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Clinical Validation of a Novel Scoring System Based on Donor and Recipient Risk Factors for Predicting Outcomes in Liver Transplantation

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Background: Adequate donor and recipient matching in liver transplantation is crucial to improve patient survival. Our objective was to propose and validate a new model for predicting outcomes using donor and recipient scoring criteria.

Material/Methods: We retrospectively analyzed data of all patients (n=932) who underwent liver transplantation (n=1106) from January 2006 to December 2018. For score standardization, 30% (n=280) of patients were randomly selected for analysis and divided into 3 categories: ≤4 points, 5 to 8 points, and >8 points. Scoring system validation was performed on a dataset with 70% (n=652) of the patients.

Results: Survival of the stratified group (30%) was significant ($P<0.001$). Scores of 4 to 8 points presented lower risk of death (1.74 [CI 0.97-3.13; $P=0.062$]), while >8 points presented higher risk (2.74 [CI 1.36-5.57; $P=0.005$]). In the validation score (70%), global survival was significant ($P<0.0016$); patients with scores of 4 to 8 points had lower risk of death (1.16 [CI 1.16-2.38; $P=0.005$]); and scores >8 points (2.22 [CI 1.40-3.50; $P<0.001$]), retransplant, fulminant hepatitis, previous large abdominal/biliary tree surgery, MELD score, and serum creatinine before liver transplantation >1.5 mg/dL ($P<0.05$) presented higher risk. Individual recipient factors with 4 to 8 points had a lower risk of death (2.29 [CI 1.82-2.87; $P<0.0001$]) than those with scores >8 points (4.02 [CI 2.22-7.26; $P<0.0001$]).

Conclusions: A novel prognostic-based scoring system using donor and recipient characteristics was proposed and clinically validated. Two-factor scoring indicated the superiority of the predictability outcome and improved prediction of higher mortality.

Keywords: Graft Survival • Liver Transplantation • Survival Analysis

Abbreviations: **LT** – liver transplantation; **ICU** – Intensive Care Unit; **DDLT** – deceased donor liver transplantation; **CI –** confidence interval; **OR** – odds ratio; **HR** – hazard ratio; **MELD** – model of end-stage liver disease

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Background

Widely regarded as a model of justice and equality for organ allocation in liver transplantation (LT), the model of end-stage liver disease (MELD) score and its variations, such as the MELD-sodium (Na) and United Kingdom model for end-stage liver disease, use the principle of the sickest first. These allocation systems have been a useful tool in reducing mortality in LT waiting lists [1,2]. Moreover, it has been advocated to push the benefit of the transplant even further to very sick patients [3].

The increasing demand of patients on waiting lists, which is associated with the continuous expansion of indications, such as cholangiocarcinoma, colorectal liver metastasis, and acute alcoholic hepatitis, have been pushing LT services to the utilization of extended criteria liver grafts [4]. The combination of having the sickest patients and extended criteria liver graft has been associated with inferior outcomes [5,6].

Because the scores based on the "sickest first" policy are not the best to predict LT outcomes, utility-based systems, such as D-MELD, donor risk index, and others, have been investigated [2,6]. However, to date, no model has achieved the best donor and recipient match. Even though donors' and recipients' risk factors are well known, an ideal model relating them to transplant outcomes remains to be established, especially in Brazil, which has a high volume of liver transplants, with 2050 completed in 2020 [7]. Some regions, such as the state of São Paulo, the most populated area of the country, face an imbalance of donor availability and recipient demand, leading to organ scarcity. Brazil had 18.1 effective donors per million in 2020 [7]. In this context, it is crucial to better understand donor and recipient matching to improve graft utilization and posttransplant results. Aiming to investigate donor and recipient data and their correlation to LT results in our service, we performed this retrospective observational study to propose a new model for predicting outcomes.

