heart-beating donor' and drafted guidelines. Suggested revisions were solicited from each member of the work group, committee and Council. The authors of this manuscript collaborated in editing the guidelines.

The Oxford Centre grading scheme was used to rate the level of scientific evidence of each reference cited in these guidelines (22). Individual ratings and a summary of the grading scheme are provided in the Table 1. These practice guideline recommendations should be supplemented with information obtained by consulting the literature citations provided. Efforts have been made in preparing these guidelines to strive for consistency with recommendations and practice guidelines on DCD published by other groups (1–3,23–27).

Recommendations

DBD provides superior transplant outcomes compared with DCD

- Given that outcomes after DCD are generally inferior to those after DBD, it is strongly preferred that organ donation be pursued according to DBD rather than DCD protocols when encountering potential organ donors who are brain dead or who will likely soon become so.
  - Compared with DBD, DCD provides a lower yield of transplantable organs (7,8), liver recipients with decreased patient and graft survivals rates and increased risk of ischemic biliary complications (9–16) and kidney recipients with increased risk of delayed graft function (17–19), although DCD kidneys from otherwise standard criteria donors provide survival outcomes similar to those of DBD kidneys (24).
- A consenting potential organ donor's family, legal decision maker(s) and healthcare providers shall be encouraged to facilitate completion of a brain death protocol when brain death seems present, even if such protocols might be viewed as cumbersome when compared with DCD protocols. If brain death seems imminent, they shall be given the opportunity to wait rather than pursue DCD.
- DCD can provide genuine expansion of the organ donor pool if DBD is not feasible, such as when (a) there is catastrophic injury but brain death is not imminent and there is a request for withdrawal of ventilatory and organ-perfusion support or (b) completion of a brain-death protocol with a seemingly brain-dead or soon to be brain-dead potential organ donor is precluded because of severe hemodynamic instability or because the family/legal decision maker(s) will not wait for completion of a brain-death protocol.
- In cases where progression to brain death might occur, consent from family/legal decision maker(s) should include the possibility of conversion to DBD from DCD should progression occur (23).

DCD protocols

- Ensure that the organ procurement organization (OPO) and transplant center have approved, detailed DCD protocols and hospital development processes in place (1–3,23–28).
- Ensure that the transplant team members are familiar with DCD protocols and with relevant ethical principles.
- Ensure that the transplant team members are not involved in decisions related to patient prognosis, withdrawal of ventilatory or organ-perfusion support or determination of death, because each would represent a conflict of interest (1–3,5,23–27). In a situation in which a transplant team member has cared for a patient who is being considered for DCD, such as in the role of a critical care or trauma specialist, the team member should transfer care of the patient to another individual and separate him- or herself from any further involvement with the patient, including involvement related to patient prognosis and decisions about withdrawal of ventilatory or organ-perfusion support; this transplant team member may then participate in DCD organ procurement.
- Uncontrolled DCD donors are substantially different from controlled DCD donors (Maastricht I, II, IV vs. Maastricht III) (1–3). Organs from uncontrolled DCD

Table 1: The level of evidence for each reference cited in these draft guidelines, based on the Oxford Centre grading scheme (22)

