# ПРОБЛЕМНІ СТАТТІ

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### Liver Transplantation in Patients with Model for End-Stage Liver Disease Score of 40 or Higher

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#### Abstract

<u>Background</u>: Patients with Model for End-Stage Liver Disease (MELD) scores of 40 or higher are at high risk for liver transplantation. In some regions, the organ donor shortage has resulted in a substantial increase in the number of patients who underwent transplantation with MELD scores of 40 or higher. The objective of this study was to characterize the outcomes of liver transplantation in these patients.

<u>Methods</u>: A single-center retrospective study evaluating the outcome of liver transplantation in 38 consecutive patients achieving a MELD score of 40 or higher from January 1, 2006, to November 30, 2010, was conducted. Patient and graft survivals and independent risk factors for postoperative death or graft loss were determined.

<u>Results</u>: Kaplan-Meier–based 1-, 2-, and 3-year patient survival rates were 89%, 82%, and 77% with 1-, 2-, and 3-year graft survival rates of 84%, 75%, and 70.3%, respectively. One of three recipients was on a vasopressor before transplantation, and 13% were mechanically ventilated. Renal replacement therapy was used before operation in 90% of the recipients. Postoperative length of stay averaged 38 days. There was a 42% incidence of postoperative bacteremia and an 18% incidence of bile duct stricture within 6 months. Univariate analysis identified admission-to-transplantation time and recipient diabetes as risk factors for graft failure and patient death. Multivariate analysis confirmed recipient diabetes as a risk factor for patient survival and admission-to-transplantation time of more than 15 days as a risk factor for graft survival.

<u>Conclusions</u>: Acceptable outcomes are achievable after liver transplantation in patients with MELD scores of 40 or higher but come at high pre-transplantation and post-transplantation resource utilization.

In the past 2 decades, liver transplantation has transitioned from a therapy offered at a few elite academic medical centers throughout the United States to an accepted operation currently performed in more than 100 academic and private institutions. The dramatic increase in the number of both centers performing and patients awaiting liver transplantation necessitated a more objective approach to the allocation of deceased-donor livers resulting in the implementation of the Model for End-Stage Liver Disease (MELD) scoring system in 2002 ( $\underline{1}, \underline{2}$ ). The aim of the MELD system was to allocate organs based on the likelihood of recipient mortality without liver transplantation in accordance with the Final Rule (Federal Register [FR Doc. 98-(3) (3). At the time of implementation, a decision was made to cap the MELD score at 40 because of the near-100% mortality of such patients at 3 months without liver transplantation. Patients with a score of 40 or higher were considered at a very high risk for transplantation and represented only 5% of all transplants (4). Although no limitations were created defining patients as "too sick to transplant," additional priority was not given to waitlisted patients with a score higher than 40 to discourage the performance of futile transplants. Since then, there has been a progressive increase in the median MELD score of liver transplant recipients, especially in larger organ procurement organizations ( $\underline{5}$ ). In organ procurement organizations with multiple transplant centers, this has resulted in more patients waitlisted at a MELD score of 40 or higher. Southern California has been particularly affected by this phenomenon, resulting in a large increase in the number of liver transplants performed for patients with a MELD score of 40 or higher. However, there are no publications specifically addressing outcomes in this group of patients. In this retrospective single-center review, we aim to better characterize this group of patients and their outcomes after liver transplantation.

### Materials and methods

A list of all liver transplantation candidates achieving a

MELD score of 40 or higher at our institution from January 1, 2006, to November 30, 2010, was obtained from UNOS. The UNOS report contained demographic data for each patient including primary diagnosis, listing date, delisting date, and the individual components of each MELD score update from the time that a MELD score of 40 or higher was reached to the time of transplantation, death, or delisting. Data were collected by retrospective chart review. Diagnosis of postoperative bacteremia or fungemia required a positive culture within 90 days of transplantation. Biliary stricture was diagnosed by endoscopic retrograde cholangiopancreatography or percutaneous transhepaticcholangiogram requiring any type of intervention including stricture dilatation or stent placement. Immunosuppression after transplantation consisted of a combination of steroids, mycophenolatemofetil, and a calcineurin inhibitor. Tacrolimus was typically instituted within 48 hr of transplantation. Antibody induction is not routinely used in our center. Similar data were collected for a comparator group of 26 consecutive deceaseddonor whole-liver transplants performed from January 1, 2010, to December 31, 2010, in which the recipient MELD score remained less than 40.Patient and graft survival rates were estimated by the Kaplan-Meier product-limit method. Univariate and multivariate Cox regression analyses were used to estimate hazard ratios for patient death and graft loss. All reported P values were two tailed. STATA version 12 (StataCorp, College Station, TX) was used in all statistical analyses.

