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Selecting DCD Recipients Using Predictive Indices

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Background. Donation after circulatory death (DCD) allografts might represent one of the largest untapped sources of liver allografts. Our aim was to identify independent recipient risk factors that predict mortality in DCD allograft recipients to preselect optimal candidates for successful transplantation. Furthermore, we compared the application of our newly constructed DCD Recipient Selector Index (RSI) score to previously developed models to determine superiority in predicting recipient survival. **Methods.** Using the Organ Procurement and Transplantation Network database, we performed univariate and multivariate retrospective analyses on 4228 DCD liver allograft recipients. **Results.** We identified 8 significant factors and incorporated them into the weighted RSI to predict 3-mo survival following DCD liver transplantation with a C-statistic of 0.6971. The most significant recipient risk factors were recipient serum sodium levels >150 mEq/L at transplant, recipient albumin <2.0 g/dL at transplant, and a history of portal vein thrombosis. Because Model for End-Stage Liver Disease (MELD) score components were included as individual predictors, the DCD RSI predicts survival independently of MELD. Upon comparison with 3 previous recipient risk scores—Balance of Risk, Renal Risk Index, Patient-Survival Outcomes Following Liver Transplantation—the DCD RSI was determined to be superior at selecting optimal candidates pre-DCD transplantation, yielding a C-statistic of 0.6971. **Conclusions.** After verifying the performance of predictive indices for selection of DCD recipients, the DCD RSI is best used to preselect patients for optimized outcomes after DCD transplantation. This can increase utilization of DCD donors by improving outcomes.(Transplantation Direct 2023;9: e1467; doi: 10.1097/TXD.0000000000001467.)

A significant organ donor shortage exists in the United States. In 2019, only 8896 liver transplants were performed while 1190 patients died on the waiting list; as of May 2020, there were 12 500 liver transplant candidates waiting to be transplanted.[1] One underutilized source of organs is from donation after circulatory death (DCD) donors. Twenty-five percent of transplant centers do not even perform DCD transplants. Many of the ones that do restrict DCD transplantation to local organs and only use organs procured by their own teams.[2] In 2019, fewer than 10% of liver transplantations involved DCD organs.[1] Although there has been some increase in DCD transplants over the last 3 y, there has been a corresponding increase in the discard rate: 306 DCD organs were discarded and 1211 not recovered in 2019.[3] Low DCD allograft utilization can be explained because of the potential for poor outcomes, rendering hospitals and Organ Procurement Organizations reluctant to initiate DCD programs.[3] DCD procurements are also costly and time-consuming, making them a wasted investment if the organ is eventually discarded.[4] One study found that up to 6% of DCD lung allografts were discarded because of the inability to locate a recipient and, ultimately, organ refusal by regional and national transplant programs.[5]

Many studies have analyzed factors influencing DCD allograft survival and outcomes, including shorter warm and cold ischemia time (CIT), younger donor age, and lower donor body mass index. Authors suggested that optimizing these factors can safely expand the number of available donors for DCD transplantation.[2,3,6,7] Consequently, several risk scores

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have been developed to predict DCD transplantation outcomes, most notably, the UK DCD Risk Score (C-statistic of 0.79).[7] The UK DCD Risk Score has been validated using the United Network for Organ Sharing (UNOS) database (C-statistic of 0.72 for 1-y graft survival) and should be used in practice to detect high-risk combinations of donor and recipient factors in DCD transplantation. However, it cannot be used to preselect candidates for DCD organs before a graft becomes available.

To have the best outcomes after DCD transplantation, a risk index solely formulated through recipient factors is required. In the previous literature, multiple risk models have been derived from donor–recipient factors to predict patient survival posttransplantation.[8] However, these scores were not specifically constructed to be used within the scope of DCD allografts.

It was our intention to create a model specifically tailored for DCD allografts and to evaluate its performance compared to other established risk indices. After evaluation, the most accurate index could then be used to preselect patients for DCD transplantation. This would enable physicians to obtain informed consent ahead of time and also to create a pool of recipients that can be quickly mobilized for expedited allocation.