Material and Methods

Study Design

We retrospectively analyzed clinical and laboratorial data of all consecutive patients who underwent LT in our center from January 2006 to December 2018. A total of 1101 LTs were performed, including 958 deceased donor LT (DDLT), 92 living donor LTs, 45 combined liver-kidney transplants, and 6 domino LTs. For DDLT, there were 932 patients who underwent 958 transplants. The number of transplants in DDLT was not the same as the number of patients because 21 patients underwent retransplant and another 5 patients needed a new transplant, thus totaling 958 LTs. The retransplant analysis considered just the first retransplant, therefore excluding eventual third LTs, since they were not common and in general occur a long time after the second LT. For building our model, we included all patients with DDLT, and randomly divided the patients into 2 stages: an initial group, 30% sample (n=280) and validation group, 70% of the patients (n=652).

Statistical Analysis

The data analysis started with a descriptive exploration. Tables including a 95% confidence interval (95% CI) were used to summarize the results of qualitative variables. Quantitative variables were described using the mean, standard deviation (SD), median, and 25th (P25) and 75th (P75) percentiles.

Based on the clinical and laboratory characteristics of the patients, a scoring system was created. These scores were calculated using discrete quantitative variables. The final version was divided into 3 categories: ≤4 points, 5 to 8 points, and >8 points. In the first stage of the research, to standardize the score, a bank with 30% of the total number of patients was randomly selected for the analysis and adjustment of the score (initial group, 30% bank). In the second stage of the analysis, the score as well as the other variables were tested on a dataset with 70% of the patients (validation group, 70% bank**)**. In this last analysis, statistical estimates were used to characterize the scores.

The risk factors related to recipient were analyzed separately, therefore excluding donor condition. The groups were separated by strata of scores as <4 points, 4 to 8 points, and >8 points. After, the scoring system using just the recipient factor was compared with the scoring using both donor and recipient scores.

The survival function considering the average estimate of time until patients reached death was performed using the Kaplan-Meier method. The hypothesis test for equality of means according to factors was performed using the non-parametric log-rank test (Mantel-Cox). Gross and adjusted hazard ratio (HR) estimates were performed using Cox regression.

All tests performed used a bidirectional α of 0.05 and a 95% CI. Analyses were done with IBM SPSS 25 (Statistical Package for the Social Sciences; IBM Corp, Armonk, NY, USA), Excel 2016 (Microsoft Office), and R package (R Core Team, Vienna, Austria).

Demographic, Clinical, and Laboratory Analysis

Parameters of Point Scoring

The factors of deceased donors analyzed for the scoring system were age ≥60 years (1 point), ≥65 years (2 points), ≥70 years (3

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Table 1. Score parameters based on donors' and recipients' risk factors.

Deceased donor's factors			Recipient's factors		
Factor		Point	Factor		Point
Age (years-old)	≥60	1 point	Age (years-old)	≥60	1 point
	≥65	2 points		≥65	2 points
	≥70	3 points		≥70	3 points
	<60	0 point	Liver retrasnplantation	Yes	2 points
pH	<7.2	1 point		No	0 point
	≥7.2	0 point	Fulminante liver failure	Yes	2 points
CRA (minutes)	>2 minutes	1 point		No	0 point
	Withou CRA	0 point	PVT	Yes	1 point
Noradrenaline (mcg/kg/min)	>1	1 point		No	0 point
	<1	0 point	Previous major abdominal surgery	Yes	1 point
Liver steatosis	Moderate/severe (>30%, grade II/III)	1 point		No	0 point
	Mild/absence (grade I or absence)	0 point			
ICU	>7 days	1 point	MELD (points)	<24	0 point
	<7 days	0 point		≥24	1 point
–	–	–		≥29	2 points
–	–	–		≥35	3 points
–	–	–	Hemodialysis before LT or acute renal disease (Cr >1.5)	Yes	2 points
–	–	–		No	0 point
–	–	–	Cardiac risk	Severe	2 points
–	–	–		Mild/moderate	0 point
–	–	–	Hospitalization for complications of cirrhosis	Yes	1 point
–	–	–		No	0 point

CRA – cardiorespiratory arrest; ICU – Intensive Care Unity; PVT – portal vein trombosis; MELD – model of end stage liver disease. The complications cosidered in "Hospitalization for complications of cirrhosis" was spontaneous bacterial peritonitis/upper digestive hemorrhage/cholangitis/hepatic encephalopathy/infection.

points), and <60 years old (0 point); pH <7.2 (1 point) and pH ≥7.2 (0 points); cardiorespiratory arrest >2 min (1 point) and without cardiorespiratory arrest (0 points); noradrenaline >1 mcg/kg/min (1 point) and without noradrenaline or <1 mcg/kg/min (0 points); moderate/severe liver steatosis (>30%, grade II/III; 1 point) and mild/absent (grade I or absence; 0 points); Intensive Care Unit (ICU) time >7 days (1 point) and ICU time <7 days (0 point) (**Table 1**).