#### Results

Between January 1, 2006, and November 30, 2010, 94 patients listed for liver transplantation achieved a MELD score of 40 or higher. Fifty (53%) patients on the list died or were delisted and subsequently died. A total of 44 patients underwent liver transplantation: 6 for acute liver failure (status 1a) and 38 for chronic liver failure (CLF). Status 1a patients were excluded from further analysis. Of the 38 CLF patients, 12 (32%) underwent combined liver and kidney transplantation, and 26 (68%) underwent liver transplantation alone.

As shown in Table 1, the average recipient age was 50 years, with the majority being male. The most common indication for liver transplantation was long-term hepatitis C viral infection (45%) followed by alcoholic cirrhosis (16%). Nearly one of four patients had undergone prior upper abdominal surgery, and 13% of recipients had undergone prior liver transplantation. The median time interval from admission at the transplantation center to liver transplantation was 15 days. The median peak MELD score of the recipients was 43 with a median time of 7.5 days at a MELD score of 40 or higher. The mean and median bilirubin level, creatinine level, and international normalized ratio are also shown. Donor data were available for 37 of the transplants and are summarized in Table 2.

Pre-transplantation critical care utilization in the CLF transplant recipients was high (Table 1). Two thirds of recipients required admission to the intensive care unit prior to transplantation. One of three recipients was on a vasopressor before transplantation, and 13% were mechanically ventilated. Renal replacement therapy in the form of either standard hemodialysis or continuous veno-venous hemodialysis was used before operation in 90% of the recipients. The mean length of surgery for liver transplantation was 8 hr, with combined kidney transplantation adding an additional 3.5 hr (Table 3).

All but one liver transplantation were performed in the piggyback fashion. An aortic conduit was required in 21% of

Age, mean (SD), median, y	36.2 (13.8), 33
Age range, y	17-64
Male, n (%)	24 (64.9)
Height, mean (SD), median, cm	171.9 (10.2), 172.7
Weight, mean (SD), median, kg	74.7 (14.9), 73
BMI, mean (SD), median	25.3 (4.5), 24.5
BMI range	15.4-36.5
Donor cause of death, n (%)	
Head trauma	19 (51)
Cerebrovascular accident	15 (41)
Anoxia	2 (5.4)
Others	1 (2.7)
Donation after cardiac death, n (%)	1 (2.7)
Whole graft, n (%)	37 (100)
Regional share, n (%)	6 (16.2)
National share, n (%)	0 (0)
Biopsy, n (%)	5 (13.5)

BMI, body mass index.