MATERIALS AND METHODS

Design

We performed a retrospective analysis of UNOS patient-level data of all recipients of orthotopic liver transplantation in the United States between March 1, 2002, the date of implementation of the Model for End-stage Liver Disease (MELD) prioritization system, and December 30, 2017. Patient consent and study approval were waived by the institutional review board because the data are deidentified, and no patient information was reported in the study.

Setting

Our analysis employed the liver registry with data collected by the Organ Procurement and Transplantation Network (OPTN). All data within the OPTN database are collected by transplant officials, laboratories, and Organ Procurement Organizations via an online application in a perioperative setting. This includes waitlist data, transplantation data, and posttransplantation follow-up data. Follow-up information is collected at 6 mo and then yearly after transplantation.

Population

Our data stem from the UNOS database, which has data for every organ donation and transplant event that occurred in the United States since October 1, 1987. Because this analysis was conducted using a national database, the conclusions drawn from the study should be generalizable to any adult patient on the transplant waitlist in the United States.

Sampling

We included all transplant recipients aged 18 y or older who have received a DCD allograft in our analysis. Patients undergoing combined or multivisceral transplants and recipients of a live-donor transplant were excluded from the study. All patients were followed from the date of transplant until either death or the date of last known follow-up.

Data Collection

Risk Factors

The organ and donor risk factors considered in this analysis are listed in Table 1. Independent variables were clinically categorized before regression analysis to maintain simplicity of the risk score calculation. The characteristics that were present in the plurality of transplants were used as reference groups. This analysis only included recipients who were transplanted after the MELD scoring system was instituted for liver allocation in 2002, resulting in high entry completion (99.9%). Serum creatinine was utilized instead of calculated creatinine clearance because serum creatinine is readily accessible for rapid assessment of donor allograft quality. Patients with malignancy were known to have cancer before transplantation and did not reflect incidentally discovered cancer at transplantation.

TABLE 1.

Factors considered in relation to success of donation after circulatory death allograft transplantation

Recipient risk factors	Blood type (ABO) incompatibility
	Age: 18–30, 60–65, >65
	Serum albumin <2.0 g/dL
	Ascites: slight, moderate
	Spontaneous bacterial peritonitis
	Cirrhosis: type C, type B and C, alcoholic with hepatitis C
	Hepatitis C: chronic or acute
	Race: African American
	Encephalopathy III/IV
	Hemodialysis before transplant
	BMI: 30–35, 35–40, >40
	MELD score 30–35, >35
	Bilirubin (g/dL): <2, 8–16, 16–32, >32
	Functional status (Karnofsky Score):
	10%—Fatal
	20%—Very sick
	50%—Requires assistance
	60%—Occasional assistance
	70 %—Self care possible
	80%—Normal activity with effort
	90%—Normal activity with minor symptoms
	100%—Normal
	Serum sodium (mEq/L): <125, 125–130, 130–135, >150
	INR: 2–2.5, 2.5–3, 3–3.5, 3.5–4, >4
	Type of exception relative to HCC: HBL, HCC, NON-HCC
	Mechanical, ventilated, or organ-perfusion support
	Hospitalized or in intensive care unit
	Previous transplants: 1, 2
	History of portal vein thrombosis
	Previous upper abdominal surgery
	UNOS regions
	Insurance: private, medicaid
	Highest education level at registration: high school, technical, bachelors, doctor
	Works for income
Other risk factors	Cold ischemia time (h): <6, 12–14, >14
	Distance from hospital (miles): 500–1000, >1000 miles
	UNOS region
	Allocation: regional or national

BMI, body mass index; HBL, hepatoblastoma; HCC, hepatocellular carcinoma; INR, international normalized ratio; MELD, Model for End-stage Liver Disease; UNOS, United Network for Organ Sharing.