The factors of recipient used for the scoring system were age ≥60 years (1 point), ≥65 years (2 points), and ≥70 years (3 points); liver retransplantation (2 points) and without retransplant (0 points); fulminant liver failure (2 points) and without fulminant liver failure (0 points); portal vein thrombosis (1 point) and without portal vein thrombosis (0 points); previous major abdominal surgery (1 point) and without previous surgery (0 point); MELD <24 (0 points), MELD ≥24 (1 point), MELD ≥29 (2 points), and MELD ≥35 (3 points); hemodialysis before LT or acute renal disease (creatinine >1.5 mg/dL) (2 points) and without hemodialysis or acute renal disease (0 points); severe cardiac risk (2 points) and mild/moderate cardiac risk (0 points); hospitalization for complications of cirrhosis (spontaneous bacterial peritonitis, upper digestive hemorrhage, cholangitis, hepatic encephalopathy, infection) (1 point) and without hospitalization (0 points) (**Table 1**).

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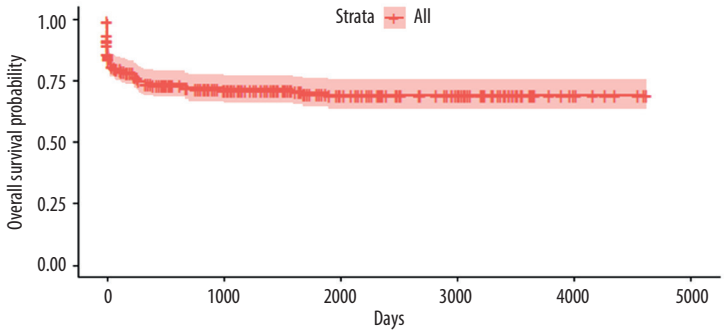

Figure 1. Kaplan-Meyer survival curve of patients who underwent DDLT – 30% sample, randomly selected.

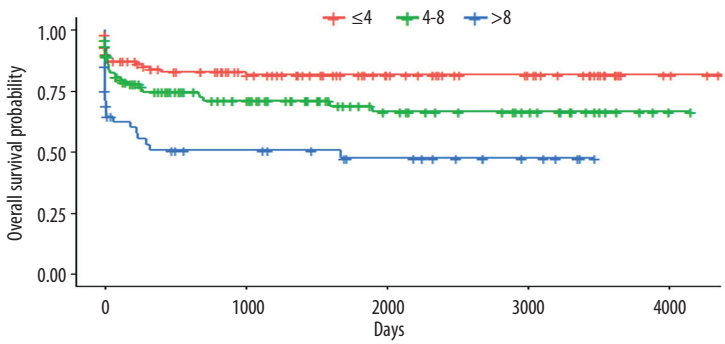

Figure 2. Kaplan-Meyer survival curves according to the scoring system – 30% sample, randomly selected (*P*<0.001).

Prognostic and Other Factors

Intraoperative factors evaluated were warm, cold, and total ischemia time, surgery time, temporary portal cava shunt performance, and intraoperative transfusion of fresh frozen plasma packs, red blood cells, and platelet concentrate packs.

In postoperative evaluation, we analyzed the serum creatinine levels in the first and third day after surgery, the total and ICU length of stay, and patient and graft survival after LT. Postoperative complications were classified according to the Clavien-Dindo score [8].

