Liver Transplantation Using Organ Donation After Cardiac Death

A Clinical Predictive Index for Graft Failure–Free Survival

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Objective: To define a prognostic scoring system for risk stratification of patients undergoing orthotopic liver transplantation (OLT) using grafts from donation after cardiac death (DCD).

Design: Retrospective study.

Setting: University transplant center.

Patients: Eighty-one patients underwent OLT using DCD grafts from March 1, 1994, to November 30, 2010. The mean follow-up was 2 years. Independent risk factors for graft failure after OLT were identified using Cox model and assigned risk score points. Points were summed and assigned to predictive index categories: 0 or 1 for low risk, 2 to 4 for intermediate risk, and 5 to 9 for high risk.

Results: Six multivariate factors predictive for graft failure after OLT using DCD grafts included the following: for recipients, (1) diagnosis of hepatitis C virus with malignancy, non–hepatitis C virus with malignancy, or hepatitis C virus only, (2) previous OLT, and (3) body mass index (calculated as weight in kilograms divided by height in meters squared) greater than 30; for donors, (4) hepatitis B core antibody positivity and (5) mean arterial pressure lower than 60 mm Hg for longer than 20 minutes after withdrawal of life support; and for grafts, (6) cold ischemia time longer than 6 hours. Five-year graft failure–free survival was significantly higher for the low-risk group (83%) compared with the intermediate-risk (62%) and high-risk (0%) groups ($P < .001$). Overall biliary complications occurred in 24 patients (29%), with ischemic cholangiopathy in 8 patients (9.9%).

Conclusions: Our study showed superior long-term patient survival with liver transplantation using DCD organs in highly selected donors and recipients. We propose a practical risk stratification system highly predictive of long-term survival outcomes after OLT using DCD grafts. Application of this predictive index for transplant candidates receiving DCD liver grafts would improve patients’ outcomes and optimize use of scarce resources.

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IN THE UNITED STATES, LAW REQUIRES THAT CRITERIA FOR BRAIN DEATH OR CARDIAC DEATH BE MET PRIOR TO ORGAN DONATION FOR TRANSPLANTATION. Brain death is defined as the irreversible cessation of all brain function, including the brainstem, and cardiac death is defined as irreversible cessation of circulation and respiratory functions. Most organs today are retrieved from donation after brain death (DBD) donors.

See Invited Critique at end of article

Donation after cardiac death (DCD) has been used to address the acute shortage of organs and to decrease waitlist mortality. There are 2 methods of organ procurement for DCD: donation after controlled cardiac death, with planned withdrawal of ventilator and organ-perfusion support in the face of catastrophic illness (Maastricht classification class III), or donation after uncontrolled cardiac death, which follows unexpected cardiopulmonary arrest and/or unsuccessful resuscitation (Maastricht classification classes I, II, and IV).1 In contrast to liver grafts from DBD donors for which blood circulation and organ perfusion are maintained by the beating heart until initiation of organ preservation, organs from DCD donors are subjected to a period of absence of blood flow before cold preservation can be administered. Diminished quality and function of DCD liver grafts after transplantation have been attributed to an additional warm ischemic insult that augments organ preservation injury.2,3

At present, long-term outcome data for orthotopic liver transplantation (OLT) using grafts procured after cardiac death
are conflicting. While studies using pooled registry data reported inferior outcomes with DCD compared with DBD,4,5,6 single-center experiences showed comparable survival outcomes for these 2 types of donors.7,11 Earlier studies also reported that ischemic cholangiopathy (IC), a diffuse stricturing of the intrahepatic bile ducts associated with ischemic insults, occurs in up to 50% of recipients following OLT using DCD donors.12,14 A clinical model to guide the use of livers from DCD donors and to predict outcomes after OLT would be of value but is lacking. Our study was undertaken to define a prognostic scoring system for risk stratification of patients undergoing OLT using livers procured after cardiac death.

