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Expedited Evaluation for Liver Transplantation: A Critical Look at Processes and Outcomes

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Abstract

Background: Most patients are listed for liver transplant (LT) following extensive workup as outpatients ("conventional evaluation"). Some patients undergo urgent evaluation as inpatients after being transferred to a transplant center ("expedited evaluation"). We hypothesized that expedited patients would have inferior survival due to disease severity at the time of transplant and shorter workup time.

Methods: Patients who underwent evaluation for LT at our institution between 2012–2016 were retrospectively reviewed. The expedited and conventional cohorts were defined as above. Living donor LT recipients, combined liver-kidney recipients, acute liver failure patients, and re-transplant patients were excluded. We compared patient characteristics and overall survival between patients who received a transplant following expedited evaluation and those who did not, and between LT recipients based on expedited or conventional evaluation.

Results: 509 patients were included (110 expedited, 399 conventional). There was no difference in graft or patient survival at one year for expedited versus conventional LT recipients. In multivariable analysis of overall survival, only Donor Risk Index (HR 1.97, CI 1.04–3.73, p=0.037, per unit increase) was associated with increased risk of death.

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Conclusions: Patients who underwent expedited evaluation for LT had significant demographic and clinical differences from patients who underwent conventional evaluation, but comparable post-transplant survival.

Introduction

According to the United Network for Organ Sharing (UNOS), there are currently 13,355 patients awaiting liver transplantation (LT) in the United States.(1) Wait times can differ significantly between regions. In regions with higher organ demad such as UNOS regions 5, 9, and 11, the majority of LT waitlist candidates wait at least 6 months from the time of listing to transplantation.(1)

Most patients with cirrhosis are referred to a transplant center and undergo evaluation and waitlisting in the outpatient setting. However, some patients are transferred to the transplant center for urgent inpatient evaluation due to greater severity of illness. At our institution, outpatient transplant evaluations are referred to as “conventional”, while evaluations that take place in the inpatient setting are referred to as “expedited”. We observed that patients admitted for expedited workup appeared sicker, lived further from the transplant center, and were evaluated in a much shorter period of time compared with patients who had conventional evaluations.

Given the advanced nature of their disease at initial presentation and the relatively cursory workup, we hypothesized that patients who underwent LT following expedited evaluation would have inferior survival compared with the conventional cohort. Therefore, the objectives of this study were two-fold: 1) to describe the cohort of inpatients who underwent expedited evaluation and report the outcome of their inpatient evaluation for transplant candidacy and 2) to compare the post-transplant survival of patients following either expedited or conventional workup.

Materials and Methods

The study was approved by the Institutional Review Board of University of California, San Francisco (IRB #17–23416).

Study Population:

All adults (age ≥ 18 years) who were admitted to the inpatient liver transplant service for the purpose of transplant evaluation at University of California, San Francisco Medical Center between June 2012 and December 2016 were included in the study (“expedited evaluation cohort”). Patients who were evaluated as outpatients and subsequently transplanted between June 2012 and December 2016 served as a comparator group (“conventional evaluation cohort”). Patients with acute liver failure, alcoholic hepatitis, those evaluated for re-transplantation, patients who subsequently underwent living donor liver- or simultaneous liver-kidney transplantation, and patients who were transferred to another transplant center were excluded.

Our conventional evaluation process consists of phase I and phase II evaluations after patients are referred to our center for transplant consideration. Phase I evaluation includes in-person assessment by a surgeon, hepatologist, and social worker, as well as an abdominal ultrasound with dopplers, basic laboratory testing, and a toxicology screen. If patients pass phase I, they then enter phase II, which includes a chest x-ray, cardiac workup, purified protein derivative test, age-appropriate screening tests such as colonoscopy or mammography, and any additional laboratory testing or imaging studies based on the etiology of liver disease and any comorbidities. After successful completion of phase II, patients are discussed at our weekly multidisciplinary selection committee meetings, where decisions surrounding waitlist eligibility are made.

Data Collection:

Patient data was extracted from our local, prospective Transplant Outcome Anesthesia Database and the UNOS - Standard Transplant Analysis and Research (STAR) dataset.