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	Total (n=38)		1 otal (n=37)
Age, mean (SD), median, y	49.8 (9.4), 49.7	Age, mean (SD), median, y	36.2 (13.8), 33
Male, n (%)	26 (68.4)	Age range, y	17-64
BMI, mean (SD), median	27.5 (6.2), 26.7	Male, n (%)	24 (64.9)
Etiology, n (%)		Height, mean (SD), median, cm	171.9 (10.2), 172.3
Autoimmune hepatitis	1 (2.6)	Weight, mean (SD), median, kg	74.7 (14.9), 73
Cryptogenic	6 (15.8)	BMI, mean (SD), median	25.3 (4.5), 24.5
Hepatitis B	3 (7.9)	BMI range	15 4-36 5
Hepatitis C	12 (31.6)	Donor cause of death n (%)	15.1 50.5
Hepatitis C and alcohol	5 (13.2)	Head trauma	10 (51)
Alcohol	5 (13.2)	Flead trauma	19 (31)
Others	5 (13.2)	Cerebrovascular accident	15 (41)
Hepatocellular carcinoma, n (%)	2 (5.3)	Anoxia	2 (5.4)
Diabetes, n (%)	11 (28.9)	Others	1 (2.7)
Prior abdominal surgery, n (%)	12 (31.6)	Donation after cardiac death, n (%)	1 (2.7)
Previous liver transplantation, n (%)	5 (13.2)	Whole graft, n (%)	37 (100)
Time on list, mean (SD), median, d	107.4 (200.4), 21.5	Regional share, n (%)	6 (16.2)
Time with MELD ≥40, mean (SD),	9.2 (7.3), 7.5	National share, n (%)	0 (0)
median, d		Biopsy, n (%)	5 (13.5)
Peak MELD, mean (SD), median	44.2 (3.6), 43.0	BML body mass index	
Bilirubin, mean (SD), median	33.9 (12.4), 35.1	bivit, body mass mucx.	
INR, mean (SD), median	2.5 (0.8), 2.3	combined liver and kidney transplantati	ion The most common
Creatinine, mean (SD), median	2.4 (1.5), 2.4	indication for transplantation was hepat	itis C (46 2%) followed
Condition before transplantation		by alcoholic cirrhosis (23.1%) Thirty-	eight percent of recipi-
ICU, n (%)	26 (68.4)	ents also had hepatocellular carcinoma.	The mean MELD score
Mechanical ventilation, n (%)	5 (13.2)	at the time of transplantation was 30, an	d the median postoper-
Vasopressors, n (%)	13 (34.2)	ative length of stay was 15.5 days. The i	ncidence of postopera-
HD/CRRT, n (%)	32 (84.2)	tive bacteremia was 7.7% with no postope	rative fungemia. Slight-
Admission to HD/CRRT initiation, mean (SD), median, d <sup>a</sup>	6.8 (6.0), 5.0	ly more than a quarter of patients (27%) One patient developed hepatic artery thro	) required reoperation. ombosis, and there were

 Table 1. Patient demographics

Table 2. Donor demographic data.

Total (n=37)

nsplantation was hepatitis C (46.2%) followed hosis (23.1%). Thirty-eight percent of recipiatocellular carcinoma. The mean MELD score splantation was 30, and the median postoperay was 15.5 days. The incidence of postoperaas 7.7% with no postoperative fungemia. Slightuarter of patients (27%) required reoperation. oped hepatic artery thrombosis, and there were no portal vein thromboses. The biliary stricture rate at 1 year was 23.1%.

Univariate analysis of transplantation patients with a MELD score of 40 or higher identified an admission-to-transplantation time of more than 15 days, combined liver and kidney transplantation, and recipient diabetes as preoperative factors associated with an increased risk of postoperative death (Table 5).

Recipient diabetes remained a significant risk factor in the multivariate analysis with both admission-to-transplantation time of more than 15 days and combined liver and kidney transplantation only trending toward an increased risk of death. Similarly,

Table 3. Perioperative data.

Total (n=37)

Three liver-alone transplant recipients with graft failure underwent retransplantation.

In comparison, the 1-year patient survival rate in 26 consecutive liver transplants for patients with a MELD score of less than 40 performed in 2010 was 92%. The mean age at transplantation for this comparator group was 53.7 years, with 77% undergoing isolated liver transplantation and 23% undergoing

ratio; MELD, Model for End-Stage Liver Disease. the recipients, and one recipient required a portal vein graft. A

choledocho-choledochostomy was performed in 82% of the recipients. An average of 16 U of packed red blood cells was trans-

" Patients already on HD/CRRT before admission are excluded from

BMI, body mass index; CRRT, continuous renal replacement therapy;

HD, hemodialysis; ICU, intensive care unit; INR, international normalized

this comparison.

fused. Outcomes after liver transplantation for patients with a MELD score of 40 or higher are shown in Table 4. Length of stay for the transplantation admission averaged