**DEFINITION OF ISCHEMIA TIMES AND OPERATIVE VARIABLES**

A timeline of different phases of ischemic injuries for organs procured after cardiac death is shown in Figure 1. Donor warm ischemia time (DWIT) is defined as the interval from withdrawal of life support to initiation of cold organ preservation; graft cold ischemia time (CIT) is defined as the interval from initiation of donor in vivo cold organ preservation to removal of the graft from 4°C cold storage; and graft warm ischemia time (WIT) is defined as the interval from removal of cold storage to establishment of reperfusion of the liver graft. Donor operative variables after withdrawal of life support were organ hypoperfusion (OH), defined by a mean arterial pressure lower than 60 mm Hg, and tissue hypoxemia (TH), defined by tissue oxygen saturation less than 70%.

**PATIENT SELECTION AND OLT PROCEDURE**

Patients diagnosed with end-stage liver disease were evaluated by a multidisciplinary team as previously described.15 Before 2002, patients were listed for liver transplant candidacy according to the United Network for Organ Sharing status categories; from 2002 to the present, the current Model for End-Stage Liver Disease system has been used.16 We used our center’s recipient-donor graft-pairing strategy as previously described.17 The surgical procedure for OLT was performed in a standard manner as previously described.18

**DCD DONOR SELECTION AND PROCUREMENT PROTOCOL**

Donor selection used stringent medical screening criteria. Donors were younger than 45 years, had a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) lower than 30, had been hospitalized for 5 days or less, and had preprocurement serum liver transaminase levels less than twice the normal values at the time of organ acceptance and procurement. Grafts that had a projected organ CIT less than 8 hours, had excellent liver parenchymal quality on intraoperative assessment, and had DWIT, OH, or TH for less than 30 minutes.

The DCD procurement protocol followed the Institute of Medicine guidelines.19 Artificial life support was withdrawn in the operating room or intensive care unit (ICU). Systemic heparin was administered prior to withdrawal of life support if the policies of the organ procurement organizations or donor hospital permitted its use. An independent physician from the donor hospital was assigned to provide end-of-life care, withdraw life support, and declare death. Following a 5-minute mandatory waiting period after asystole to ensure that autoreperfusion did not occur,20 cold organ preservation with University of Wisconsin solution (4-6 L) was infused. Organs were stored in University of Wisconsin solution at 4°C for transport. In 2006, we initiated a center protocol of administering tissue plasminogen activator (TPA) to all DCD livers before implantation. The TPA (Actiplase), in a total dose of 2 mg in 100 mL of sterile water, was injected into the donor hepatic artery on the back table and then contained within the arterial system by a vascular clamp on the donor hepatic artery until vascular anastomosis.

**RECIPIENT, DONOR, AND OPERATIVE VARIABLES**

For both recipients and donors, variables collected for analysis included age, ethnicity, sex, and BMI. For recipients, the following were noted: primary liver disease, Model for End-Stage Liver Disease score, prior OLT, need for hospitalization, renal replacement therapy, and ventilator support before OLT. For donors, the following were collected: length of hospitalization before donation, history of exposure to hepatitis B virus (HBV) (HBV core antibody positivity), presence of hepato-
titis C virus (HCV) infection, cause of death, need for vasopressors prior to donation, location of life support withdrawal (in the operating room vs ICU), DWIT, and duration of OH and TH after life support withdrawal. Operative variables included graft CIT and WIT.

OUTCOME MEASURES

The primary end point was 5-year graft failure–free survival. Graft failure was defined as either the need for retransplantation or death due to primary graft nonfunction or biliary complication. Secondary outcome measures focused on biliary complications and causes of graft failure. Biliary complication type was classified as either IC or anastomotic leak or stricture.