The following recipient variables were included: date of waitlist registration, date of transplantation, date of discharge following inpatient evaluation, height, weight, ethnicity, type of insurance (public vs. private), etiology of liver disease, diagnosis of hepatocellular carcinoma, grade of encephalopathy, history of previous abdominal surgery and history of portal vein thrombosis, Model for End-Stage Liver Disease (MELD) score, and its components (bilirubin, INR, creatinine, need for renal replacement therapy) and serum sodium both at time of listing and at time of transplantation. Graft- and patient survival were retrieved from the UNOS STAR dataset, and granular details on the cause of death of patients who died within one year following transplant were collected via manual chart review.

Donor variables were retrieved from the UNOS STAR dataset and the donor risk index (DRI) was calculated as described by Feng and colleagues.(2)

The R-package *gmapsdistance* (3) was used to calculate the driving distance between the patient's ZIP code and the closest of the following three northern California liver transplant centers: University of California, San Francisco Medical Center, California Pacific Medical Center and Stanford Health Care. Median household income for the patient's ZIP code was retrieved from the University of Michigan Population Studies Center Dataset.(4)

Study Endpoints:

The primary outcome was overall survival (OS), definded as the time of LT to the last known date of follow-up or death. Graft survival was defined as the time of LT to the date of retransplantation or death. One-year patient- and graft survival rates served as secondary endpoints.

Statistical Methods:

Data were reported as mean and standard deviation (SD) or median and interquartile range (IQR) if normality assumption didn't hold. Categorical data were reported as n and percentage. The Shapiro–Wilk test was used to test for normality. The Student's t-test was

used to compare normally distributed data between groups, the Mann–Whitney test was used for non-normally distributed data, and the Chi-squared test was used for categorical data. The Kaplan–Meier curves were used to describe OS and graft survival, and the log-rank test was used to compare OS and graft survival among groups. To evaluate if patients with different types of evaluation ("expedited" vs. "conventional") would have different OS, univariable and multivariable Cox proportional hazards models were used. We adjusted the Cox models for MELD score at the time of transplant, history of hepatocellular carcinoma (HCC) and the donor risk index (DRI). These variables were selected because of their known association with post-transplant survival outcomes.

Data were analyzed using R version 3.5.1. (R Foundation for Statistical Computing, Vienna, Austria). No multiple testing adjustment was performed. Statistical significance was declared based on $P < 0.05$.

Results:

Cohort derviation is shown in Figure 1. In brief, during the study period, 408 patients underwent expedited evaluation for LT at our center, and 321 patients met criteria for inclusion in this study. Of these, 155 (48.3 %) patients were listed for LT, and 110 (34.3 %) ultimately underwent LT.

Inpatients who underwent expedited evaluation

The characteristics of all inpatients who underwent expedited evaluation are given in Table 1. Patients who underwent expedited evaluation and subsequently underwent LT had higher MELD scores ($p < 0.001$) and higher INR and bilirubin levels ($p < 0.001$) compared to those who were not transplanted. There was no difference in serum creatinine (1.3 vs. 1.24 mg/dl, p-value=0.82). There was no difference in age or etiology of liver disease between patients who were transplanted and those who were not. A greater proportion of expedited patients who underwent LT were Asian, Hispanic, African American, and White (p-value=0.02).

Transplant recipients

Characteristics of all LT recipients by type of evaluation are shown in Table 2. LT recipients who underwent expedited evaluation were significantly younger, were more likely to have alcoholic liver disease (ALD) and had a smaller proportion of patients transplanted with HCC. Patients who underwent LT following expedited evaluation had more advanced disease both at the time of listing and at LT compared those who underwent conventional evaluation. Patients who underwent expedited evaluation lived significantly further from the transplant center, lived in ZIP codes with lower median household incomes, and were more predominantly publicly insured compared with patients who underwent conventional evaluation.

A total of 64 patients underwent LT for ALD (24 expedited, 40 conventional). The median time since last drink was significantly shorter among the expedited cohort (366 vs. 989 days, $p <0.001$). Following LT, 5/24 expedited recipients (21%) and 2/40 (5%) conventional recipients experienced one or more episode of relapse to substance use.

