

The Donor Risk Score: A Simpler Method to Grade Liver Allografts

Keywords: Liver transplantation; Graft survival; Donor risk index

Abstract

Context: Growing need for liver transplantation has led to increased efforts to utilize allografts for transplantation from an expanding donor pool ("marginal" donor livers).

Objective: To devise a simplified practical donor allograft scoring system based primarily on allograft survival following liver transplantation.

Methods: The United Network of Organ Sharing (UNOS) provided de-identified patient-level data. This study included all liver transplant recipients who received allografts between March 1, 2002 and December 31, 2012. Patients who received combined, multivisceral, or live donor transplants and those with no available follow-up data were excluded from this study. We therefore analyzed a total of 49,656 liver transplant recipients for this study. Kaplan-Meier analysis with log-rank test and Cox proportion hazards regression were used for time-to-event analysis. Univariate and multivariate analyses identified significant and independent risk factors.

Results: In addition to cold ischemia time we identified nine donor risk factors as significant for graft failure: 1) donor age, 2) donor height, 3) CVA as cause of death, 4) donor renal insufficiency, 5) diabetes in the donor, 6) national sharing, 7) hepatitis C in the donor, 8) ABO incompatible transplants and 9) donation after cardiac death. The most significant of these were 1) donation after cardiac death (RR 1.6) and 2) donor age > 70 (RR 1.6). Our novel Donor Risk Score assigns points to each donor risk factor on the basis of severity and these are ultimately added to each other to derive the final DRS score (total points) for a given allograft. Extended criteria donor allografts are defined as an allograft with five or more risk points which represent the worst 20% of allografts.

Conclusion: The novel Donor Risk Score (DRS) is a simplified and practical method to evaluate and grade liver allografts. The derived risk points are simply added to each other to assign a DRS to the donor which is simpler to use to predict donor liver function than the presently recommended Donor Risk Index (DRI) that employs a complex exponential function. The DRS that we propose is also more marginally more predictive of graft survival compared to the DRI (c-statistic 0.58 vs 0.57, p<.001).

Introduction

Increased demands for liver transplantation along with shortage of deceased donor liver allografts have led to the use of organs from extended donor pool ("marginal" donors) for transplantation [1]. It is therefore necessary to develop methods to accurately evaluate or grade the quality of such allografts obtained from Extended Criteria Donors (ECD) on the basis of their expected survival to be able to provide adequate information to the potential recipients to obtain informed consent. Risk assessment of ECD allografts should also permit clinicians to determine whether an allograft's projected risk is suitable for a particular recipient. The previously described Donor Risk Index (DRI) addresses this need for assessment of the quality of the donor allografts [2]. Since the DRI is calculated from an exponential function composed of seven donor factors and cold ischemia time it is somewhat complex and fails to take into account



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other significant risk factors that affect eventual allograft survival. The calculations for DRI are shown below.

$$\text{Donor risk index} = \exp[(0.154 \text{ if } 40 \leq \text{age} < 50) + (0.274 \text{ if } 50 \leq \text{age} < 60) + (0.424 \text{ if } 60 \leq \text{age} < 70) + (0.501 \text{ if } 70 \leq \text{age}) + (0.079 \text{ if COD} = \text{anoxia}) + (0.145 \text{ if COD} = \text{CVA}) + (0.184 \text{ if COD} = \text{other}) + (0.176 \text{ if race} = \text{African American}) + (0.126 \text{ if race} = \text{other}) + (0.411 \text{ if DCD}) + (0.422 \text{ if partial/split}) + (0.066 \text{ ((170 - height)/10)}) + (0.105 \text{ if regional share}) + (0.244 \text{ if national share}) + (0.010 \times \text{cold time})]^2$$

The Scientific Registry for Transplant Recipients (SRTR) has proposed another risk adjusted allocation model in the format of a computer program to grade allografts and guide allocation that is based on both recipient and donor risk factors [3]. There are two additional models which integrate donor and recipient risk factors to predict patient [4] and graft survival [5], but they both use complex statistical equations to do so. Since offers of donor organs occur at all times of day from various sources, we felt that a simplified and practical system that is not based on complex calculations is still needed to rapidly assess the quality of offered donor livers. Furthermore, a simplified donor scoring system allows the clinician to form an accurate perspective on the relative risk of particular risk factors.