Data Entry

Most variables significant in univariate and multivariate analyses are very well populated (~100%), with serum sodium levels at transplant (92%) and CIT (97%) representing the lowest entry completion rates. Donor warm ischemia time, defined by oxygen saturation in peripheral blood below 70% or by a decrease of systolic blood pressure or mean arterial pressure below 50 mm Hg, was not included in the study because of its poor entry completion rate (69%). Recipient warm ischemia time was not supplied by UNOS. Recipients with missing entries were not dropped but, rather, added to the reference group under the assumption that the missing reports were randomly distributed. Given a large number of risk factors analyzed, this was necessary to preserve the total number of patients studied.

Data Analysis

Regression

Data were analyzed using a standard statistical software package, Stata R 13.0 (Stata Corp, College Station, TX). Continuous variables were reported as a mean ± SD and compared using the Student *t*-test. Contingency table analysis was used to compare categorical variables. Results were considered significant at a *P* value of <0.05. All reported *P* values were 2-sided. The primary outcome measure was patient death. Time to death was assessed as time from the date of transplantation to the date of death. Kaplan-Meier analysis with log rank test and logistic regression were used for time-to-event analysis. Three-month survival was the dependent variable and the risk factors were the independent variables in the logistic regression analysis. Patients lost to follow-up (n = 142) or alive (n = 2656) on December 30, 2017, were censored at the date of last known follow-up.

Logistic regression analysis determined the predictors of patient death at 3 mo posttransplantation. Three-month survival was chosen as the endpoint for risk calculation to allow adequate time for recovery after transplantation. Additionally, some complications of DCD transplants, such as ischemic-type biliary lesions, do not manifest within a month. In addition, MELD and many posttransplant utility scores—including the Balance of Risk (BAR) Scoring System and Survival Outcomes Following Liver Transplantation (SOFT) Score—use 3-mo survival. To demonstrate the accuracy of the risk score calculation, patient survival scores at 1 mo, 6 mo, and 1 y posttransplant were used as alternative endpoints.

Risk Score

Recipient and organ risk factors were first analyzed with univariate analysis. Variables found to be significant in univariate analysis ($P < 0.05$) were then subjected to multivariate analysis. Points were assigned to each factor based on odds ratio (OR) for patient death at 3 mo. One point was awarded, positive or negative, for every 10% change in risk for death at 3 mo. The overall score for each variable was rounded to 1 decimal point.

We assigned 3 risk groups based on predicted 3-mo waitlist mortality and formulated one score, the DCD Recipient Selector Index (RSI). The DCD RSI is based only on recipient factors and predicts the most optimal patients on the waitlist to receive a DCD allograft. Model discrimination was assessed using the area under the receiver operating characteristic curve.

Score Validity

The DCD RSI score was cross-analyzed with 3-mo patient mortality to calculate the positive/negative predictive values and specificity/sensitivity. The analysis thresholds were set according to the DCD RSI score percentiles; a score <5 tested for patient survival (true positive), and a score >10 tested for patient mortality (true negative). The thresholds were categorized as low-risk (78th percentile and below patient population) and high-risk (95th percentile and above patient population) accordingly. For comparison with the BAR, Renal Risk Index (RRI), and Patient-SOFT (P-SOFT), identical analyses were assessed according to percentiles.

RESULTS

Patient Demographics

A total of 4228 DCD organ recipients with 15.663 y-at-risk were analyzed. Mean graft survival was 3.69 y. Mean follow-up was 3.70 y. Demographic and clinical characteristics of the study population are summarized in Table 2.

