Model for End-Stage Liver Disease (MELD) and Allocation of Donor Livers

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Background & Aims: **A consensus has been reached that liver donor allocation should be based primarily on liver disease severity and that waiting time should not be a major determining factor. Our aim was to assess the capability of the Model for End-Stage Liver Disease (MELD) score to correctly rank potential liver recipients according to their severity of liver disease and mortality risk on the OPTN liver waiting list.** ***Methods:*** **The MELD model predicts liver disease severity based on serum creatinine, serum total bilirubin, and INR and has been shown to be useful in predicting mortality in patients with compensated and decompensated cirrhosis. In this study, we prospectively applied the MELD score to estimate 3-month mortality to 3437 adult liver transplant candidates with chronic liver disease who were added to the OPTN waiting list at 2A or 2B status between November, 1999, and December, 2001.** ***Results:*** **In this study cohort with chronic liver disease, 412 (12%) died during the 3-month follow-up period. Waiting list mortality increased directly in proportion to the listing MELD score. Patients having a MELD score <9 experienced a 1.9% mortality, whereas patients having a MELD score ≥40 had a mortality rate of 71.3%. Using the c-statistic with 3-month mortality as the end point, the area under the receiver operating characteristic (ROC) curve for the MELD score was 0.83 compared with 0.76 for the Child-Turcotte-Pugh (CTP) score ($P < 0.001$).** ***Conclusions:*** **These data suggest that the MELD score is able to accurately predict 3-month mortality among patients with chronic liver disease on the liver waiting list and can be applied for allocation of donor livers.**

The number of patients waiting for liver transplantation on the OPTN waiting list has increased dramatically in the last decade. Today, more than 18,000 patients with end-stage liver disease await liver transplantation, whereas the number of available cadaveric donor livers remains static at approximately 5000 per year.[1] As a result, the number of patients dying while on the liver waiting list has continued to increase in recent years.[1]

In the past, livers were allocated to potential liver recipients based on the Child-Turcotte-Pugh (CTP) score, ABO blood type compatibility, and overall waiting time.[2] Categories for liver allocation included the following: status 1, patients with acute fulminant hepatic failure or patients with primary graft dysfunction or hepatic artery thrombosis occurring within the first week posttransplantation, or pediatric patients who decompensate and require continuous care in the intensive care unit. Status 1 patients received priority for liver allocation over all patients with chronic liver disease. Patients with chronic liver disease were classified and ranked as status 2A, 2B, or 3 as defined in Table 1.[2] The "tiebreaker" within each of these broad disease severity categories was waiting time.[2]

With over 18,000 patients awaiting liver transplantation and only 3 categories of liver disease severity to classify patients with chronic liver disease, waiting time by default represented the major determinant for liver allocation. However, recent studies have demonstrated that longer waiting times are not associated with increased risk of death while on the waiting list.[3,4] Based on these data, a consensus was reached that waiting time should be de-emphasized in the liver allocation policy. These realizations led to the final rule mandate of 1998,

Abbreviations used in this paper: CTP, Child-Turcotte-Pugh; INR, international normalized ratio; MELD, Model for End-Stage Liver Disease; TIPS, transjugular intrahepatic portosystemic shunt.

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which compelled development of a new prioritization system that was not based on waiting time.[3]

Further deficiencies in the old allocation system, which used the CTP score in addition to waiting time, became evident with experience. The CTP score, originally developed to determine preoperative risk of surgical shunt surgery, formed the basis on which liver disease severity was assessed.[5] However, its usefulness was limited by a number of inherent problems. The most important deficiency in the CTP score is that it uses 2 very subjective variables in its calculation, namely portosystemic encephalopathy and severity of ascites. The original CTP score used only the physical examination assessment of ascites to define this variable, but current clinical practice today uses much more sensitive imaging studies such as ultrasonography to detect ascites. Even more problematic is the assessment of portosystemic encephalopathy. In current practice, fatigue, occasional forgetfulness, and insomnia may qualify as a symptom of portosystemic encephalopathy in some clinician's assessments but not in others. Sedative medications can induce drowsiness, which can also be interpreted or misconstrued as signs of encephalopathy and can increase the CTP score and, consequently, priority in the past allocation system. Even the more objective laboratory parameters such as serum albumin, which reflects the state of a patient's nutrition, can be iatrogenically manipulated with infusion of albumin. Prothrombin time can vary from laboratory to laboratory and institution to institution depending on the control measures used, which frequently were not comparable.[6] Moreover, the CTP score has never been validated for the purpose of estimating survival in patients with chronic liver disease and poorly differentiates between the most ill patients. For example, the CTP score allots patients with serum bilirubin values of 3.5 mg/dL the same score as those with serum bilirubin levels of 10 mg/dL or even 40 mg/dL, although these high bilirubin values clearly indicate significantly worse liver disease. These cumulative problems associated with our past allocation system intensified the search for a continuous disease severity score system that used more objective, readily verifiable parameters, which could be validated as a measure of liver disease severity and predictor of mortality.