Reference	Authors	Organ	Major focus
Level of evidence: B			
7	Sung RS et al.	All	Organ donation and utilization (SRTR)
8	Merion RM et al.	Liver	DCD livers: increased use and increased risk of graft failure (SRTR)
9	Freeman Jr RB et al.	Liver	DCD livers: increased use and increased risk of graft failure (SRTR)
10	Abt PL et al.	Liver	DCD livers prone to graft failure, especially with longer cold ischemia or unstable recipients (UNOS)
11	Lee KW et al.	Liver	Risk factors for DCD LTX, including older DCDs and longer ischemia times (UNOS)
12	Mateo R et al.	Liver	Risk factors for DCD LTX, including longer ischemia times and high risk recipients (UNOS)
13	Foley DP et al.	Liver	DCD LTX: increased patient and graft loss and biliary complications (University of Wisconsin, Madison, WI)
14	Abt P et al.	Liver	DCD LTX prone to biliary complications (University of Pennsylvania, Philadelphia, PA)
17	Rudich SM et al.	Kidney	DCD KTX outcomes same as DBDs, except for increased DGF (USRDS)
18	Weber M et al.	Kidney	DCD KTX outcomes same as DBDs, except for increased DGF (University of Zurich, Switzerland)
19	Locke JE et al.	Kidney	Risk factors for DCD KTX, including age >50 years and CIT >12 h (UNOS)
29	Otero A et al.	Liver	Uncontrolled (Maastricht II) DCD LTX (Spain)
30	Suárez F et al.	Liver	Uncontrolled (Maastricht II) DCD LTX: increased biliary complications (Spain)
31	Sanchez-Fructuoso AI et al.	Kidney	Uncontrolled (Maastricht II) DCD KTX (Spain)
38	Fernandez LA et al.	Kidney, pancreas	DCD SPK outcomes same as DBDs, except for increased renal DGF (University of Wisconsin, Madison, WI)
42	Guichelaar MM et al.	Liver	Risk factors for nonanastomotic biliary strictures post-LTX, including longer ischemia times (Mayo Clinic, Rochester, Minnesota)
43	Sankary HN et al.	Liver	Simultaneous hepatic artery and portal vein revascularization protects against nonanastomotic biliary strictures post LTX (Rush University, Chicago, IL)
Level of evidence: C			
15	Lee HW et al.	Liver	Classification of biliary strictures after DCD LTX (Seoul, Korea)
16	Maheshwari A et al.	Liver	Biliary complications after DCD LTX (Johns Hopkins University, Baltimore, MD)
32	Casavilla A et al.	Liver, kidney	Super rapid recovery technique and DCD LTX and KTX (University of Pittsburgh, PA)
34	D'Alessandro AM et al.	All	Premortem cannulation technique and DCD organ transplantation (University of Wisconsin, Madison, WI)
35	Magliocca JF et al.	All	ECMO and DCD organ recovery (University of Wisconsin, Madison, WI)
36	Jeon H et al.	Pancreas	Surgical techniques for procuring DCD pancreas in addition to liver (Albert Einstein Medical Center, Philadelphia, PA)
37	Muiesan P et al.	Liver	DCD LTX provided safe donor pool expansion (King's College Hospital, London, UK)
41	Buis CI et al.	Liver	Risk factors for nonanastomotic biliary strictures (University of Groningen, The Netherlands)
44	Snell GI et al.	Lung	DCD lung transplantation (Melbourne, Australia)
45	Boucek MM et al.	Heart	DCD heart transplantation (Denver Children's Hospital, Colorado)
Level of evidence: D			
1	Institute of Medicine	All	DCD history, ethics, medical issues and policies
2	Institute of Medicine	All	How to facilitate DCD protocol development and practice
3	Institute of Medicine	All	Current and potential rates of uncontrolled and controlled DCDs
4	Kootstra G	All	DCD overview
5	Arnold RM et al.	All	Ethical and public policy implications of procuring DCD organs
6	Kootstra G et al.	All	Maastricht categories of DCDs
20	Federal Register	All	Requirements for OPOs providing DCD
21	The Wall Street Journal	All	Lawsuit involving DCD
23	UNOS	All	Critical pathway for DCD

Continued.

Table 1: Continued

Reference	Authors	Organ	Major focus
24	Bernat JL et al.	All	U.S. consensus conference recommendations about DCD
25	Society of Critical Care Medicine	All	Recommendations for DCD policies
26	OPTN Bylaws	All	Model elements for DCD protocols
27	UNOS	All	Reference guide for DCD
28	Arnold RM et al.	All	Need for DCD policies
33	Reich DJ	All	Surgical techniques for procuring DCD organs
39	Federal Register	All	Requirement to disclose to patient risks and benefits of transplantation
40	Reich DJ et al.	Liver	Textbook chapter on DCD LTX