58 days with a mean postoperative length of stay of 38 days. There was a 21% perioperative reoperation rate mostly for evacuation of hematoma. Eleven percent of patients developed a culture-positive postoperative intraabdominal infection. There were no hepatic artery thromboses, and a single patient developed portal vein thrombosis requiring reexploration. One patient developed a bile leak after operation, and 18% of patients developed a bile duct stricture within 6 months diagnosed by either endoscopic retrograde cholangiopancreatography or percutaneous transhepatic cholangiography. Bacteremia diagnosed by positive blood culture developed in 42% of the patients within the first 90 days after operation, and 8% of patients developed fungemia. Kaplan-Meier-based 1-, 2-, and 3-year patient survival rates were 89%, 82%, and 77% with 1-, 2-, and 3-year graft survival rates of 84%, 75%, and 70%, respectively (Fig. 1)

Table 4. Post-operative outcomes.	Total (n=38) 38 (29.1), 23	
Postoperative length of stay, mean (SD), median, d		
Dialysis received at discharge, n (%)	2 (5.3)	
Reoperation, n (%)	8 (21.1)	
Vascular complication, n (%)		
Hepatic artery thrombosis	0 (0)	
Portal vein thrombosis	1 (2.6)	
Biliary complication, n (%)		
Bile duct stricture	9 (23.7)	
Bile leak	1 (2.6)	
Bile duct casts	2 (5.3)	
Any biliary complication	11 (29.0)	
Infectious complication, n (%)	4 (10.5)	
Intraabdominal infection, n (%)		
Bacteremia	16 (42.1)	
Fungemia	3 (7.9)	

univariate analysis identified an admission-to-transplantation time of more than 15 days and combined liver and kidney transplantation as preoperative factors associated with an increased risk of graft loss (Table 6). Admission-to-transplantation time of more than 15 days remained a significant risk factor in the multivariate analysis.

## Discussion

Although the number of liver transplants performed annually seems to have plateaued at 6000 per year, Scientific Registry of Transplant Recipients data indicate that the degree of illness of liver transplant recipients continues to rise. The percentage of transplant recipients nationally achieving a MELD score of 40 or higher increased from 6.8% in 2006 to 10.7% in 2010 (www.ustransplant.org, Accessed April 18, 2012). In our center, more than 50% of transplant recipients with a MELD score of 40 or higher waited more than 7 days to receive a suitable organ offer. As both the number of transplants performed for patients with a MELD score of 40 or higher rises and the amount of time that the recipients spend waiting for an organ increases, it becomes important to characterize this specific group of patients. To our knowledge, no publications address outcomes in this unique group of patients.

Several single-institution series have reported inferior outcomes for liver transplant recipients stratified by an increasing MELD score at the time of transplantation (6, 7). Onaca et al. (6) grouped 669 patients according to their MELD scores: those with a MELD score of less than 15, those with a MELD score of 15 to 24, and those with a MELD score of 25 or higher. Patients



Fig 1. Kaplan-Meier overall graft and patient survival rates for recipients who underwent transdplantation for chronic liver failure with a MELD score of 40 or higher

with a MELD score of 25 or higher showed a significantly inferior 12- and 24-month survival rate compared with those with a MELD score of less than 15. Saab et al. (7) grouped 404 patients as follows: those with a MELD score of less than 10, those with a MELD score of 11 to 18, those with a MELD score of 19 to 24, those with a MELD score of 25 to 35, and those with a MELD score of 36 or higher. Patients with a MELD score of 36 or higher showed a 1-year survival rate of 69% compared with 79% for those with a MELD score of 25 to 35 and 90% for all other groups. Similar outcomes were described in a study by Jacob et al. (8). However, all the aforementioned studies group together patients with a MELD score of less than 40, who are ranked in descending order based on a dynamic numerical score, with patients with a MELD score of 40 or higher, who are ranked in descending order based on the time at a MELD score of 40 or higher. Our 1-year patient survival rate of 89% in patients with a

Factors	Levels/reference	Unadjusted		Adjusted	
		HR (95% CI)	P	HR (95% CI)	P
Recipient					
Age, y	>60 or ≤60	0.91 (0.23-3.69)	0.900	2.27 (0.29-18.0)	0.437
Diabetes		8.65 (1.63-45.8)	0.011	15.1 (1.16-196)	0.038
Ethnicity	Hispanic vs. others	2.06 (0.25-16.9)	0.501	2.84 (0.12-65.4)	0.514
Etiology					
	Alcoholic	4.00 (0.73-21.9)	0.110	3.51 (0.23-54.7)	0.367
	Cryptogenic	6.82 (0.92-50.4)	0.060	7.82 (0.22-282)	0.261
	Others	1.0		1.0	
ICU at transplantation		1,89 (0.38-9.42)	0.437	16.5 (0.77-353)	0.073
Liver-kidney	vs. liver alone	9.9 (1.9-50.5)	0.006	13.1 (0.98-174)	0.052
Admission to transplantation, d	≥15 vs. ≦15	11.7 (1.4-97.4)	0.023	10.3 (0.83-128)	0.069
IC11 intension care unit					