Regression

The significant risk factors, presented in Table 3, were recipient serum sodium at transplant >150 mEq/L (OR 8.387; confidence interval [CI], 3.231-21.769), recipient albumin at transplant <2.0 g/dL (OR 1.894; CI, 1.280-2.802), a history of portal vein thrombosis (PVT; OR 1.855; CI, 1.150-2.994), intensive care unit or hospital setting (OR 1.661; CI, 1.125-2.451), and a history of previous upper abdominal surgery (OR 1.338; CI, 1.027-1.744). The significant protective factors were CIT <6 h (OR 0.617; CI, 0.471-0.808), 80% functional status (OR 0.610; CI, 0.381-0.976), and 90% functional status (Karnofsky Score) (OR 0.157; CI, 0.038-0.651).

Risk Score

Table 3 summarizes recipient factors and their assigned point values. The DCD RSI for each transplant recipient is calculated by summing the point values for corresponding individual risk and protective factors. Figure 1 illustrates the Kaplan-Meier curve and life-table analysis of immediate patient survival post–liver transplantation based on risk point totals from the DCD RSI. Using the DCD RSI score, the 3-mo patient survival of recipients with <5 points was 94.7%, 5 to 10 points was 85.4%, and >10 points was 78.5%. The groups were labeled according to 3-mo mortality risk, with <5 points designated as acceptable risk (85% of patients in the study), 5 to 10 points as moderate risk (10% of patients in the study), and >10 points (5% of patients in the study) as high risk. The difference between the moderate-risk and high-risk groups with reference to the acceptable risk group is statistically significant, with $P < 0.001$ by log rank test. Table 4 provides examples of transplant candidates allocated to the different risk groups according to assigned point values of the risk factors.

Calculations of area under the receiver operating characteristic curve for 3-mo survival are shown in Figure 2 and show a DCD RSI C-statistic value of 0.6971 (CI, 0.6640-0.7305). The accuracy of the DCD RSI was validated by applying the calculation to alternative endpoints, such as patient survival

TABLE 2.

Demographic and clinical characteristics of the study population

	Donor	Recipient (at transplant)
Age (y)	34.7 ± 13.7	55.6 ± 9.5
Female (%)	32.1	30.2
African American (%)	8.7	8.0
Height (cm)	172.3 ± 12.0	172.6 ± 10.0
Weight (kg)	79.4 ± 20.2	85.8 ± 19.4
BMI	26.6 ± 5.9	28.7 ± 5.6
INR	NA	1.8 ± 1.1
Creatine (mg/dL)	1.1 ± 1.3	1.3 ± 0.9
Bilirubin (g/dL)	0.8 ± 0.7	6.0 ± 8.6
Serum sodium (mEq/L)	NA	136.0 ± 5.2
Serum albumin (g/dL)	NA	3.1 ± 0.7
MELD	NA	19.1 ± 9.1
Cause of liver failure	NA	Cirrhosis type B 1.6% Cirrhosis type C 20.4% Cirrhosis cryptogenic 4.3% Fatty liver 8.1% Alcoholic cirrhosis 14.5% Hepatocellular carcinoma 6.0% Hepatocellular carcinoma and cirrhosis 21.1%
Patients in ICU or hospital (%)	NA	20.27%
Previous upper abdominal surgery	NA	42.83%
History of portal vein thrombosis	NA	4.94%
AST or SGOT (IU/L)	84.0 ± 116.7	NA
ALT or SGPT (IU/L)	71.1 ± 105.5	NA
DRI	2.2 ± 0.4	NA
% Regional allocation	25.2%	NA
% National allocation	8.0%	NA
Cold ischemia time (h)	6.3 ± 2.8	NA
Warm ischemia time (min)	16.6 ± 8.4	NA
Cause of death	Anoxia 41% CVA 17.5% Trauma 37.1%	NA

ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMI, body mass index; CVA, cardiovascular accident; DRI, donor risk index; ICU, intensive care unit; INR, international normalized ratio; MELD, Model for End-stage Liver Disease; SGOT, serum glutamic-oxaloacetic transaminase; SGPT, serum glutamic pyruvic transaminase.

at 1 mo (C = 0.7312; CI, 0.6922-0.7702), 6 mo (C = 0.6809; CI, 0.6511 0.7106), and 1 y (C = 0.6538; CI, 0.6271-0.6805). The DCD RSI also correlates with posttransplant graft survival at 1 mo (C = 0.6742; CI, 0.6233-0.6817) and 3 mo (C = 0.6525; CI, 0.6233-0.6817).