STATISTICAL ANALYSES

Graft failure–free patient survival curves were computed using Kaplan-Meier methods and compared using log-rank tests. Means were compared using Wilcoxon test, and proportions were compared using chi² test. Univariate and multivariate analyses were conducted using Cox proportional hazards model. The backward stepwise procedure was used for variable selection with retention criteria at a P ≤ .25 level of significance. Statistical analysis was performed using SAS version 9.1 statistical software (SAS Institute, Inc, Cary, North Carolina).

PROGNOSTIC SCORING MODEL

AND CALCULATION OF GRAFT FAILURE

PREDICTIVE INDEX

A Cox proportional hazards model was used to identify independent risk factors for graft failure after OLT. Each independent predictor was assigned risk score points ranging from 1 to 3, proportional to the corresponding parameter estimate (log of hazard ratio) under the Cox model. The graft failure predictive index (PI) was established by the sum of all risk score points for each patient. Based on the observed distribution of graft failure, the patients were assigned to the following PI risk categories: 0 or 1 for low risk, 2 to 4 for intermediate risk, and 5 to 9 for high risk. The outcome data were analyzed by PI category.

RESULTS

RECIPIENT CHARACTERISTICS

AND SEVERITY OF ILLNESS

The study group included 81 patients who received OLT with DCD grafts. The mean (SD) age was 54 (11) years; 52 patients (64%) were male; and 35 patients (43%) were white, 29 (36%) were Hispanic, 10 (12%) were Asian American, 5 (6%) were Middle Eastern American, and 2 (2%) were African American. The mean (SD) BMI was 25 (5); and the mean (SD) donor age was 36 (14) years; 53 donors (65%) were male; the mean (SD) BMI was 25 (5); and the mean (SD) duration of hospitalization prior to organ procurement was 5.6 (3) days. Six donors (7%) had HBV core antibody positivity, and 2 donors (2%) had HCV infection. Systemic heparin was administered to 70 of 81 donors (86%) prior to withdrawal of life support. From the time of life support withdrawal to cardiac arrest, the mean (SD) duration of OH was 18 (7) minutes and the mean (SD) duration of TH was 22 (8) minutes. The mean (SD) DWIT was 26 (9) minutes, the mean (SD) graft CIT was 375 (138) minutes, and the mean (SD) WIT was 39 (10) minutes. Tissue plasminogen activator, administered into the graft hepatic artery before implantation, was used in 50 livers (62%).

DONOR CHARACTERISTICS

AND ISCHEMIA TIMES

The mean (SD) donor age was 36 (14) years; 53 donors (65%) were male; the mean (SD) BMI was 25 (5); and the mean (SD) duration of hospitalization prior to organ procurement was 5.6 (3) days. Six donors (7%) had HBV core antibody positivity, and 2 donors (2%) had HCV infection. Systemic heparin was administered to 70 of 81 donors (86%) prior to withdrawal of life support. From the time of life support withdrawal to cardiac arrest, the mean (SD) duration of OH was 18 (7) minutes and the mean (SD) duration of TH was 22 (8) minutes. The mean (SD) DWIT was 26 (9) minutes, the mean (SD) graft CIT was 375 (138) minutes, and the mean (SD) WIT was 39 (10) minutes. Tissue plasminogen activator, administered into the graft hepatic artery before implantation, was used in 50 livers (62%).

GRAFT FAILURE AND

BILIARY COMPLICATIONS

Graft failure occurred in 14 patients (17%) at a median interval of 5.4 months (range, 0.79 months) after transplantation. Biliary complications were the cause of graft failure in 7 patients (IC in 5 and anastomotic strictures in 2). Other causes of graft failure included recurrence of HCV infection in 2 of 38 patients (5%) undergoing transplantation for HCV, primary graft nonfunction in 2, hepatic artery thrombosis in 2 (one immediately postoperatively and the other 157 days after OLT), and disseminated fungal sepsis in 1 patient 25 days after OLT. Among these 14 patients, 10 (71%) required retransplantation, and 4 (29%) died due to sepsis (n=3) and current HCV–related graft failure (n=1).