Methods

Study population

The UNOS provided de-identified patient-level data. Our analysis employed the liver registry with data collected by the Organ Procurement and Transplantation Network. This study includes all transplant recipients transplanted between March 1, 2002 and December 31, 2012. The latest data include follow-ups through December 31, 2012. Donor and recipient characteristics were collected at the time of transplantation. Follow-up information was collected at six months and then yearly after transplantation. In this retrospective study we have included all transplant recipients 18 years of age or older but excluded 1) recipients of combined or multi-visceral transplants (n=3,741) receiving; 2) recipients of live-donor allografts (n=2,189) and 3) patients with insufficient follow-up data for analysis (n=0). All patients were followed from the date of transplant until either death (n=12,852), retransplantation (n=2,821) or date of last known follow-up (n=31,812). After exclusions, this analysis included a total of 49,656 recipients.

Data analysis

All data was analyzed using a standard statistical software package, Stata 9 (Stata Corp, College Station, TX). Continuous variables were reported as a mean ± standard deviation and compared using the Student’s *t*-test. The Chi-square test was used to compare categorical variables. Results were considered significant at a p-value of <0.05. All reported p-values are two-sided. The primary outcome measure was graft failure. Time to graft failure was assessed as time from date of transplantation to the date of death or of re-transplantation. Kaplan-Meier analysis with log-rank test and the Cox proportional hazards regression model were used for time-to-event analysis.

Risk factors

The recipient and donor risk factors considered in this analysis are listed in Table 1. We used characteristics most representative of the majority of liver transplant recipients as the reference groups. Serum creatinine was utilized instead of a calculated creatinine clearance because serum creatinine is most readily accessible for rapid assessment of quality of donor liver. In addition to 40 covariates listed in Table 1 we have included the majority of covariates previously analyzed in the SRTR risk adjusted models.

Risk score

To determine the predictors of graft failure after transplantation, Cox regression analysis of all donor and recipient risk factors was performed. The donor and recipient variables initially underwent a separate univariate analysis, as shown in Table 1. Donor and recipient variables found to be significant in univariate analysis then together underwent multivariate analysis. Points were only assigned to each donor risk factor based on the risk factor’s associated relative risk of

Table 1: Risk factors under consideration.

Donor Risk Factors	Recipient Risk Factors
ABO Incompatible Transplant	Previous Transplants
Cold Ischemia Time	One
0 - 6 hours	Two
12 - 16 hours	Diagnosis
16 - 20 hours	Acute Hepatic Necrosis
> 20 hours	Metabolic Liver Disease
Donation After Cardiac Death	Malignancy
Diabetes Mellitus (Type Unspecified)	Ascites Pre-transplant
Insulin Dependent Diabetes Mellitus	Creatinine (mg/dL)
Hypertension	>1.5
Less than 10 yr duration	>2.0
Greater than 10 yr duration	Body Mass Index
Unknown duration	30-35
Deceased Donor After Cardiac Death	> 35
Donor Age	Hepatitis B (Core Ab positive)
0-10 years	Hepatitis C (positive serology)
10-20 years	CMV Status
20-30 years	History of Angina of Coronary Artery Disease
45-55 years	Hypertension
55-60 years	ALT (SGPT) > 100 IU/L
60-70 years	Total Bilirubin
> 70 years	≤ 2 mg/dL