CIT Sensitivity

A sensitivity analysis of the score was run to test for significance of the variable CIT. The reference in Table 3 was changed to 6 to 8 h, and a new risk group (CIT 8–12 h) was subjected to univariate and multivariate analyses. The analysis yielded a DCD RSI C-statistic of 0.6978, yet was not statistically different in significance from the original score.

Recipient Risk Index Comparison

The comparative analysis of the statistical relevance between risk models was achieved through recreating the RRI, P-SOFT, and BAR scores, and the C-statistics were ranked accordingly. The calculation of the P-SOFT and BAR scores was modeled to logistic regression, and the RRI was fit into a Cox-regression model. The following covariates significant at the time of transplantation were included in the recipient risk models based on previous studies: RRI; P-SOFT—Table 4: P-SOFT and SOFT scores elaborated on by Rana et al; and BAR.[9-11]

According to the validation analysis, the results are as follows: DCD RSI sensitivity was 24.46%, specificity was 94.87%, positive predictive value was 20.83%, and negative predictive value was 95.79%; P-SOFT sensitivity was 26.06%, specificity was 94.52%, positive predictive value was 21.12%, and negative predictive value was 95.78%; BAR sensitivity was 23.63%, specificity was 94.72%, positive predictive value was 20.67%, and negative predictive value was 95.51%; RRI sensitivity was 30.17%, specificity was 79.68%, positive predictive value was 33.58%, and negative predictive value was 77.02%.

The DCD RSI is the best at predicting DCD patient survival (C = 0.6971) using solely recipient factors. Following are the P-SOFT (C = 0.6870), BAR (C = 0.6618), and RRI (C = 0.6278).

DISCUSSION

By combining 8 prominent recipient variables, we created a simple risk index that predicts patient survival after DCD transplantation: the DCD RSI. Furthermore, when compared with established indices using only recipient parameters, we found the DCD RSI maintained the superior C-statistic of 0.6971; we are therefore advocating that the DCD RSI is the best index to use for preselection of candidates pre-DCD transplantation. The DCD RSI is unlike previously established risk scores that rely on donor and recipient parameters, considering indices such as the SOFT and BAR exclusively predict posttransplant survival. Instead, the DCD RSI can theoretically be used to preselect optimal candidates for DCD allografts and create a patient pool that can be preconsented for transplantation. This can help combat low DCD transplantation rates that are due in part to high assumed risk and resource cost for transplant coordinators who cannot guarantee that a transplant center will use the organ in question. With a pool of potential DCD transplant recipients, risks associated with finding a recipient and with organ refusal by regional programs decrease. However, we emphasize that the tool not be used to screen any viable candidates from receiving an allograft but, rather, to aid the process of selecting optimal patients.