Results

Initial Stage (30% of the Sample)

In this group, 280 patients who underwent DDLT between January 2006 and December 2018 were evaluated. A total of 159 individuals were still alive until the end of this analysis, 77 had died, 23 were lost to follow-up, and 21 had undergone retransplantation. The global survival in this group is shown in **Figure 1.**

Each patient in this group received a score determined by the risk factors described above. The survival of the stratified group according the scoring system is shown in **Figure 2** (*P*<0.001). Patients with scores of 4 to 8 points had a lower risk of death (1.74 [CI 0.97-3.13; *P*=0.062]), while those with scores >8 points had higher risk (2.74 [CI 1.36-5.57; *P*=0.005]).

The variables with *P* values <0.05 in the log-rank test were cardiopulmonary arrest >5 min, ≥7 days in ICU (donor), fulminant hepatitis, MELD (24-29), MELD (29-35), MELD (≥35), and serum creatinine before LT >1.5 mg/dL (**Tables 2, 3**).

Validation Stage (70% of the Sample)

For validation of the score, we evaluated 652 patients who underwent DDLT in the same period as the first analysis group. A total 359 individuals were still alive until the end of this analysis, 177 had died, 46 were lost to follow-up, and 70 had undergone retransplantation. The global survival in this group is shown in **Figure 3.**

The risk factor scores applied in this validation group and the survival of the stratified groups according the scoring system are shown in **Figure 4** (*P*<0.0016). Patients with scores of 4 to 8 points had a lower risk of death (1.16 [CI 1.16-2.38;

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Table 2. Log-rank test of all scores variables (30% bank randomly selected).

		n	Events	Mean	SD	IC (95%)	p-value
Donor age	<60	249	66	2753	113	(2739-2767)	0.435
	60-65	16	5	2610	454	(2388-2832)	
	65-70	12	4	2477	532	(2176-2778)	
	≥70	3	2	1285	1041	(107-2463)	
Steatosis ≥30%	No	185	45	3065	136	(3045-3085)	0.141
	Yes	61	20	2619	269	(2551-2687)	
Nora ≥1 mcg/kg/min	No	255	70	2980	124	(2965-2995)	0.545
	Yes	10	2	3366	531	(3037-3695)	
Cardiopulmonary arrest >2 minutes	No	234	72	2941	141	(2923-2959)	0.002
	Yes	41	3	4055	186	(3998-4112)	
pH ≥7.20	No	236	65	3233	145	(3215-3251)	0.966
	Yes	37	10	3325	346	(3214-3436)	
≥7 days ICU	No	195	44	3498	147	(3477-3519)	0.006
	Yes	81	32	2670	262	(2613-2727)	
Recipient's age	<60	198	55	2865	135	(2846-2884)	0.878
	60-65	45	11	3048	262	(2971-3125)	
	65-70	30	9	2530	417	(2381-2679)	
	≥70	7	2	2780	754	(2221-3339)	
Retransplant	No	259	77	2500	102	(2488-2512)	0.196
	Yes	21	0	3570	0	(3570-3570)	
Fulminant	No	257	65	2942	116	(2928-2956)	0.004
	Yes	23	12	1842	431	(1666-2018)	
Portal trunk thrombosis	No	226	60	2717	118	(2702-2732)	0.990
	Yes	35	9	2689	316	(2584-2794)	
Large surgery/biliary tree surgery	No	220	57	3105	136	(3087-3123)	0.695
	Yes	45	13	3021	301	(2933-3109)	
Cardiac risk >moderate	No	95	15	1947	92.5	(1928-1966)	0.216
	Yes	6	2	1099	634.4	(591-1607)	
MELD	<24	165	27	3135	120	(3117-3153)	<0.001
	24-29	35	12	2480	313	(2378-2582)	
	29-35	36	12	2534	299	(2436-2632)	
	>35	42	24	1535	296	(1445-1625)	

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Table 2 continued. Log-rank test of all scores variables (30% bank randomly selected).

		n	Events	Mean	SD	IC (95%)	p-value
Cause of donor death	CVAh	132	34	2644	144	(2619-2669)	0.102
	CVAi	17	7	2037	442	(1827-2247)	
	TCE	99	29	2489	176	(2454-2524)	
	Anoxia	20	2	3232	264	(3116-3348)	
	Brain tumor	4	3	927	779	(164-1690)	
	Others	7	1	3108	479	(2753-3463)	
Creatinine before transplant >1.5 mg/dL	No	216	44	3177	119	(3161-3193)	<0.001
	Yes	63	33	1812	262	(1747-1877)	

SD – standard deviation; IC – confidence index. ICU – Intensive Care Unit; MELD – model of end stage liver disease.