Race - African American	8-15 mg/dL
Donor Cause of Death	INR
Cerebral Vascular Accident	2.0-2.5
Anoxia	> 2.5
Other (not Anoxia, CVA, or Trauma)	Albumin
Partial/Split Liver	2.0-2.5 g/dL
Donor Weight	< 2.0 g/dL
> 75 th percentile	Dialysis Prior to Transplantation
< 25 th percentile	UNOS Status 1
Female	MELD score
Donor Creatinine	< 9
> 1.5 mg/dl	10-19
> 2.0 mg/dl	20-29
AST (SGOT)	30-39
< 90 IU/L	> 40
> 140 IU/L	Encephalopathy at Transplant
ALT (SGPT)	Portal Vein Thrombosis at Transplant
< 60 IU/L	Time on Waitlist
> 100 IU/L	1 - 2 years
Hepatitis B (Core Ab positive)	> 2 years
Hepatitis C (positive serology)	Transplant performed between 4-1-1994 to 1-1-1998
Total Bilirubin (mg/dL)	Transplant performed between 1-1-1998 to 1-1-2002
1-1.8	Ventilator Dependent Pre-Transplant
> 1.8	History of Peripheral Vascular Disease
Donor Height	History of COPD
>75 th percentile	Portal Bleed within 48hrs Pre-Transplant
<25 th percentile	Any Previous Malignancy
Use of ≥ 3 Inotropic Agents	Variceal Bleeding within 2 weeks of Registration
Graft Allocation	Spontaneous Bacterial Peritonitis Pre-Transplant
Regional	Pulmonary Embolus within 6 months of Registration
National	TIPS prior to Transplant
History of Alcohol Dependency	Warm Ischemia Time
History of Cigarette Use > 20 pack years	≤30 minutes
History of Cocaine Use in the Past	60-75 minutes
History of IV Drug Use	> 75 minutes
Donors with Tattoos	Age
Resuscitation following Cardiac Arrest	18-30 years
	30-40 years
	60-70 years
	> 70 years
	Diabetes Mellitus
	Height
	>75 th percentile
	<25 th percentile
	Incidental Tumor Found at Transplant
	Pre-Transplant Care
	Intensive Care Unit
	Admitted to Hospital
	Life Support
	Previous Abdominal Surgery
	Race - African American
	Female

Table 2: Demographic characteristics of donors and recipients.

	Recipient	Donor
Age (Years)	53.1 ± 10.2	41.5 ± 17.2
% Female	32.4%	40.5%
% African American	9.3%	16.0%
Height (cm)	172.3 ± 10.4	171.6 ± 10.9
Weight (kg)	84.8 ± 19.4	79.2 ± 19.5
INR	1.9 ± 1.5	NA
Creatinine (mg/dl)	1.4 ± 1.1	1.5 ± 1.6
MELD	21.2 ± 10.1	NA
Cold Ischemia Time (Hours)	NA	7.3 ± 3.5
Cause of Death		
• CVA	NA	42.7%
• Trauma	NA	37.7%

NA: Not Applicable to this group of patients; **INR:** International Normalized Ratio; **CVA:** Cerebrovascular Accident; **MELD:** Model for End Stage Liver Disease

graft failure. One point was awarded to each risk factor for every 10% increase in risk for graft failure. Importantly, negative points were also awarded for every 10% decrease in risk for graft failure.

The donors were then arbitrarily divided into four donor risk groups based on the DRS point distribution of donor allografts: Low Risk (less than 0 points), Moderate Risk (0 or 1 point), High Risk (2-4 points), and Extended Criteria (greater than or equal to 5 points).

The four groups were designed to ensure equal distribution among transplanted allografts (Table 4). Model discrimination was assessed using the area under the receiver operating curve (c-statistic). The c-statistic is commonly used in evaluating a prognostic model. A c-statistic of 1 would result from perfect prognostic accuracy while a c-statistic of 0.5 results from a model without prognostic accuracy [6].