CIT = cold ischemia time; DBD = donation after brain death; DCD = donation after cardiac death; DGF = delayed graft function; ECMO = extracorporeal membrane oxygenation; KTX = kidney transplantation; LTX = liver transplantation; OPO = organ procurement organization; SPK = simultaneous pancreas and kidney transplantation; SRTR = Scientific Registry of Transplant Recipients; UNOS = United Network for Organ Sharing; USRDS = United States Renal Data System.
A brief summary of the Oxford Centre grading scheme follows (see reference 20 for detailed criteria):
Level A—consistent randomized controlled clinical trial or cohort study (as yet, there is no level A reference on DCD).
Level B—consistent retrospective cohort, exploratory cohort, outcomes research, case–control study or extrapolations from level A studies.
Level C—case-series study or extrapolations from level B studies.
Level D—expert opinion without explicit critical appraisal.

donors may pose different risks than those from controlled DCD donors (29–31). Principles of consent for donation and interventions prior to declaration of death may be significantly different for uncontrolled and controlled DCD (3).

Potential DCD donor characteristics (1–3,23–27)

- Medically suitable for donation
- Brain death criteria not met (except in rare circumstances), although a potential DCD donor may progress to become a DBD donor
- Catastrophic brain injury or other illness such as end-stage musculoskeletal disease, pulmonary disease or high spinal cord injury
- No expectation of meaningful survival, as determined by the patient's treating physician(s); request for withdrawal of ventilatory and organ-perfusion support by the patient's legal decision maker(s) and/or by properly executed prior first-party declarations by the potential donor.
- Informed consent obtained from the patient's legal decision maker(s) (obtained after decision to withdraw support): the possibility that the patient may not die or may not provide transplanted organs shall be communicated to the patient's legal decision maker(s) as a component of the informed consent process, as well as to operating room and other relevant hospital personnel, before withdrawal of ventilatory or organ-perfusion support.

Withdrawal of ventilatory and organ-perfusion support

- Optimally, withdrawal of ventilatory and organ-perfusion support will occur in the operating room. However, it is recognized that this is not always possible and that OPO efforts to facilitate the potential DCD donor's family wishes shall be supported.
- The family can be given the opportunity to spend time with the patient immediately prior to and during discontinuation of support and until cessation of cardiorespiratory function.
- Heparin shall be administered, prior to withdrawal of support, except in the rare case when it might be expected to hasten death and/or is prohibited per local procurement protocol (3,23,24,26). Phentolamine may be administered per local procurement protocol as long as it is not expected to hasten death. Specific informed consent for administration of each of these agents shall be obtained from the patient's legal decision maker(s) prior to withdrawal of support (3,23,24,26).
- Morphine and/or other analgesics may be given at the discretion of the patient's treating care team if the purpose is to minimize discomfort in a dying patient according to accepted end-of-life protocols, even if this might hasten death as an unintended consequence. Procurement team members shall not participate in decisions regarding the use of such agents (3,23,24,26).
- Members of the procurement team may be present prior to withdrawal of ventilatory and organ-perfusion support to prepare and drape the patient. During such preparation and draping, it is critical to recognize that the potential DCD donor is a patient who is still alive.
- Members of the procurement team shall not be in the presence of the patient at the time of withdrawal of support and until the declaration of death (this includes absence during withdrawal of ventilatory and organ-perfusion support, until the time of cardiorespiratory arrest, and through the waiting period until declaration of death—see below) (23,26).
- The patient's treating care team stops ventilation.