Table 3. COX regression analysis (30% bank randomly selected).

	Coefficient	Risk	SD	IC 95%	Wald teste	p-value
Cardiopulmonary arrest >5 minutes	-0.80	0.45	0.29	(0.25-0.8)	7.3	0.007
≥7 days ICU (donor)	0.63	1.90	0.23	(1.20-3.00)	7.4	0.007
Fulminant hepatitis	0.96	2.60	0.31	(1.40-4.80)	9.3	0.002
MELD (24-29)	0.93	2.526	0.347	(1.28-4.98)	23.06	0.008
MELD (29-35)	0.72	2.056	0.255	(1.04-4.06)	23.06	0.038
MELD (>35)	1.59	4.915	0.282	(2.83-8.54)	23.06	<0.001
Creatinine before transplant >1.5 mg/dL	1.20	3.40	0.23	(2.10-5.30)	28	<0.001

SD – standard deviation; IC – confidence index; ICU – Intensive Care Unit; MELD – model of end stage liver disease. log-rank demonstrated p<0.05.

P=0.005]), and those with scores >8 points had a higher risk (2.22 [CI 1.40-3.50; *P*<0.001]).

The variables with *P* values <0.05 in the log-rank test were retransplant, fulminant hepatitis, previous large abdominal/biliary tree surgery, MELD (24-29), MELD (29-35), MELD (≥35), and serum creatinine before LT >1.5 mg/dL (**Table 4**).

Recipient Dependent 1-Factor Scoring Analysis

For study of mortality with recipient factors isolated, we evaluated the total of 932 patients who underwent DDLT in the study period. A total of 254 patients died, 69 were lost to follow-up, and 91 underwent retransplantation. The risk factor scores applied in this group and survival were stratified using Kaplan-Meyer curves according the scoring system (**Figure 5**; *P*<0.0001). Individuals with scores of 4 to 8 points had a lower risk of death (2.29 [CI 1.82-2.87; *P*=0.0001]) than those with scores >8 points, who had a higher risk of death (4.02 [CI 2.22-7.26; *P*<0.0001]).

The variables with *P* values <0.05 in the log-rank test using the recipient variables are the same found in the general analysis: retransplant, fulminant hepatitis, previous large abdominal/biliary tree surgery, MELD (24-29), MELD (29-35), MELD (≥35), and serum creatinine before LT >1.5mg/dL.

Comparing Score System-Recipient Dependent 1-Factor Scoring vs Donor-Recipient 2-Factor Scoring

The receiver operating characteristic (ROC) curve was drawn to compare the competence of these scores to predict mortality in liver transplantation. The area under the curve (AUC) using just the donor factors was 0.680 (*P*<0.001), while the AUC in donor-recipient 2-factor scoring was 0.70 (*P*<0.001; **Figure 6**). Both scoring systems individually showed a worst result with higher scores.

To demonstrate the distribution of our data, we comparatively evaluated the mortality involving each of the strata of scores of each type of scoring system (1-factor scoring vs 2-factor scoring;

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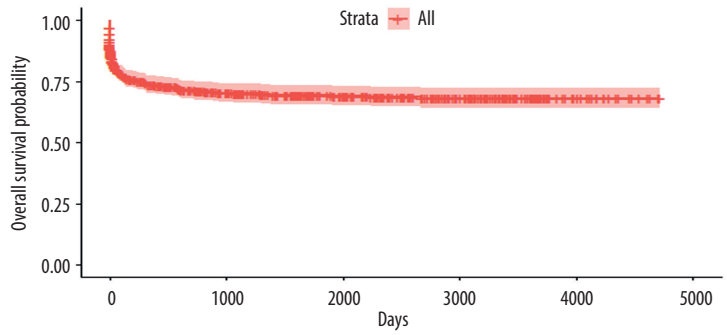

Figure 3. Kaplan-Meyer survival curve of patients who underwent DDLT – 70% sample, randomly selected.