LT recipients who underwent expedited evaluation received grafts from younger donors (median age: 34 (25– 49) vs. 43 (27 – 55) years, p = 0.009), and grafts with a lower DRI (1.34 (1.13 – 1.61) vs. 1.45 (1.19 – 1.72), p = 0.045) when compared to patients who underwent conventional evaluation.

Graft and Patient Survival

There was no difference in one-year patient survival (expedited: 92.7%, conventional: 95.2%, p = 0.423) or one-year graft survival rate (expedited: 92.7%, conventional: 93.2%, p = 1) between the two groups. Kaplan Meier curves for overall patient- and graft survival are given in Figures 2A and 2B, respectively. Median follow up time for patient- and graft survival was 4 years (IQR 2.9 – 5.1 years).

Individual causes of death for patients who died within one year after transplant are listed in Table 3. LT recipients who underwent expedited evaluation who died within one year of transplant died primarily from cardiac or infectious causes, while patients who underwent expedited evaluation had more diverse causes of death including malignancy.

There was also association between the type of evaluation for LT and survival in the univariable model (HR 1.34, 95% CI: 0.81 – 2.32, p = 0.255). When adjusting for the type of evaluation, a diagnosis of HCC, MELD score and DRI in the multivariable analysis, only DRI (HR = 1.97, 95% CI 1.04 – 3.73, p = 0.037, per unit increase) was associated with increased risk of death (Table 4).

Discussion:

The purpose of this study was to describe characteristics and outcomes of patients who underwent expedited evaluation for LT, and to compare post-transplant survival between LT recipients who underwent expedited evaluation and those who underwent conventional evaluation. We identified significant clinical and demographic differences between transplant recipients who underwent expedited evaluation and those who underwent conventional evaluation. There was no difference in overall survival after transplant between the two groups in the univariable model or multivariable model. Transplant recipients who underwent expedited evaluation received higher quality-grafts (grafts with a lower DRI).

There were several demographic characteristics that differed between LT recipients who underwent expedited evaluation and those who underwent conventional evaluation. Patients undergoing expedited evaluation lived further from a LT center, had a lower median household income, and were more likely to be publicly insured. These findings highlight a disparity in access to advanced care. Health care disparities are multifactorial, and are impacted by a variety of demographic and socioeconomic factors including place of residence and insurance status. Recent literature has suggested that patients who live further from LT centers have inferior outcomes both before and after transplant when compared with patients who live in closer proximity. In a 2014 study of veterans with decompensated cirrhosis or HCC, the authors found that longer distance to a Veterans Affairs transplant center or any transplant center was associated with significantly lower odds of being listed for transplantation, receiving a transplant once waitlisted, and surviving more than one year

after transplant.(5) More recently, another group examined the results of all LT recipients using UNOS data and found that waitlist mortality, but not post-transplant survival, was impacted by greater distance from a transplant center.(6) Insurance status is also known to impact transplant outcomes. DuBay et al. reported that Medicaid LT waitlist candidates had higher MELD scores and shorter waitlist times compared to private and Medicare insured patients, but that their post-LT survival was lower.(7) The demographics of our patients who underwent expedited workup suggest this cohort represents a group of patients that is typically at risk for inferior outcomes after transplant. Our results suggest expedited evaluation may serve as a safety net with acceptable post-transplant outcomes in this vulnerable population.

Historically, patients with cirrhosis have been categorized as having compensated, decompensated, or late decompensated disease. More recently, the definition of acute on chronic liver failure (ACLF) has been introduced as a distinct clinical entity that portends prognosis.(8) In 2015, the European Association for the Study of the Liver-Chronic Liver Failure Consortium published the results of a prospective observational study (CANONIC), which was aimed at classifying patients with ACLF; the definition of ACLF included acute decompensation, associated organ failure, and 28-day mortality rate >= 15%.(9) The CANONIC study found that patients with ACLF tended to be younger, had a greater prevalence of cirrhosis from alcoholic liver disease, had no prior history of decompensation in 25% of cases, and only progressed to transplant in 1 of 3 cases.(9) The authors also presented a review of small retrospective studies which reported the one year survival of patients with ACLF was around 80%. (10) Although our expedited evaluation cohort was defined by the setting in which the LT evaluation occurred, this cohort shares some characteristics commonly used to define ACLF: they were younger, had a higher incidence of alcoholic liver disease, and had a higher incidence of renal failure. Consistent with prior literature, 32% of patients referred to our center for expedited evaluation underwent subsequent LT. However we did see improved one year survival rates of 93%, compared with prior reports of approximately 80% in patients with ACLF. (10) Our findings reinforce the notion that patients who initially present with ACLF will have acceptable post-transplant outocmes if they are appropriately selected for LT.