Results

Study population

The study population included 50,725 patients. Analysis included 181,769 years at risk for all liver transplant recipients. Mean follow-up was 3.9 years, and restricted mean survival was 8.3 years. Demographic and clinical characteristics are summarized in Table 2.

Data entry rate

The data entry completion rate for donor variables that were significant in univariate analysis is listed in Table 3. The majority of variables are well populated.

Univariate and multivariate analysis

The multivariate analysis of donor risk factors that were significant in multivariate analysis is presented in Table 3. The most significant

Table 3: Univariate and multivariate analysis of donor factors that affect liver allograft survival.

Reference Group	Study Group	% entry filled	% of Patients	Uni RR	Multivariate RR (CI)	p -value	Points
ABO compatible	ABO incompatible	100.0	0.7	1.4	1.2 (1.01-1.48)	0.04	2
Age 30-45	Age < 20	99.9	14.6	0.7	0.84 (0.79-0.90)	< 0.01	-2
	Age 20-30	99.9	17.6	0.8	0.92 (0.88-0.98)	< 0.01	-1
	Age 45-55	99.9	21.2	1.1	1.13 (1.08-1.20)	< 0.01	1
	Age 55-60	99.9	8.8	1.2	1.30 (1.21-1.40)	< 0.01	3
	Age 60-70	99.9	11.3	1.3	1.44(1.36-1.54)	< 0.01	4
	Age > 70	99.9	5.0	1.5	1.63(1.51-1.77)	< 0.01	6
Brain Death	Cardiac Death	98.2	4.3	1.34	1.57 (1.45-1.70)	< 0.01	6
COD Trauma	COD CVA	99.8	42.7	1.3	1.07 (1.02-1.11)	< 0.01	1
CIT 6-12	CIT < 6	93.0	37.8	0.9	0.91 (0.84-0.90)	< 0.01	-1
	CIT > 12	93.0	11.7	1.2	1.18 (1.11-1.28)	< 0.01	2
Cr < 1.5 mg/dL	1.5 ≤ Cr < 2.0	99.9	11.1	1.1	1.09 (1.03-1.15)	< 0.01	1
	Cr ≥ 2.0	99.9	15.5	1.1	1.07 (1.02-1.12)	0.04	1
Donor Height – 25 th -75 th percentile	Height > 75 th percentile	99.6	26.4	0.9	0.93 (0.89-0.98)	0.002	-1
	Height < 25 th percentile	99.6	23.3	1.1	1.10 (1.05-1.15)	< 0.01	1
Local Share	Regional Share	100.0	22.3	1.1	1.02 (0.98-1.07)	0.244	0
	National Share	100.0	5.9	1.3	1.09 (1.02-1.17)	0.016	1
Non-DM	DM	99.9	10.0	1.3	1.08 (1.01-1.16)	0.03	1
No HCV	HCV serology positive	99.8	2.9	1.2	1.12 (1.02-1.23)	0.002	1

Uni: Univariate; **RR:** Relative Risk; **CI:** Confidence Interval; **Cr:** Creatinine; **COD:** Cause of Death; **CVA:** Cerebrovascular Accident; **CIT:** Cold Ischemia Time; **DM:** Diabetes Mellitus; **HCV:** Hepatitis C virus

donor risk factors were 1) donation after cardiac death (RR 1.6 CI 1.5-1.7), donor age > 70 (RR 1.6 CI 1.5-1.8); 2) donor age 60-70 (RR 1.4 CI 1.4-1.5); 3) donor age 55-60 (RR 1.3 CI 1.2-1.4).

The following recipient risk factors were the most significant in multivariate analysis: previous transplant (RR 2.2 CI 2.0-2.4); life support (RR 1.6 CI 1.5-1.7); recipient age over 70 (RR 1.4 CI 1.3-1.6); and African-american race (RR 1.4 CI 1.3-1.5).