After an extensive assessment of various liver disease severity scores, the Model for End-Stage Liver Disease (MELD) was selected for further evaluation because it fulfilled many of the guidelines outlined in the final rule mandate issued by Health and Human Services.[7] MELD is based on 3 biochemical variables, which are readily available, reproducible, and objective. These variables consist of serum bilirubin, serum creatinine, and the international normalized ratio (INR) of prothrombin time. Originally, this model was developed to predict the outcomes of the transjugular intrahepatic portosystemic shunt (TIPS) procedure in patients with chronic liver disease.[8] However, more recently, MELD has been validated retrospectively on 5 independent chronic liver disease data sets representing diverse patient populations having a broad spectrum of liver disease etiologies and disease severity.[8,9] Moreover, the model has been shown to be able to rank patients according to their probability of dying over a defined time period. The model has also been shown to predict mortality independent of etiology and the occurrence of complications of portal hypertension such as esophageal variceal bleeding, spontaneous bacterial peritonitis, and portosystemic encephalopathy.[9,10]

In this article, we report the results of a prospective study, demonstrating the ability of the MELD score to correctly rank patients with chronic liver disease on the OPTN waiting list according to their risk of death over a 3-month time period.

Materials and Methods

Patient Population

The cohort of patients used for this analysis included adults (≥18 years of age) with chronic liver disease who were added to OPTN liver waiting list at a 2A or 2B status between November, 1999, and December, 2001. Of the 6651 adult patients with chronic liver disease who were listed during this time period, 3437 (52%) had complete MELD data at the time of listing, including serum creatinine, serum bilirubin, and INR. Because prothrombin time rather than INR was often reported for patients at listing, these patients were excluded for purposes of this analysis because of the variability in the methods used for determining prothrombin time. Of the 3437 patients with complete data, 1040 underwent liver transplantation before 3 months of follow-up, and 126 patients were removed from the OPTN list. Of those removed, 95 patients were judged to be too sick to undergo the liver transplant procedure. Of the remaining 2271 patients, 1859 patients survived, and 412 died during the 3-month follow-up period.

MELD Scores

The MELD score for each patient was computed at time of listing using the method of Malinchoc et al.[8] with 2 exceptions. To avoid negative scores, laboratory values such as serum creatinine levels that were less than 1 mg/dL were rounded off to 1. In addition, the factor for diagnosis of liver disease was not used. Preliminary studies in cohorts of nontransplantation candidates demonstrated that the inclusion of the liver disease diagnosis variable as originally described by Malinchoc et al.[8] does not increase the predictive value of the

Table 1. United Network for Organ Sharing Status Criteria for Patients With Chronic Liver Disease

Status 2a	CTP score ≥10, ICU care, and estimated to have <7 days to live
Status 2b	CTP score ≥10 or ≥7 associated with refractory complications of portal hypertension or hepatocellular cancer meeting the following criteria: 1 lesion <5 cm or ≤3 lesions all <3 cm each and no evidence of metastatic disease
Status 3	CTP ≥7 minimal listing

MELD score.[8,10] Thus, in our final calculation, 6.4 points were added to each patient's score to make the results comparable with that of the original published studies.[8,9] The MELD equation used to calculate the severity score was as follows: MELD score = [9.57 × $\log_e$ creatinine mg/dL + 3.78 × $\log_e$ bilirubin mg/dL + 11.20 × $\log_e$ INR + 6.43 (constant for liver disease etiology)]. Three-month survival possibilities (S_{3mo}) were derived from a Cox proportional hazards model: $S_{3mo} = 0.98465^{\exp(\text{MELD score}-10)*0.1635}$, in which 0.98465 is 3-month baseline survival, 10 is the reference MELD score, and 0.1635 is the estimated MELD score coefficient.

Statistical Methods

To assess the MELD score's ability to correctly rank order patients according to risk of death while on the waiting list, our analysis was performed by measuring the concordance (c-statistic) equivalent to the area under the receiver operating characteristic curve (ROC).[10,11] The outcome we assessed was 3-month mortality on the waiting list. A c-statistic between 0.8 and 0.9 indicates excellent diagnostic accuracy, and a model with a c-statistic over 0.7 should be considered clinically useful. To assess the statistical significance of the difference in concordance obtained using MELD and CTP, we used a bootstrapping procedure.[12]

Results

The mean age of the study cohort was 50.7 years (range, 18–79 years), and two thirds of the patients were men (Table 2). The majority of the patients were white (70.1%), and 14% were Hispanic, 9.1% African-American, 3.4% Asian, and 3.4% other races. The most common primary diagnosis for end-stage liver disease in this group of patients was hepatitis C (34.0%), followed by alcoholic liver disease (27.3%) and cryptogenic cirrhosis (10.4%). In this study cohort, 536 patients were initially listed on the OPTN list as status 2A, and 2901 were listed as status 2B. During the 3-month follow-up period, 412 of 3437 patients (12%) died. Of the patients listed at 2A status, 144 of 536 (26.9%) died, whereas 268 of 2901 patients listed at status 2B (9.2%) died. Another 95 patients were removed from the OPTN list because they became too ill to undergo the transplantation procedure. The other patients were removed from the OPTN list because of clinical improvement or a lack of desire to proceed with the liver transplantation procedure.