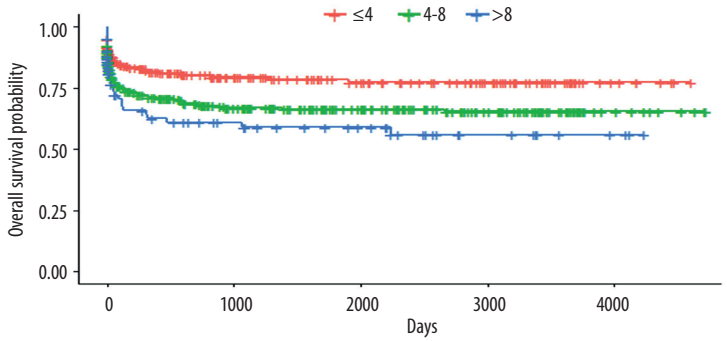

Figure 4. Kaplan-Meyer survival curves according to the scoring system – 70% sample, randomly selected (*P*<0.0016).

Table 4. COX regression analysis (validation group – 70% bank randomly selected).

	Coefficient	Risk	SD	IC 95%	Wald teste	p-value
Retransplant	-17	1.60	0.29	3.6e-08 (0-Inf)	0	0.99
Fulminant hepatitis	0.66	0.20	0.23	1.90 (1.30-2.90)	11	<0.001
Large surgery/biliary tree surgery	0.45	0.21	0.21	1.60 (1.10-2.40)	4.9	0.03
MELD (24-29)	0.26	1.30	0.77	1.30 (0.70-2.23)	25.6	0.34
MELD (29-35)	0.51	1.66	0.60	1.66 (1.12-2.46)	25.6	0.01
MELD (>35)	0.90	2.46	0.41	2.46 (1.72-3.54	25.6	<0.001
Creatinine before transplant >1.5 mg/dL	0.77	0.15	0.46	2.20 (1.60-2.90)	26	<0.001

SD – standard deviation; IC – confidence index; MELD – model of end stage liver disease. Log-rank demonstrated p<0.05.

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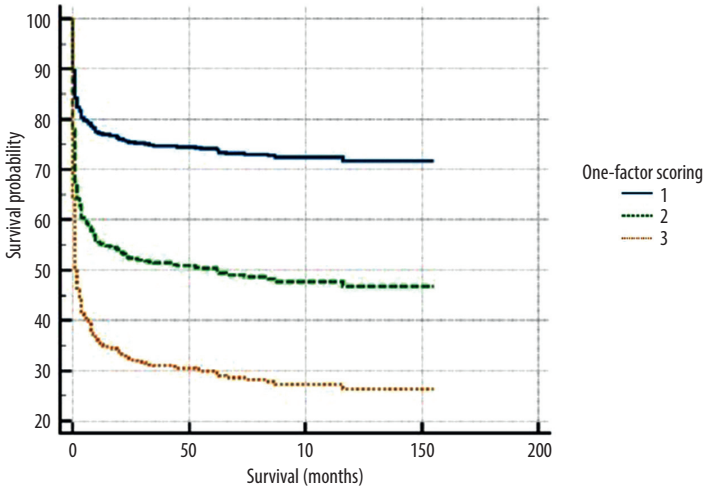

Figure 5. Kaplan-Meyer in recipient-dependent 1-factor scoring.