Biliary complications occurred in 24 of the 81 patients (29%), with IC in 8 and anastomotic leak or strictures in 16. Figure 2 shows the cumulative incidence

![Figure 2. Cumulative incidence for biliary complications after orthotopic liver transplantation using organs from donation after cardiac death.](https://jamanetwork.com/)

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rates for both types of biliary complication. The incidence of IC was 9.9%. The median interval from OLT to occurrence of biliary complication was 2.4 months (range, 0-46 months). While the median interval to development of IC was 1.9 months (range, 0.1-19 months), it was 3.4 months (range, 0.8-46 months) for anastomotic strictures. Comparing types of biliary complication between grafts that received TPA (n=50) and those that did not (n=31), the proportions of livers that developed IC were comparable between treatment groups.

### GRAFT FAILURE–FREE SURVIVAL ANALYSIS

The overall 1-, 3-, and 5-year graft failure–free survivals after OLT were 78%, 62%, and 53%, respectively. Univariate predictors of diminished graft failure–free survival included in the multivariate analysis were recipient diagnosis of HCV with malignancy (HR=15.1; P <.001), non-HCV with malignancy (HR=5.5; P=.06), recipient BMI greater than 30 (HR=7.8; P=.02), and HCV (HR=4.8; P=.04), prior OLT (HR=3.8; P=.03), and BMI greater than 30 (HR=1.4; P=.45). Donor factors included DWIT longer than 30 minutes (HR=3.2; P=.12), OH for longer than 20 minutes (HR=2.5; P=.13), requiring 2 or more vasopressors at the time of organ procurement (HR=2.3; P=.27), TH less than 70% for more than 20 minutes (HR=1.5; P=.48), being older than 45 years (HR=1.6; P=.24), withdrawal of life support outside the operating room (HR=1.4; P=.64), and cerebrovascular event as the cause of donor death (HR=1.3; P=.56). Graft CIT longer than 6 hours also was a risk factor for graft failure after OLT (HR=1.5; P=.33).

Multivariate analysis for graft failure–free survival is shown in Table 1. Significant independent predictors of transplant graft failure included recipient diagnosis of HCV + M (HR=15.1; P =.001), non-HCV + M (HR=5.5; P =.06), and HCV only (HR=4.5; P =.07), prior OLT (HR=11.6; P =.002), recipient BMI greater than 30 (HR=2.8; P =.03), donor HBV core antibody positivity (HR=4.2; P =.009), donor OH longer than 20 minutes (HR=1.9; P =.23), and graft CIT longer than 360 minutes (HR=2.7; P >.05).

### PI CATEGORIES FOR GRAFT FAILURE

Based on the results of the multivariate analysis, risk score points were assigned to the 6 independent risk factors for graft failure after OLT (Table 1). The PI was established by the sum of all risk score points for each patient. The range of possible PIs in our model was 0 to 9. Patients were assigned to 1 of the 3 PI categories, with 18 patients (22%) in the low-risk group, 46 (57%) in the intermediate-risk group, and 17 (21%) in the high-risk group.

The PI category was highly predictive of long-term graft failure–free survival outcome (Figure 3). While the 5-year graft failure–free patient survival was significantly higher in the low-risk group compared with the intermediate-risk group (83% vs 62%, respectively; P <.001), survival benefit was also seen in the intermediate-risk group compared with the high-risk group. There were no survivors in the high-risk group after 21 months.

The use of liver grafts from DCD donors remains controversial because of the high rates of graft failure and biliary complications compared with grafts from DBD donors.6,21 Notwithstanding these complications, DCD liver grafts are precious life-saving organs that can reduce wait-list deaths and have been reported to provide survival benefits in patients with high acuity of illness (Table 2).7,8,20 Our study was undertaken to develop a clinical model to guide the use of livers from DCD donors and predict outcomes after OLT.