In our multivariable model, only a higher DRI was associated with decreased post-transplant patient survival. This association between DRI and post LT survival highlights the impact of donor risk factors on outcomes after LT.(2) In our cohort, patients who underwent expedited evaluation received organs from donors with significantly lower DRI compared with those who underwent conventional evaluation. In both the unadjusted and adjusted survival models, expedited evaluation was not associated with inferior survival. This suggestes that organ quality may be the most notable driver of post-operative survival among LT recipients.

There are several limitations to our study. First, the results presented here are from a single transplant center with a protocolized system of LT evaluation and therefore may be limited in generalizability. We were also limited by the data collected in the inpatient versus outpatient settings; for example, our center routinely scores and tracks frailty among patients who are evaluated for transplant in the outpatient setting, but we do not ascertain these measurements for expedited or inpatients.. Second, our follow up data on the patients

who underwent expedited evaluation and were not transplanted is limited, as 29% of those patients were lost to followup within one year. Third, while we demonstrate slight differences in overall survival between patients who underwent expedited and conventional evaluations for approximately 4 years after LT, long-term survival remains unknown. The findings of our retrospective study will need to be confirmed in a larger, prospective multicenter study. Despite these limitations, however, we find the results of this study to be valuable, in that we can still achieve excellent outcomes with LT for patients previously unknown to the transplant system who present with acute, decompensated disease.

Conclusions

Patients who underwent expedited evaluation for LT had significant demographic and clinical differences from patients who underwent conventional evaluation, but both cohorts had comparable one year- and overall survival rates.

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Data Statement:

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations:

ACLF	acute on chronic liver failure
DRI	donor risk index
HCC	hepatocellular carcinoma
HR	hazard ratio
INR	international normalized ratio
IQR	inter-quartile range
LT	liver transplantation
MELD	model for end stage liver disease
STAR	Standard Transplant Analysis and Research
UNOS	United Network for Organ Sharing

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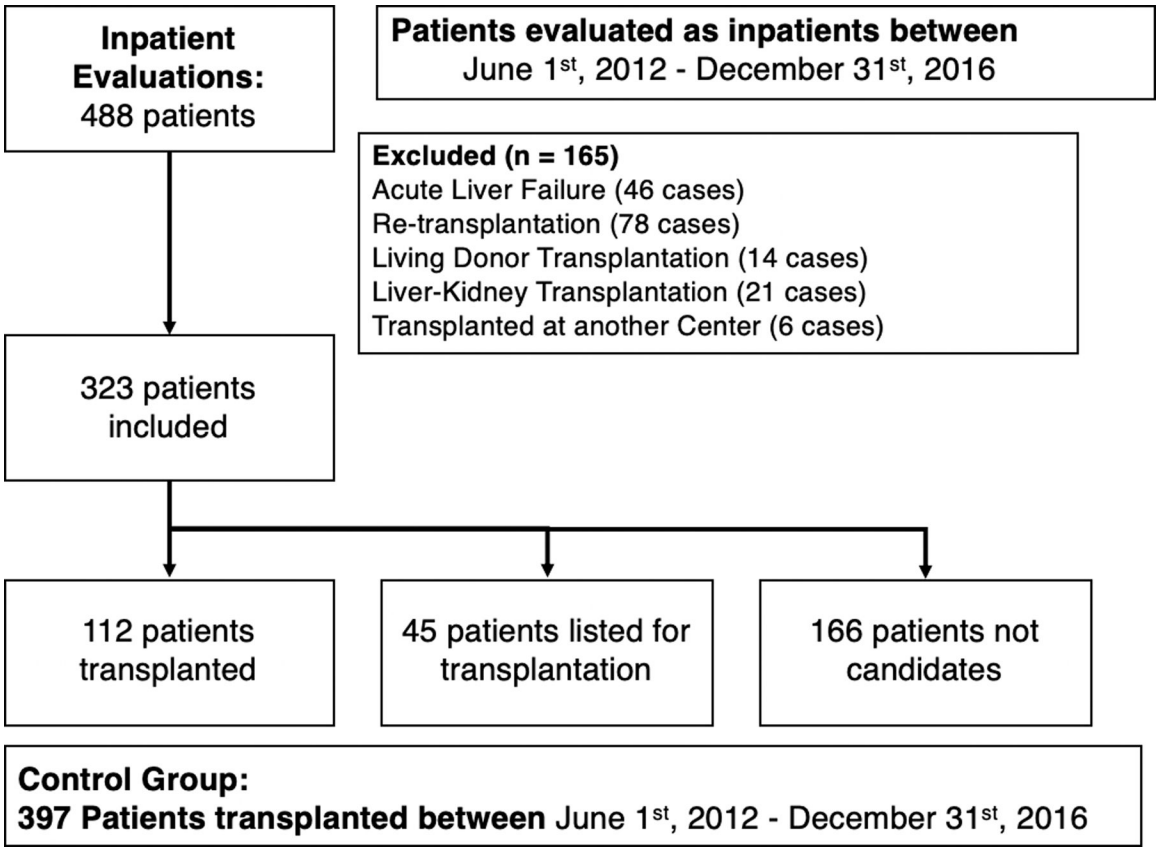