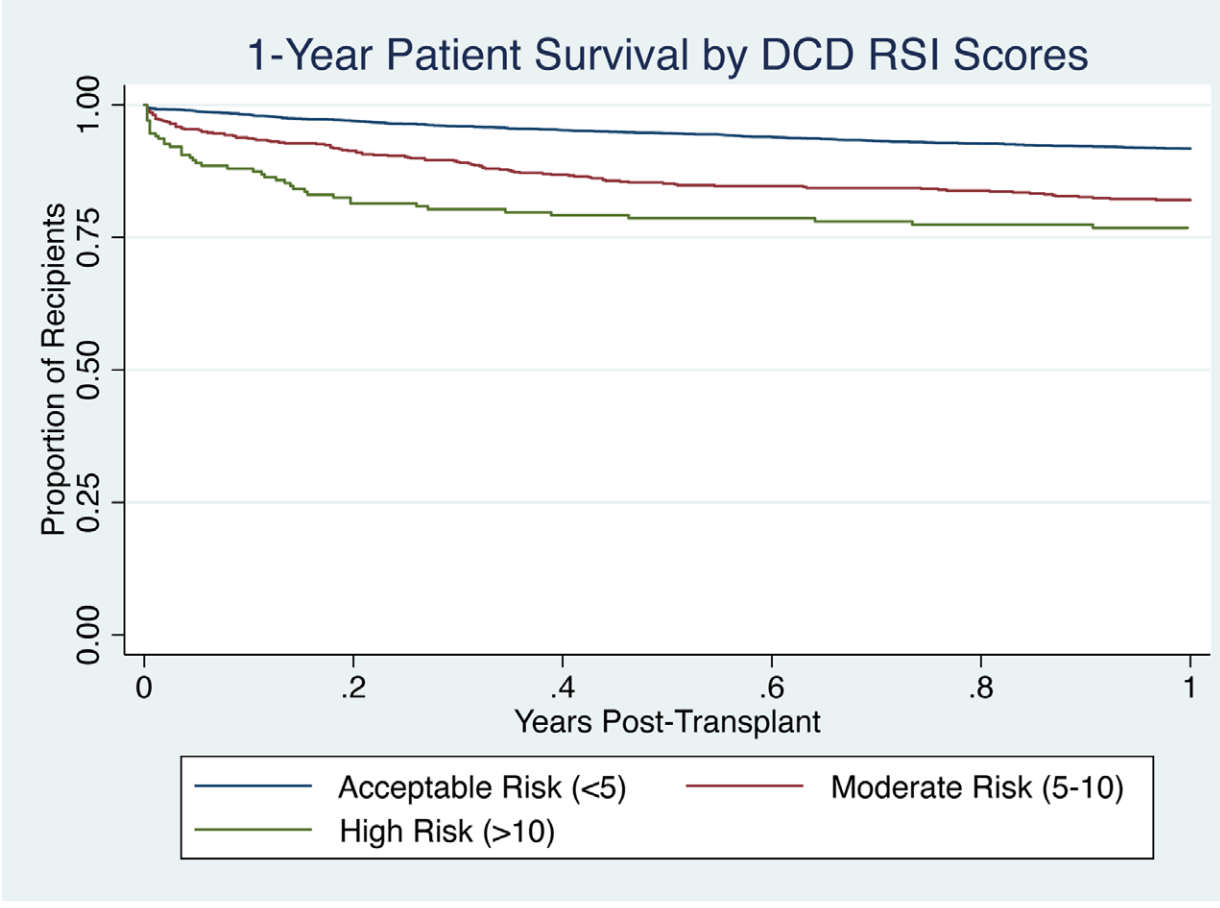
Several risk factors included in the DCD RSI are linked to increased mortality and complications in orthotopic liver transplants (OLTs) using non-DCD donors, supporting the validity of our score. Our analysis identified hypernatremia, defined as serum sodium >150 mEq/L, as an important risk factor for decreased 90-d posttransplant survival. These findings were mirrored in a study of 20 000 patients who underwent OLTs; pretransplant hypernatremia was linked to an increase in hospital mortality, longer posttransplant hospitalization, and decreased 90-d survival.[12] There is also evidence linking hypernatremia to thrombotic vascular complications in pediatric patients; however, high sodium was not found to affect short-term posttransplant survival in this patient cohort,[13] indicating that further analysis is necessary to adapt the DCD RSI to pediatric applications.

TABLE 3.