Although several investigators have identified predictors for graft failure using DCD grafts,7,8,20 ours is the first study to our knowledge to define a prognostic scoring

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**Table 1. Multivariate Analysis of Transplant Graft Failure and Assignment of Risk Score Points**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hazard Ratio</th>
<th>P Value</th>
<th>Points</th>
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</thead>
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<tr>
<td>Recipient Diagnosis</td>
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<td></td>
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</tr>
<tr>
<td>HCV with malignancy</td>
<td>15.1</td>
<td>.001</td>
<td>3</td>
</tr>
<tr>
<td>Non-HCV with malignancy</td>
<td>5.5</td>
<td>.06</td>
<td>2</td>
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<tr>
<td>HCV only</td>
<td>4.5</td>
<td>.07</td>
<td>2</td>
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<tr>
<td>Prior OLT</td>
<td>11.6</td>
<td>.002</td>
<td>2</td>
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<tr>
<td>BMI &gt;30</td>
<td>2.8</td>
<td>.03</td>
<td>1</td>
</tr>
<tr>
<td>Donor HBV core antibody positivity</td>
<td>4.2</td>
<td>.009</td>
<td>1</td>
</tr>
<tr>
<td>MAP ≤60 mm Hg for &gt;20 min</td>
<td>1.9</td>
<td>.23</td>
<td>1</td>
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<tr>
<td>after withdrawal of life support</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Organ</td>
<td></td>
<td></td>
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<td>Cold ischemia time &gt;360 min</td>
<td>2.7</td>
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Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HBV, hepatitis B virus; HCV, hepatitis C virus; MAP, mean arterial pressure; OLT, orthotopic liver transplantation.

**Figure 3.** Graft failure–free survival after orthotopic liver transplantation using organs after cardiac death by predictive index categories.
system, based on clinically relevant information available at the time of organ acceptance, for risk stratification of patients undergoing OLT using livers procured after cardiac death. We identified 6 independent risk factors for graft failure that included 3 recipient risk factors (diagnosis of HCV + M, non-HCV + M, or HCV only; BMI > 30; and prior OLT), 2 donor factors (HBV core antibody positivity and OH > 20 minutes), and an operative factor (CIT > 6 hours). While these risk factors were predictive of diminished survival outcomes in our study, certain recipient characteristics may not be exclusive to the use of DCD grafts. In OLT using grafts from DBD donors, HCV and/or primary hepatic malignancy also have significantly inferior long-term survival outcomes compared with other liver diseases such as primary biliary cirrhosis.13

Unique predictors for graft failure related to organs from DCD donors included donor HBV core antibody positivity, prolonged OH, and CIT longer than 6 hours. A possible explanation for diminished survival using livers from donors with HBV core antibody positivity might be that these donors frequently have occult HBV infection and ongoing viral replication in the liver, despite the absence of serologic evidence of active HBV infection, that may augment hepatocyte necrosis when subjected to ischemic insults.10-22 While the association between donor HBV core antibody positivity and graft failure in DCD livers remains unproven, this relationship is not seen in livers from DBD donors.32

We also investigated several factors related to DCD procurement that may increase risk of graft nonfunction, including the interval from donor extubation to asystole, the duration of postextubation hypotension, and the duration of hypoxemia.8,24 We found that OH longer than 20 minutes after withdrawal of life support was correlated strongly with post-OLT graft failure. This finding supports a procurement protocol for withdrawal of life support in the operating room rather than in the ICU or preoperative holding unit. The need to transport donors from these locations to the operating room after declaration of cardiac death could further increase warm ischemia times and diminish the quality of livers.