Figure 1.
STROBE flow diagram of cases included and excluded from the study

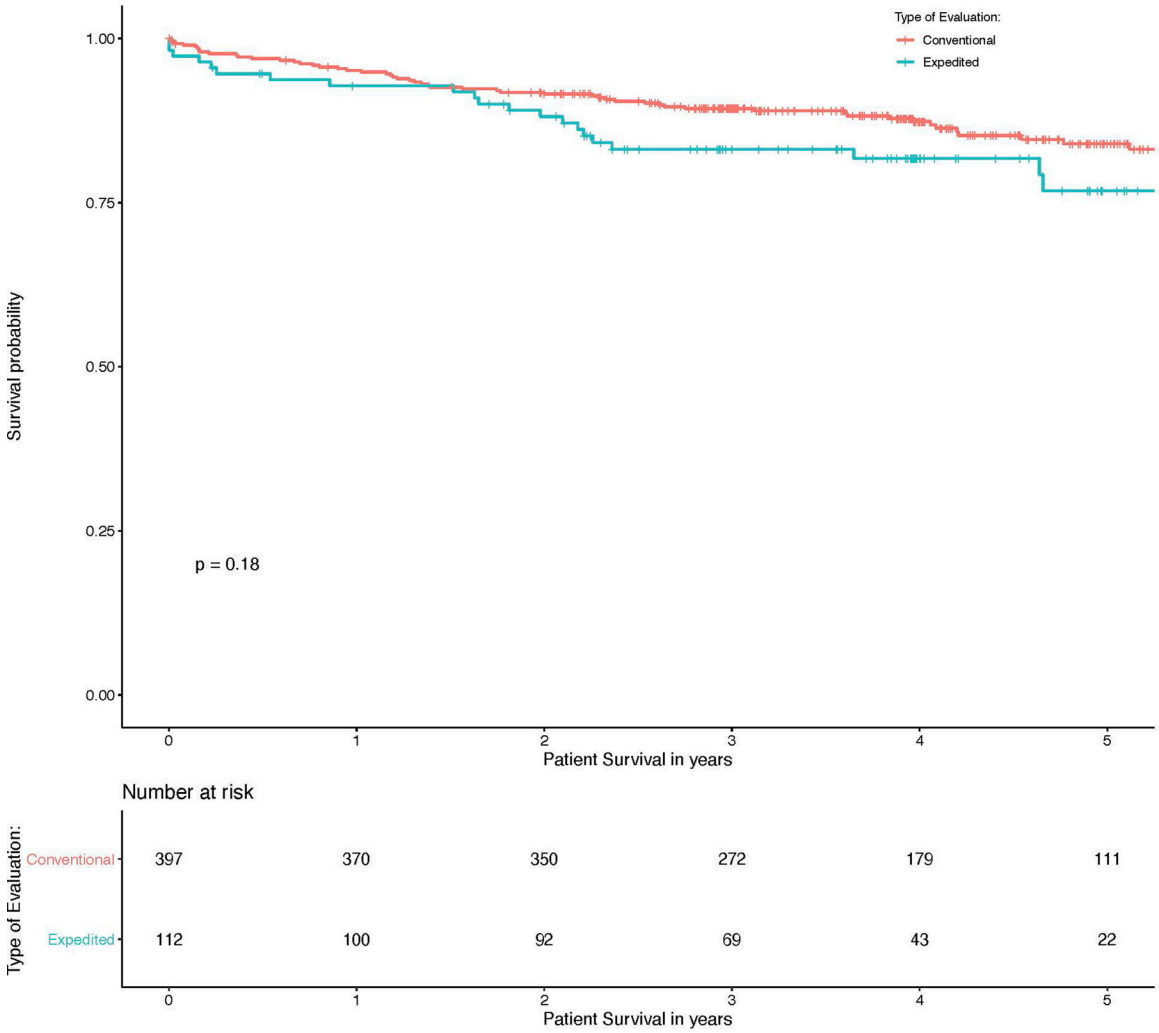

Figure 2:
Kaplan-Meier survival curve for overall patient survival (2A) and graft survival (2B)

Table 1:

All inpatients undergoing expedited workup

	Transplanted	Not Transplanted	P
Total number of patients	**110 (34.3%)**	**211 (65.7%)**	
Age (years)	58 (51–62)	56 (50–63)	0.83
Ethnicity:			0.02
Asian American	15 (13.6%)	17 (8.1%)	
African American	6 (5.5%)	9 (4.3%)	
Hispanic	29 (26.4%)	50 (23.7%)	
White	57 (51.8%)	102 (48.3%)	
Other	3 (2.7%)	26 (12.3%)	
Unknown	0 (0.0%)	7 (3.3%)	
Etiology of liver disease			0.36
Hepatitis C	44 (40.0%)	65 (30.8%)	
Hepatitis B	8 (7.3%)	14 (6.6%)	
Alcoholic	24 (21.8%)	52 (24.6%)	
Non-alcoholic steato-hepatitis	8 (7.3%)	23 (10.9%)	
Cryptogenic	10 (9.1%)	13 (6.2%)	
Other	16 (14.5%)	44 (20.9%)	
Disease severity at time of evaluation			
Laboratory MELD	32 (25–36)	26 (18–32)	<0.001
INR	2.30 (1.90–2.98)	1.90 (1.50–2.50)	<0.001
Bilirubin (mg/dL)	14.50 (5.70–23.88)	5.00 (1.90–16.60)	<0.001
Creatinine (mg/dL)	1.30 (0.89–2.12)	1.24 (0.85–2.37)	0.82
Outcome of inpatient evaluation:			
Transplanted during hospitalization	52 (47.3%)	-	
Listed, transplanted after discharge*	58 (52.7%)	-	
Listed	-	45 (21.3%)	
Not listed, condition improved	-	19 (9.0%)	
Died during evaluation	-	9 (4.3%)	
Declined	-	138 (65.4%)	
Patient status at one year:			<0.001
Alive	103 (93.6%)	64 (30.3%)	
Dead	7 (6.4%)	85 (40.3%)	
Lost to follow-up	0 (0.0%)	62 (29.4%)	

Continuous variables are summarized by median (IQR)

Categorical variables are summarized by n (%)

* patient discharged between admission for expedited evaluation and transplantation.