Multivariate logistic regression for factors that predict 3-mo survival in DCD transplant recipients

Variable	Reference group	Study group (at transplant)	Percent entry filled (%)	Percent of study patients with characteristic (%)	Odds ratio	*P*	95% confidence interval	DCD RSI point contribution
Cold ischemia time	6–8 h	<6 h	97	52.91	0.617	0.000	0.471–0.808	−3.8
Recipient serum sodium	135–150 mEq/L	>150 mEq/L	92	0.50	8.387	0.000	3.231–21.769	73.9
Recipient albumin	>2.0 g/dL	<2.0 g/dL	100	7.12	1.894	0.001	1.280–2.802	8.9
Setting	None	ICU or hospital	100	20.27	1.661	0.011	1.125–2.451	6.6
Functional status	30%–50%	90%	100	5.72	0.157	0.011	0.038–0.651	−8.4
History of portal vein thrombosis	No	Yes	100	4.94	1.855	0.011	1.150–2.994	8.6
Previous upper abdominal surgery	No	Yes	100	42.83	1.338	0.031	1.027–1.744	3.4
Functional status	30%–50%	80%	100	16.79	0.610	0.039	0.381–0.976	−3.9

DCD, donation after circulatory death; ICU, intensive care unit; RSI, Recipient Selector Index.



Actuarial Survival for Liver Allograft Recipients Divided According to DCD RSI Score			
	1 Month	2 Months	3 Months
Acceptable Risk	98.4%	96.5%	94.7%
Moderate Risk	94.3%	90.4%	85.4%
High Risk	87.8%	81.3%	78.5%

FIGURE 1. Kaplan-Meier curve of recipient survival by the Donation after Circulatory Death Recipient Selector Index (DCD RSI) score. The y-axis is the percentage recipient survival of total recipients, and the x-axis is the months post–liver transplant. $P < 0.001$ for each group by log-rank test with reference to acceptable risk DCD RSI score group.

TABLE 4.

Examples of candidates stratified into 3 different risk groups with point allocation

Risk group	CIT <6 h	Serum sodium >150 mEq/L	Albumin <2 g/dL	ICU or hospital	Func 80%	Func 90%	Portal vein thromb	Previous upper abdominal surgery	Total point allocation
Acceptable, <5	NA	NA	NA	NA	NA	NA	3.4	NA	3.4
Moderate, ≥5 and ≤10	NA	−3.8	NA	NA	NA	8.6	3.4	NA	8.2
High, >10	8.9	−3.8	NA	NA	6.6	N/A	3.4	NA	15.1

CIT, cold ischemia time; ICU, intensive care unit.