- The patient's treating care team monitors the patient and notes the time of cessation of cardiorespiratory function.
- Subsequently, a waiting period is observed prior to declaration of death to ensure that autoresuscitation does not occur. In as much as autoresuscitation has not been reported after 2 min (3,24), the ASTS recommends a 2-min waiting period in order not to unnecessarily increase warm ischemia time. However, the ASTS recognizes that a range of waiting period durations have been endorsed, primarily because data on autoresuscitation are limited. The Society of Critical Care Medicine recommends at least 2 min of observation (25) and the Institute of Medicine recommends 5 min (1–3). Until additional information is available, the duration of the waiting period shall be compliant with local OPO and donor hospital policies (2- to 5-min period).
  - Some DCD policies define the waiting period as a 'time-out' period after declaration of death. Whether declaration of death in the DCD setting requires a prior waiting period (following cessation of cardiorespiratory function) or such declaration requires a subsequent time-out period, in no instance shall organ procurement proceed until both the waiting period and declaration of death are completed.
- Declaration of death is the responsibility of the patient's treating care team. Assessment for cessation of cardiorespiratory function is made using accepted medical standards, in compliance with donor hospital policy. If withdrawal of support occurs outside the operating room, the patient shall be quickly moved to the operating room after the death pronouncement. Organ procurement may be temporarily delayed if a postmortem reperfusion technique such as normothermic extracorporeal membrane oxygenation (ECMO) is used (see below).
- If the patient has not been declared dead within the time frame stipulated by the local procurement protocol, then the donation is aborted and the patient is returned to the ward/intensive care unit for comfort care (1,23,26). The OPO coordinator shall document, on a preprinted flow sheet, hemodynamic measurements every minute, as well as the times of discontinuation of mechanical ventilation, cessation of cardiorespiratory function, waiting period, declaration of death, incision and perfusion of each organ. After procurement, careful assessment of this information is critical for assessing ischemic injury (23,24).

Operative technique (liver, kidney and/or pancreas procurement)

- An experienced donor procurement surgical team shall procure organs from DCD donors. The senior surgeon shall have reviewed the local OPO DCD protocol(s), be familiar with these ASTS DCD guidelines and be an experienced donor surgeon.
- There shall be adequate planning and communication with the donor coordinator(s) and operating room personnel.
- Each member of the surgical team shall behave professionally and courteously throughout the donor facility stay and shall always exhibit mutual respect for the hosting facility staff, even in the face of the often hectic and demanding nature of DCD organ procurement.
- The super rapid recovery (see below) or premortem cannulation (see below) techniques may be used for DCD organ procurement.
- Most surgeons use some modification of the super rapid recovery technique (32,33). Prior to withdrawal of support, the donor is typically prepared and draped, and the surgical instruments, preservation solution and tubing are set up to facilitate rapid recovery. Following the waiting period and declaration of death, the surgeons return to the operating room and expeditiously perform lower midline laparotomy and aortic cannulation. Ischemia time may be reduced by starting the aortic flush and topical ice cooling immediately after cannulation. Thereafter, the thoracic or supraceliac aorta is cross-clamped, and the vena cava is vented into the right chest. It is easier to cross-clamp the aorta in a dry field, but the vena cava should be vented first if cross-clamping is not expeditious, in order to avoid organ engorgement. The portal system is cannulated *in situ* via the inferior mesenteric vein or the portal vein may be flushed on the back table. The organs may be removed en bloc or separately.
- The premortem cannulation technique decreases the rush inherent with the super rapid recovery technique and may decrease warm ischemia time, particularly if withdrawal of support is performed outside the operating room. This technique requires cannulation of a femoral artery and femoral vein prior to withdrawal of support (33,34). Specific informed consent shall be obtained if this technique is to be used (1–3,23,24,26). Local anesthesia shall be used as appropriate. After declaration of death, a cold preservation solution is immediately infused via the femoral artery cannula, and the femoral vein cannula is opened to gravity to decompress the venous system. Thereafter, median sternotomy and midline abdominal incisions are made and the intraabdominal organs are topically ice cooled and then removed en bloc or separately.
  - A few centers use premortem cannulation in conjunction with postmortem ECMO to restore the flow of warm oxygenated blood to the intraabdominal organs during the interval between death and organ procurement, further facilitating unhurried organ procurement and possibly improving graft function (35).
- Special care is required to avoid damage to vital structures during DCD organ procurement, whether super rapid or premortem cannulation techniques are used. There must be particular concern about the possibility of aberrant arterial vasculature because all DCD visceral dissection is performed in a cold field without