Risk score

Table 4 presents the Donor Risk Score (DRS), which includes the following ten factors: 1) donor age, 2) donor height, 3) cold ischemia time, 4) cause of death from cerebrovascular accident, 5) creatinine > 1.5 mg/dL, 6) donor diabetes, 7) national sharing, 8) donor hepatitis C, 9) abo incompatibility, and 10) donation after cardiac death. Table 5 illustrates the population distribution based on the group with less than 0 points (≡ Low Risk). Figure 1 presents the Kaplan-Meier curves and life-table analysis of liver allograft survival based on DRS groups. The 1 year, 5 year, and 10 year graft survival was respectively: 89.1%, 76.0%, and 61.9% for the Low Risk group; 87.4%, 71.7%, and 56.0% for the Moderate Risk group; 83.4%, 66.9%, and 49.7% for the High Risk group; and 79.9%, 59.8%, and 41.5% for the ECD group.

The area under the receiver operating curve

The c-statistic for the DRS, when used as a model to predict graft failure, was 0.58 (CI 0.57-0.58). The DRS appeared more accurate than the Donor Risk Index (DRI), which had a c-statistic of only 0.57 (confidence interval 0.56-0.57 and *p* <.001) for the same cohort of patients in the UNOS database.

Discussion

The increasing public demand for liver transplantation has led to the wider use of extended criteria donor (ECD) allografts [1].

Table 4: Donor Risk Score.

Risk Factors	Risk Points
Donor Age 10-20 years	-2
Donor Age 20-30 years	-1
Donor Height > 179 cm (5 feet 10 inches)	-1
Cold Ischemia Time < 6 hours	-1
Donor Age 45-55 years	1
Donor Height < 164 cm (5 feet 5 inches)	1
Cause of Death from CVA	1
Creatinine > 1.5 mg/dL	1
Donor Diabetes Mellitus	1
National Share	1
Donor Hepatitis C	1
ABO incompatible	2
Cold Ischemia Time > 12 hours	2
Donor Age 55-60 years	3
Donor Age 60-70 years	4
Donor Age > 70 years	6
Donation after Cardiac Death	6

*CVA: Cerebrovascular Accident

Table 5: Risk Classification by the Donor Risk Score.

Risk Group	Point Range	Number of Patients	% of Donors	Proposed Distinction
1	< 0	14,296	28.8	Low Risk
2	0,1	12,126	24.4	Moderate Risk
3	2,3,4	13,301	26.8	High Risk
4	≥ 5	9,933	20.0	ECD donors
Total		50,725	100	

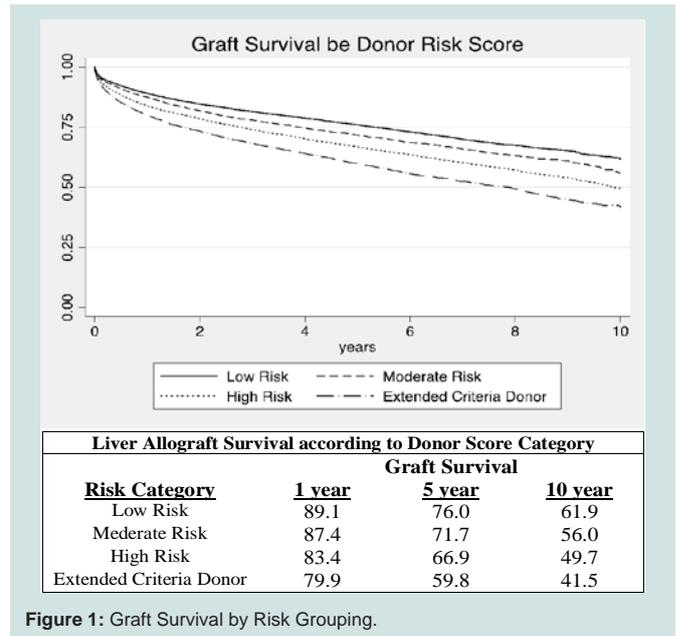


Figure 1: Graft Survival by Risk Grouping.