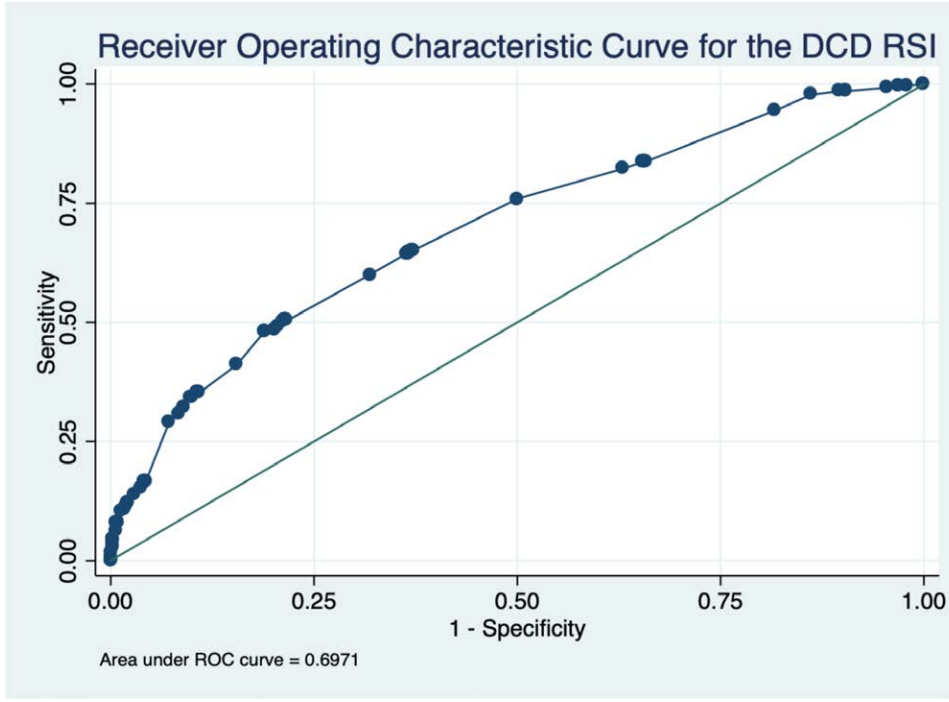


FIGURE 2. Calculations of area under the receiver operating characteristic (ROC) curve for 3-mo survival show a Donation After Circulatory Death Recipient Selector Index (DCD RSI) C-statistic value of 0.6971 (CI, 0.6640-0.7305). CI, confidence interval.

Our study identified hypoalbuminemia, defined as serum albumin <2.0 g/dL, as a risk factor for posttransplant mortality. Hypoalbuminemia is more commonly associated with high pretransplant mortality and lower chances of receiving a transplant;[14] however, other studies have also found that low serum albumin and grade 3 albumin–bilirubin levels are associated with decreased overall survival after liver transplantation.[15,16] The link between low albumin–bilirubin levels and high risk of early allograft dysfunction supports the use of serum albumin as part of a holistic evaluation to predict allograft survival.

Low functional status (Karnofsky Score) is consistently cited as an independent predictor of low posttransplant survival[17] but was not a significant predictor of the DCD RSI. The negative impact of a low Karnofsky Score before OLT is reflected in the relationship between high posttransplant costs—due to the necessary rehabilitation and rehospitalization more common in patients with low functional status—and low 1-y posttransplant survival,[14] which is why it may not have been important to 3-mo survival outcomes.

The DCD RSI identifies prior PVT as a risk factor for 90-d survival in DCD allograft recipients. However, there is a lack of consensus on the effect of PVT on OLT outcomes. Although some studies cite PVT as an independent risk factor associated with increased risk for intracardiac and pulmonary thromboembolic events and hepatic artery stenosis posttransplant,[18,19] other studies have found that PVT in cirrhotic patients does not influence long-term survival.[20] Still, the fact that PVT has been linked to higher posttransplant mortality, an effect that is amplified by low MELD scores and high-risk organs,[21] underscores the need for high-quality organs to improve the survival of patients with specific risk factors.

The result of the risk index comparison identified the DCD RSI as superior at selecting optimal candidates pre-DCD transplantation—out of a cohort including the RRI, P-SOFT, and BAR scores. The SOFT and BAR scores were developed as prognostic tools utilizing both recipient and donor factors to predict recipient survival after liver transplantation.[10,11] To ensure the scores were relevant to the DCD RSI analysis, we recreated the BAR index to be composed exclusively of recipient factors and used an offshoot of the SOFT index—the P-SOFT. Alternatively, the RRI assessed the risk of end-stage renal disease post–liver transplantation, compiling an index of 14 significant recipient risk factors to yield a Cox equation that calculated a score for each recipient.[9] Despite being recalibrated to fit the scope of our study, when the RRI, P-SOFT, and BAR were applied toward preselecting candidates for DCD

transplantation, the DCD RSI maintained the most accurate results. The measure quantified a C-statistic of 0.6971.

The development of the DCD RSI is intended as a proof of concept study—a step in the right direction to producing more accurate scores in the future. Although the DCD RSI can be utilized in selecting optimal patients, its instrumentation as a screening tool lacks the standard sensitivity/specificity to be implemented. A more accurate index is required to develop a tool with sufficient enough parameters to be valid as a common clinical practice. Therefore, as a future endeavor, we plan to validate our data with the contemporaneous by applying a machine-learning model to achieve a more robust index.

CONCLUSIONS

After verifying the performance of predictive indices for the selecting of DCD recipients, the DCD RSI can be used to preselect patients most suitable for DCD transplantation. This can increase the utilization of DCD donors by optimizing outcomes.

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