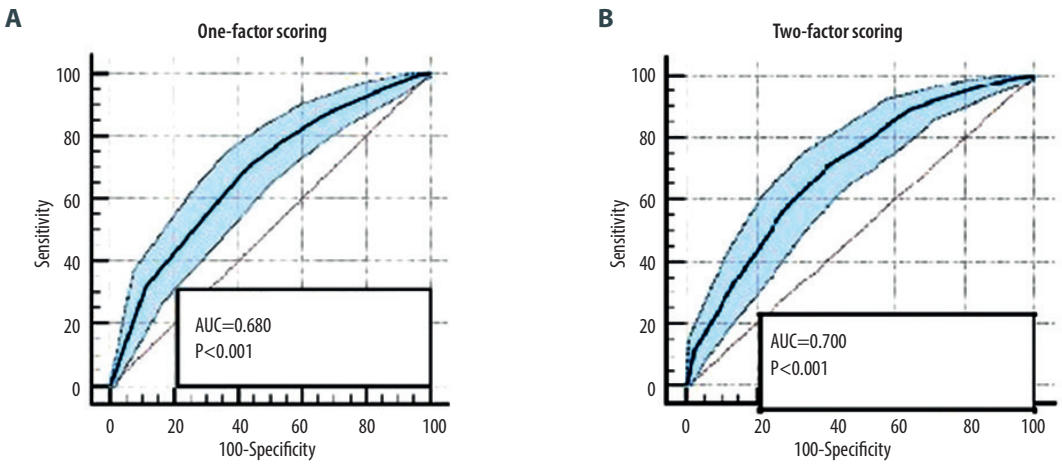

Figure 6. (**A, B**) Receiver operating characteristic curve of recipient-dependent 1-factor scoring vs donor-recipient 2-factor scoring.

Table 4; Figure 7), which more effectively indicated the difference (superiority) of the predictability of outcomes of liver transplantation of the new scoring method (**Table 5; Figure 7**).

Discussion

It is paramount that LT offers good survival rates for patients after the procedure. On the other hand, it is also important to look after patients on the waiting list, allowing as many patients as possible to get the benefit of the transplant. This is the challenge that surgeons, hepatologists, and ICU staff face on a daily basis. Organ shortages, especially in some countries like Brazil, push transplant teams to use expanded criteria liver grafts. In our study, we developed a scoring system and validated it using clinical data in order to stratify patient groups to aid the organ allocation system.

Our hospital is one of the largest transplant centers in South America, currently performing more than 120 LT per year. This long-term study analyzed the data of 1101 patients (959 DDLT, 92 living donor LT, 45 combined liver-kidney transplants, and 6 domino LT). Optimized donor-recipient matching is still necessary to improve graft and patient survival. In this study, we identified prognostic factors for donor and recipient selection that may aid in avoiding futile LT.

Donor variables that have been previously identified as risk factors for early graft dysfunction include age (≥60 years), female sex (especially in male recipients), steatosis, race, elevated liver function tests, hypotension/increased vasopressor use, non-heart-beating donor (also known as donation after cardiac death donors), split liver grafts, elevated serum sodium levels, and prolonged cold ischemia time (>12 h) [9-12]. However, we have also identified others important donor

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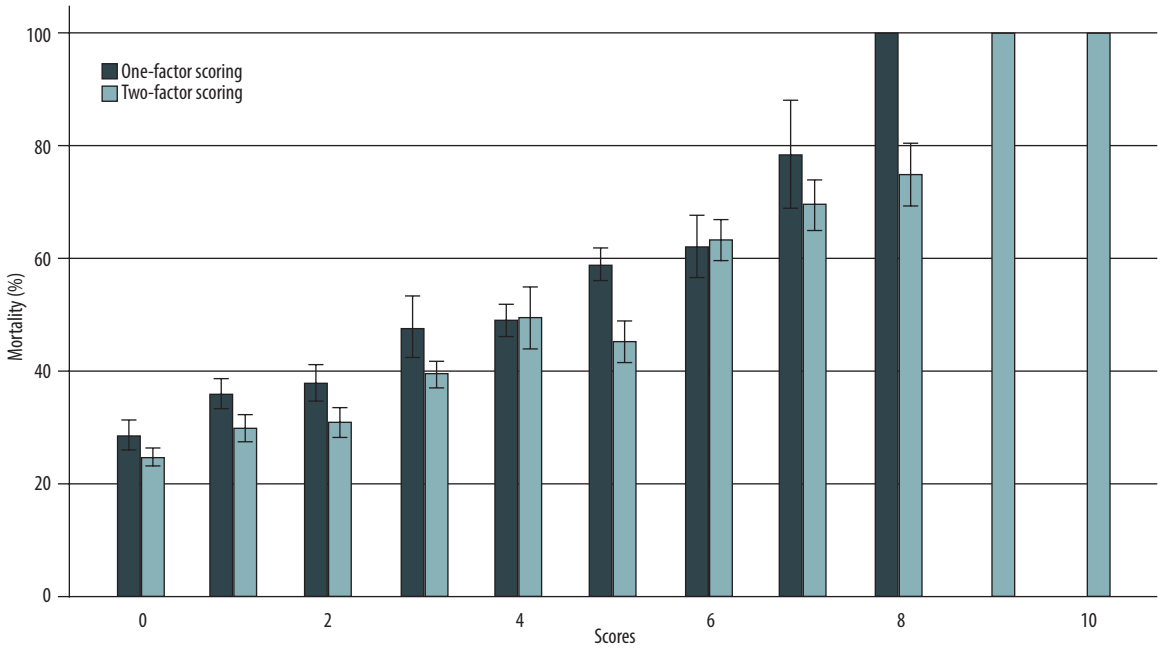