An accurate, simple, and practical model to assess the quality of a potential donor allograft is required to allow the recipient of an ECD allograft to give a truly informed consent. The development of such a model should also be able to predict the risk for allograft survival to assist in the allocation of a particular donor organ to an appropriate liver transplant candidate. The DRI model has been widely accepted as a method of assessing the quality of donor liver allografts [2]. The DRI, however, depends on complex calculations of an exponential function which includes seven donor factors in addition to cold ischemia time.

In the present study, we have formulated through a multivariate analysis, a new model, the Donor Risk Score (DRS), which does not require any complex calculations and facilitates a slightly more accurate prediction of graft survival than the DRI. The DRS is composed of nine donor factors and cold ischemia time; this includes all factors used in the DRI with the exception of split allografts and African American race. In addition, the DRS incorporates the risks of donor diabetes mellitus, donor creatinine > 1.5 mg/dL, and ABO incompatibility. These risk factors are clearly established in the literature [2,4,5,7-17] as negative influences on liver allograft survival. Diabetes mellitus as a liver donor risk factor is likely related to localized atherosclerotic changes in the donor allograft [2].

When the use of DRS is compared to that of DRI, it is found to be simpler despite the inclusion of additional donor risk factors, and has a slightly better predictive value for the donor liver allograft

survival. The use of DRS requires only the arithmetic addition of points previously assigned to the various donor factors. The DRS has a significantly better c-statistic when used as a model to predict graft survival (0.58 vs. 0.57, $p < .001$) in this study's transplant recipients' cohort. The DRS and DRI did not have statistically different c-statistics when they were used to predict patient survival.

The DRS and DRI are both relatively ineffective in predicting graft and patient survival. However, among all formulas that use donor risk factors available for study, these two models provide the most accurate model for predicting eventual graft survival [2,18]. They therefore are the best available tools to assess the quality of donor allografts. The low c-statistics obtained using both methods may reflect the known fact that donor factors offer only one significant influence on graft and patient survival. The recipient risk factors are numerous and have also been shown to wield significant influence on graft and patient survival; these include recipient age, previous transplant, serum creatinine, bilirubin, UNOS priority status, BMI, Meld Score, African American race, serum albumin, etc [4,5,19]. We realize that there are other significant donor risk factors not amenable for study in this retrospective registry review. Although macrosteatosis of the donor liver is a well known donor risk factor in clinical experience [20-22] it has been left out of the DRS as well as out of the DRI because of lack of sufficient data for analysis since only 33.4% of allografts had documented liver biopsies. Micro- and macrosteatosis were not differentiated in the data entry, and steatosis levels were recorded only in broad percent ranges. Steatosis (without differentiation of micro and macrosteatosis) of the liver allograft was previously included in the DRI analysis but was not found to be a significant risk factor [2]. The donor surgeon's impression of the donor allograft based on its color and consistency is undoubtedly an essential factor but difficult to quantify and study.

The newly developed DRS provides a simple and flexible definition for ECD donors - any liver allograft that receives five or more risk points. This definition includes about 20% of available donor liver allografts. This classification incorporates all of the significant donor risk factors in all possible combinations and can be rapidly applied to donor allograft selection as offers are made. At this point, there is no consensus over the definition of ECD allografts in liver transplantation [26]. This is an important definition for patient consent.

Conclusion

The Donor Risk Score (DRS) is a simple and reliable method to evaluate and grade the quality of donor liver allografts. The provided risk points are arithmetically added to each other to define the risk group to which the organ belongs. This approach is simpler to use than the Donor Risk Index (DRI) that employs a complex exponential function. The DRS is also slightly more accurately predictive of liver allograft survival compared to the calculations using DRI (c-statistic 0.58 vs 0.57, $p < .001$).

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