Factors	Levels/reference	Unadjusted		Adjusted	
		HR (95% CI)	P	HR (95% CI)	P
Recipient					
Age, y	>60 or ≤60	0.53 (0.16-1.84)	0.320	0.63 (0.11-3.58)	0.601
Diabetes		3.22 (0.91-11.4)	0.069	7.73 (0.99-60.3)	0.051
Ethnicity	Hispanic vs. others	1.37 (0.29-6.40)	0.686	1.74 (0.17-17.5)	0.637
Etiology					
	Alcoholic	2.47 (0.66-9.21)	0.178	0.70 (0.75-6.60)	0.758
	Cryptogenic	3.11 (0.56-17.3)	0.196	7.45 (1.08-51.2)	0.391
	Others	1.0		1.0	
ICU at transplantation		2.75 (0.59-12.8)	0.196	7.83 (0.91-67.2)	0.061
Liver-kidney	vs. liver alone	3.66 (1.09-12.2)	0.035	2.93 (0.37-23.3)	0.310
Admission to transplantation, d	>15 vs. ≤15	6.97 (1.48-32.8)	0.014	7.45 (1.08-6.60)	0.041

MELD score of 40 or higher is superior to that of the highest MELD groups reported in the aforementioned series and similar to the 92% 1-year patient survival rate in patients with a MELD score of less than 40 in our center.

An increasing amount of attention has recently been focused on donor factors that affect recipient outcomes. Some metrics such as the Donor Risk Index predict recipient outcome solely based on donor information, whereas others such as the D-MELD, the product of the donor age and recipient MELD score, use a combination of donor and recipient information (9, 10). Merion et al. demonstrated that waitlisted patients with a MELD score of 40 or higher achieved the most significant survival benefit from liver transplantation irrespective of donor allograft quality due to their high waitlist mortality rate and short life expectancy (4, 11). In practice, however, selection of a donor allograft with a 50% likelihood of failure at 1 year would be unacceptable even if declining the organ transplant resulted in a greater than 50% likelihood of mortality on the waitlist. We preferentially used high-quality donors in this critically ill group of patients to minimize the incidence of graft dysfunction during and after operation. This approach is conceptually similar to attempting to minimize the D-MELD score. The typical accepted organ donor was from a man in his mid-30s with a body mass index of 25. We avoided using partial allografts or those from donation after cardiac death. Despite this, our average peak D-MELD score was still 1599 (range, 792-3008) with 17 patients having a peak D-MELD score of greater than 1628 and an estimated 3-year survival rate of less than 70% (12). However, analysis of our data did not demonstrate any significant difference in patient or graft survival rate between the group whose D-MELD is greater than 1628 and the group whose D-MELD is equal to or less than 1628 at 3 years.

Several studies have found high MELD score to be associated with an increased risk for posttransplantation infection, intensive care utilization, length of stay, and cost (13-15). Most of our recipients required intensive care with a significant percentage needing hemodynamic, ventilatory, or renal support. We found that the likelihood of being placed on renal replacement therapy increased with an increasing time from admission to transplantation. Although not statistically significant because of small sample size, we also found an increasing rate of combined liverkidney transplantation of 44% in recipients waiting more than 15 days from the time of admission to transplantation as compared with a 20% rate in those waiting for 15 days or less. By comparison, the rate of combined liver-kidney transplantation was 23% in 2010 for recipients with a MELD score of less than 40 at our institution. One of five recipients required reoperation, and nearly 20% developed a bile duct stricture within 6 months. These complication rates are similar to those seen in our transplant recipients with a MELD score of less than 40. A 42% posttransplantation bacteremia rate reflects the profound immunosuppression associated with end-stage liver disease and liverrelated malnutrition in this critically ill population and is much higher than the 7.7% rate we have seen in our patients with a MELD score of less than 40. The degree of recipient deconditioning resulted in the need for prolonged hospital-level care and a median postoperative length of stay of 23 days as compared with 15.5 days in our patients with a MELD score of less than 40. Despite these challenges, an acceptable 1-year patient survival rate is achievable. Our 2- and 3-year outcomes are consistent with the published United Network for Organ Sharing (UNOS) data. Causes of postoperative mortality included recurrent hepatitis C graft failure, sepsis, cardiac dysfunction, and ischemic cholangiopathy.