Figure 7. Mortality histogram of recipient-dependent 1-factor scoring vs donor-recipient 2-factor scoring.

Table 5. Death rate according scores and comparison of groups.

Points	One-factor scoring		Two-factor scoring	
	Death rate	CI 95%	Death rate	CI 95%
0	0.28	0.25-0.31	0.24	0.23-0.26
1	0.35	0.33-0.38	0,29	0.27-0.32
2	0.37	0.34-0,41	0.30	0.28-0.33
3	0.47	0.42-0.53	0.39	0.37-0.41
4	0.48	0.46-0.51	0.49	0.43-0.54
5	0.58	0.56-0.61	0.45	0.41-0.49
6	0.62	0.56-0.67	0.63	0.59-0.66
7	0.78	0.68-0.88	0.69	0.64-0.74

CI 95% – confidence Interval 95%.

variables as prognostic factors, such as cardiopulmonary arrest >5 min and donor ICU stay ≥7 days. On the other hand, we identified some recipient variables associated with worse prognosis, such as fulminant hepatitis, MELD (24-29), MELD (29-35), MELD (>35), and creatinine level before transplant >1.5 mg/dL. When using the combination of those risk factors, we developed a scoring system that significantly correlated to the clinical data. Patients with 4 to 8 points indeed presented a lower probability of death than those with more than 8 points. These findings may assist in conducting better patient selection for LT and in performing more adequate donor-recipient matching, which may ultimately not only improve posttransplant results but also decrease mortality on the waiting list.

This discussion of the literature makes a few points clear: no matter whether the allocation policy offers the graft directly to the patient or to the center, determining "who should get the liver graft" is increasingly being done with more sophisticated prognostic models based on patients' specific data rather than defined measures [13-15]. In the present study, we proposed, developed, and validated a novel prognostic-based scoring system. Patients with scores of 4 to 8 points had a lower risk of death and those with score >8 points had a higher

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risk. Organ allocation systems with optimized donor and recipient selection may increase graft survival and reduce waiting list mortality.

The addition of donor factors in these scores resulted in a significant gain in the ROC curve. We observed that the donor-recipient 2-factor scoring in lower scores was able to determine better outcomes and to indicate a worst result with higher scores. The recipient-dependent 1-factor scoring demonstrated less accuracy of lower scores to indicate fewer deaths. The 2-factor scoring indicate the superiority of the predicting the outcome of liver transplantation. The model was able to predict worse results in liver transplantation. More donor variables must be studied and added to improve the capacity of this model.

As a single-center retrospective analysis, this study had some limitations. However, it proposes a novel prognostic-based scoring system for liver transplant recipients, which has been clinically validated. We hope that our findings can aid liver transplant centers worldwide to improve the matching of recipients and donors. This study may thus ultimately contribute to the increase in patient and graft survival.

Conclusions

In this study, we identified important risk factors in donor-recipient liver transplantation matching. A novel prognostic-based scoring system was proposed and clinically validated. The 2-factor scoring system was superior in predicting the outcome of liver transplantation. The additive analysis using donor factors (2-factor scoring) improved the capacity to predict higher mortality. Patients with scores of 4 to 8 points had a lower risk of death, and those with scores >8 points had a higher risk. Organ allocation systems with optimized donor and recipient selection may increase graft survival and reduce waiting list mortality.

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Declaration of Figures' Authenticity

All Figures submitted have been created by the authors, who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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