MELD, Model for End-Stage Liver Disease; INR, International Normalized Ratio

Table 2:

Recipients Characteristics

	expedited	conventional	P
Total number of patients	**110 (21.6%)**	**399 (78.4%)**	
Age (years)	58 (52–63)	61 (56–65)	0.001
Gender: male	68 (61.8%)	286 (71.7%)	0.06
Ethnicity:			0.54
Asian American	15 (13.6%)	82 (20.6%)	
African American	6 (5.5%)	23 (5.8%)	
Hispanic	29 (26.4%)	100 (25.1%)	
White	57 (51.8%)	187 (46.9%)	
other	3 (2.7%)	7 (1.8%)	
Body mass index (kg/m^2)	30 (25–36)	28 (24–32)	0.07
Weight (kg)	85 (71–103)	81 (70–96)	0.19
Height (cm)	169 (160–178)	170 (165–178)	0.25
Etiology of liver disease			0.001
Hepatitis C	44 (40.0%)	217 (54.4%)	
Hepatitis B	8 (7.3%)	51 (12.8%)	
Alcoholic	24 (21.8%)	40 (10.0%)	
Non-alcoholic steato-hepatitis	8 (7.3%)	26 (6.5%)	
Cryptogenic	10 (9.1%)	13 (3.3%)	
Other	16 (14.5%)	52 (13.0%)	
Hepatocellular carcinoma	13 (11.8%)	258 (64.7%)	<0.001
History of Portal Vein Thrombosis	17 (15.5%)	63 (15.8%)	1.0
Previous Abdominal Surgery	40 (36.4%)	167 (41.9%)	0.35
Disease Severity at time of listing:			
Laboratory MELD	32 (25–36)	12 (9–16)	<0.001
INR	2.30 (1.90–2.98)	1.30 (1.10–1.50)	<0.001
Bilirubin (mg/dL)	14.50 (5.70–23.88)	1.85 (1.10–3.00)	<0.001
Creatinine (mg/dL)	1.30 (0.89–2.12)	0.86 (0.74–1.00)	<0.001
Time on waitlist until transplant (days)	13 (5–61)	502 (258–659)	<0.001
Disease Severity at time of transplant			
Laboratory MELD	35 (28–39)	16 (10–26)	<0.001
INR	2.40 (1.80–3.40)	1.50 (1.20–2.20)	
Bilirubin (mg/dL)	15.30 (8.85–31.28)	2.10 (1.10–7.55)	<0.001
Creatinine (mg/dL)	1.80 (1.16–2.73)	0.96 (0.79–1.41)	<0.001
Renal replacement therapy prior to transplant | Yes or No	39 (35.5%)	45 (11.3%)	<0.001
Serum Sodium, mmol/L	136 (132–139)	137 (134–139)	0.04
Distance to nearest liver transplant center (km)	148 (48–269)	79 (33–159)	<0.001
Median household income (USD, by ZIP Code)	60,051 (46,918–75,789)	64,712 (52,027–80,846)	0.050
Public Insurance n (%)	48 (43.6%)	93 (23.3%)	<0.001

Continuous variables are summarized by median (IQR)

Categorical variables are summarized by n (%)

*Discharged between admission for expedited evaluation and transplantation.

MELD, Model for End-Stage Liver Disease; INR, International Normalized Ratio; USD, United States dollar;

Table 3:

Causes of death for patients who died within one year after transplant

Patient #	Post-operative day	Cause of Death
expedited evaluation (n = 8 / 110 7.3%)		
1	0	Cardiac
2	1	Graft failure
3	8	Cardiac
4	59	Infection
5	82	Cardiac
6	93	Infection
7	197	Infection
8	313	Other
conventional evaluation (n = 19 / 399, 4.8%)		
1	3	Graft failure
2	8	Graft failure
3	13	Infection
4	28	Cardiac
5	52	Pulmonary
6	56	Graft failure
7	59	Infection
8	59	Pulmonary
9	78	Other
10	131	Malignancy
11	134	Malignancy
12	161	Cardiac
13	216	Infection
14	244	Trauma
15	255	Malignancy
16	280	Infection
17	293	Malignancy
18	329	Malignancy
19	346	Malignancy

Table 4:

Multivariable Cox Proportional Hazard Model for overall survival*

Variable	Hazard Ratio	95% Confidence interval	P
Inpatient Evaluation	**1.775**	**(0.94 – 3.36)**	**0.079**
MELD score (per point increase)	1.001	(0.98 – 1.03)	0.965
Donor Risk Index	1.972	(1.04 – 3.73)	0.037
Hepatocellular carcinoma	1.560	(0.85 – 2.85)	0.149

MELD, Model for End-Stage Liver Disease