Similar to previous studies, prolonged graft CIT is an independent predictor for DCD graft failure.7,8,28 We found that organ cold storage longer than 6 hours conferred nearly a 3-fold increased risk of graft failure. Moreover, prolonged CIT has been shown to augment the adverse effects of donor warm ischemia in the development of IC due to the vulnerability of biliary epithelium to ischemia and reperfusion injury.12,23 While IC remains a major complication after OLT using DCD grafts,14 centers that have implemented rigid donor selection criteria and use of TPA in DCD livers have reported IC incidence rates of 8% to 10%, comparable to DBD grafts.7,28 We found no difference in the occurrence of IC between grafts treated with TPA (10.0%) and grafts not treated with TPA (9.7%). The relatively low incidence rates of IC in both groups may be attributed to the short DWIT (mean, 26 minutes) and graft CIT (mean, 375 minutes) in our cohort. Future studies evaluating the potential role of TPA in protecting DCD grafts from IC after a prolonged DWIT and CIT would be of value in expanding the DCD donor pool.

Using our risk stratification PI, we found that 5-year graft failure-free survival was 83% in the low-risk group and 62% in the intermediate-risk group. For the high-risk group, the 1-year survival was 35% and no patient survived beyond 21 months. Our DCD protocol at UCLA follows stringent recipient-donor pairing selection criteria. Consequently, variables such as donor and recipient age, duration of predonation donor hospitalization, and other risk factors for graft failure were not included in the prognostic scoring model. In addition, there is no system to measure the surgeon’s expertise in DCD proc-

### Table 2. Collected Series for Liver Transplantation Using Grafts From Donation After Cardiac Death

<table>
<thead>
<tr>
<th>Source</th>
<th>Period</th>
<th>DCD, No.</th>
<th>Overall Biliary Complication Rate, %</th>
<th>IC, %</th>
<th>1y</th>
<th>3y</th>
<th>5y</th>
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<tr>
<td>Abt et al,12 2003</td>
<td>1996-2001</td>
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<td>25</td>
<td>12.5</td>
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Abbreviations: DCD, donation after cardiac death; IC, ischemic cholangiopathy.
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REFERENCES

Liver Transplantation With Donation After Cardiac Death

A Treacherous Field!

Livers from DCD are occasionally used as a means to increase the donor pool. The number of DCD liver transplants continues to be very small due at least in part to the reluctance by transplant surgeons to accept the potential risks associated with such organs, particularly biliary and vascular complications, a high retransplantation rate, and exorbitant long-term costs. Hong et al\(^1\) conducted a retrospective analysis of their experience with the use of DCD liver allografts. Their objective was to identify donor and recipient factors that predict outcomes. To do so, they developed a predictive index based on donor and recipient risk factors that allows them to group transplants in low-, intermediate-, and high-risk categories. Based on such analysis, the graft survival was good in the low-risk group, acceptable in the intermediate-risk group, and poor in the high-risk group. In the high-risk group, there were no survivors beyond 21 months after transplantation. But, it is not so simple! Statistical formulas (particularly when they are based on small sample sizes such as this series) may lead to erroneous conclusions. Some of the calculations in this UCLA series are based on 6 observations. A minor change to erroneous conclusions. Some of the calculations in this UCLA series are based on 6 observations. A minor change in the intermediate risk group may result in a finding not being statistically significant. However, the biggest limitation of this particular study is the inherent bias while selecting the donor and recipient criteria for the transplants. In fact, such criteria may be considered too strict by some and too lax by others. For example, one can argue that a DCD graft from someone older than 45 years may not be a good option for a certain type of patient (eg, a patient with HCV) but may be a lifesaving alternative for another patient (eg, a patient without HCV). Such a possibility and many other permutations were not addressed in this particular study. The authors’ efforts to create a better path to assist the clinician with tangible criteria to mitigate the potential problems with DCD liver transplants must be commended. However, their conclusions must be acknowledged as just guidelines. Studies from large databases may identify factors, other than the ones included in this study, that may lead to improved outcomes in DCD liver transplantation. The organ donor shortage is so severe that physicians should not shy away from using DCD liver allografts. On the contrary, DCD transplantation must be encouraged. It is likely that the best solution to lower the high complication rate associated with DCD liver transplantation is to allow for a better match between donor and recipient, something that cannot be effectively done with the current organ allocation policies.

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