blood flow (unless the ECMO technique is used) and there are no opportunities to assess pulses (33).
- If the DCD pancreas is not going to be procured, then the liver may be removed with the pancreatic head to avoid transecting an aberrant right hepatic artery and to minimize extraction time. The DCD liver and pancreas may be removed en bloc. If the organs are to be removed separately, the need to minimize ischemia time and the desire to procure the pancreas need to be balanced; it may be impractical to add whole-organ pancreatectomy to hepatectomy during DCD recovery in the face of unfavorable donor body habitus or long warm ischemia time (33,36).
- As with DBD organ procurement, there shall be a diligent search in both the abdominal and thoracic cavities for any neoplastic or infectious processes that may present risk for donor-related transmission.
- There shall be a low threshold for obtaining donor organ biopsies, to exclude predictors of poor graft quality such as centrilobular hepatic necrosis or intravascular renal microthrombosis.
- Careful consideration of risks and benefits is necessary when deciding whether or not to transplant a DCD organ with additional extended criteria donor or graft characteristics such as older donor age, hepatic steatosis or glomerulosclerosis.

Ischemia times

- Efforts shall be made to minimize both warm and cold ischemia times during DCD organ procurement and transplantation (11,13,14,19,24,33).
- Controlled DCD liver transplantation beyond the following time frames may be associated with increased complications:
  * True warm ischemia time (interval between significant ischemic insult, such as a drop in mean arterial pressure below 60 mmHg, and initiation of perfusion) longer than 20–30 min (33,37).
  * Total warm ischemia time (interval between discontinuation of mechanical ventilation and initiation of perfusion) longer than 30–45 min (11,13,14,24,33).
  * Cold ischemia time longer than 8–10 h (10,11,24).
- Controlled DCD kidney or pancreas transplantation beyond the following time frames may be associated with increased complications:
  * Total warm ischemia time longer than 45–60 min (24,38).
  * Cold ischemia time longer than 24 h for kidneys and longer than 18 h for pancreata (24).

Machine perfusion

- *Ex vivo* machine perfusion of organs may improve transplant outcomes.
- Pulsatile perfusion of DCD kidneys is used by many to decrease vasospasm and also to exclude kidneys with persistently high vascular resistance. Although insufficient scientific data are currently available to warrant mandating that DCD kidneys be pumped (7), there shall be a low threshold for using this technique in an effort to decrease delayed graft function (19).
- Techniques for machine perfusion of liver and of lung are currently investigational.

Recipient considerations

- The possibility of DCD organ transplantation shall be discussed with transplant candidates during the transplant evaluation process so that they have some knowledge about this type of organ transplantation (3,24).
- Transplant teams shall discuss the specific risks and benefits of controlled DCD organ transplantation with their patients. When pertinent, the possibility of biliary complications (liver) or delayed graft function (kidney) shall be disclosed (3,24,39,40).

Biliary issues

- DCD liver transplantation has been associated with the development of ischemic biliary complications (11,14–16). Although there is a paucity of scientific evidence regarding optimal management of the biliary system in controlled DCD liver donors, the following strategies may reduce biliary complications and improve outcomes:
  * Perform an expeditious, *in situ* biliary flush to minimize bile-induced epithelial damage; the common bile duct and gallbladder shall be generously irrigated early after initiating the cold flush (33).
  * Limit the use of DCD livers with longer ischemia times or from older donors (11,13,14,41–43).
  * Consider arterial revascularization before or simultaneously with portal revascularization of DCD livers (14,43).
  * Consider the use of a T-tube to facilitate interrogation of the biliary tree and therapeutic intervention (e.g. removal of biliary sludge and dilation of biliary stricture(s) prior to cast formation) (33).

Cardiothoracic organs

Pioneering surgeons have recently performed DCD lung transplants (44) and DCD heart transplants (45) with success. There are issues unique to DCD cardiothoracic organ procurement and transplantation in addition to those also relevant to DCD abdominal organs. The ASTS anticipates advances in the field of DCD cardiothoracic organ transplantation. When sufficient information and consensus are available, guidelines specific to cardiothoracic organs will be added to this document.

Conclusion

Best-practice guidelines for DCD organ transplantation will evolve as experience in this field increases. The ASTS encourages procurement and transplantation of DCD organs and continued research on ways to increase feasibility and improve outcomes of DCD organ transplantation.

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