Identifying preoperative factors associated with poor postoperative outcomes is critically important in liver transplantation because of the scarcity of suitable donor organs. A limited univariate analysis identified three factors that influenced postliver transplantation outcomes in patients who underwent transplantation with a MELD score of 40 or higher: admission-totransplantation time of more than 15 days, combined liver and kidney transplantation, and recipient diabetes. Our multivariate analysis is limited by our small sample size but confirmed the deleterious effect of prolonged pretransplantation hospitalization and pretransplantation diabetes on posttransplantation outcome. As expected, the nutritional, immunologic, and renal deteriorations associated with prolonged pretransplantation hospitalization and diabetes should and do manifest in posttransplantation mortality. Our findings emphasize that time is of essence in this critically ill group of patients. Waiting in the hospital for a prolonged period increases the likelihood of not only pretransplantation mortality but also posttransplantation graft loss and death in patients with a MELD score of 40 or higher. However, it is important to emphasize that liver transplantation in patients with a MELD score of 40 or higher can have acceptable outcomes, and an optimal scoring index to consistently predict futile transplantation remains to be identified.

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Трансплантація печінки у хворих, які мають 40 і більше балів згідно шкали для оцінки захворювання печінки останньої стадії.

Відділ хірургії печінки, жовчного тракту та підшлункової залози і трансплантації органів черевної порожнини

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Резюме. Історія питання: Пацієнти, що набирають 40 і більше

балів за шкалою оцінки захворювання печінки останньої стадії (ШОЗПОС), мають високу ймовірність у потребі пересадки печінки. У деяких регіонах обмеженість донорських органів привела до суттєвого зростання числа пацієнтів, які отримали трансплант, маючи 40 і більше балів згідно ШОЗПОС. Ціллю цієї статті було описання наслідків трансплантації печінки у цих пацієнтів.

<u>Методи:</u> Ретроспективне дослідження проводилось в одному центрі і оцінило результати трансплантації печінки у 38 пацієнтів, що набрали 40 і більше балів згідно ШОЗПОС у період з 1 січня 2006 року до 30 листопада 2010 року. Визначили рівень виживання пацієнтів, довговічності трансплантів і незалежних факторів ризику у післяопераційній смерті.

<u>Результати:</u> Згідно Каплана і Меєра рівень виживання пацієнтів після 1 року складав 89%, після 2 років – 82%, після 3 років – 77%. З пересаджених органів після 1 року продовжували функціонувати 84%, після 2 років – 75%, після 3 років – 70.3%. Кожен третій з пацієнтів отримував вазопресори перед трансплантацією, а 13% були на механічному вентилюванні. Терапія обміну ниркових речовин проводилась у 90% пацієнтів перед операцією. У середньому післяопераційне перебування тривало 38 днів. Бактеріємія трапилась у 42% пацієнтів, а звуження жовчного тракту відбулось у 18% пацієнтів протягом 6 місяців після операції. Одновимірний аналіз показав, що тривалість перебування у лікарні (від прийому до трансплантації) і наявність діабету в пацієнтів є факторами ризику, що можуть провести до смерті пацієнта і відмови транспланта. Багатовимірний аналіз підтвердив, що діабет є фактором ризику, що впливає на виживання пацієнта, а перебування у лікарні більше 15 днів (від прийому до трансплантації) є фактором ризику для пересадженого органу.

<u>Висновки:</u> Задовільні результати можуть досягатись після пересадки печінки у пацієнтів, які набрали 40 і більше балів згідно ШОЗПОС, при інтенсивнішому використанні ресурсів перед та після трансплантації.

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