Table 2. Epidemiology of Study Cohort

Age (*yr*), mean (range)	50.7 (18–79)
Male, (%)	67.8
Race, (%)	
White	70.1
Hispanic	14.0
African American	9.1
Asian	3.4
Other	3.4
Underlying liver disease (%)	
Hepatitis C	36.4
Alcohol	27.6
Cryptogenic	11.0
Hepatitis B	5.8
Autoimmune hepatitis	4.9
Nonalcoholic steatosis	2.4
α-1 Antitrypsin	2.1
Wilson's	0.2
Sarcoid	0.2
PSC	1.8
PBC	1.1
Drug induced	0.6
Amyloid	0.3
Other	5.6

The mean MELD score of the 2A status patients was 28.0, and the mean MELD score of the status 2B patients was 18.3. As expected, those patients who died had significantly higher serum creatinine levels, INR scores, and serum bilirubin levels (Table 3). Mortality increased in proportion to the increase in the MELD score. Patients

Table 3. Meld Parameters at Time of Listing in Patients Who Survived and Patients Who Died While on the Waiting List

	Survival (n = 1859)	Transplanted (n = 1040)	Died within 3 months (n = 412)
Creatinine	1.2 ± 1.4 (1.0)	1.4 ± 1.2 (1.1)[a]	2.0 ± 1.6 (1.4)[a]
Bilirubin	4.2 ± 3.5 (3.0)	8.0 ± 9.4 (4.0)[a]	12.2 ± 11.2 (7.6)[a]
INR	1.6 ± 0.5 (1.5)	1.9 ± 0.8 (1.7)[a]	2.2 ± 1.0 (1.9)[a]
MELD	16.9 ± 5.4 (16.3)	21.5 ± 8.3 (19.9)[a]	27.0 ± 9.6 (25.5)[a]
CTP	10.5 ± 1.4 (10.0)	11.2 ± 1.9 (11.0)	12.1 ± 1.6 (12.0)

NOTE. Expressed as mean ± standard deviation (median). One hundred eight patients were excluded (CTP < 7) granted 2B status for tumor or metabolic disease. Eighteen patients were removed because they improved.
[a]$P < 0.01$ compared with survival group.

Table 4. Three-Month Mortality Based on Meld and CTP Score

	MELD					CTP		
	<9	10–19	20–29	30–39	>40	<7–9	10–12	13–15
No.	124	1800	1098	295	120	318	2357	588
Mortality	1.9	6.0	19.6	52.6	71.3	4.3	11.2	40.1
Mortality + too sick	2.9	7.7	23.5	60.2	79.3	5.6	13.4	48.5

NOTE. There were 66 patients for whom the CTP score was not available, and 108 patients had a CTP score of <7 and were granted 2B status because of HCC or metabolic liver disease and were not included in this analysis.

with a MELD score <9 experienced a 1.9% mortality at 3 months, whereas patients with a MELD score ≥40 had a mortality rate of 71.3% (Table 4). Similarly, mortality increased as the CTP score increased but to a lesser extent than compared with the MELD score (Table 4). There were 440 patients who had a CTP score of less than 10 at time of listing who were granted UNOS status 2B because of special considerations such as tumor, pruritis, metabolic disease, and others. Of these patients, 110 underwent transplantation and 14 (0.03%) died, of which only 6 deaths were related to the underlying liver disease. There were no significant differences between the study cohorts and those patients excluded because of incomplete data at listing with regard to entry UNOS status, CTP score, and 3-month survival with and without liver transplantation (data not shown).

The relationship between the MELD score and the CTP score is shown in Figure 1. Although a definite relationship does exist, both scores were noted to vary considerably at each severity score. For example, patients who had a CTP score of 11 had MELD scores ranging from 8 to 46. The relationship between the MELD score and estimated 3-month mortality in patients with chronic liver disease is shown in Figure 2.

Using the c-statistic with 3-month mortality as the end point, the area under the ROC curve for the MELD score was 0.83 (95% confidence interval 0.81 to 0.84) compared with 0.76 (95% confidence interval 0.74 to 0.79) for the CTP score (Figure 3). This difference was statistically significant ($P < 0.001$). However, in the old allocation scheme, the c-statistic overestimates the ability of the CTP score to estimate pretransplant mortality. This is because, in this analysis, the CTP score is treated as a continuous variable, whereas, in the past allocation scheme, it was used as a categorical (or ordinal) variable with waiting time being the final determinate of allocation priority.

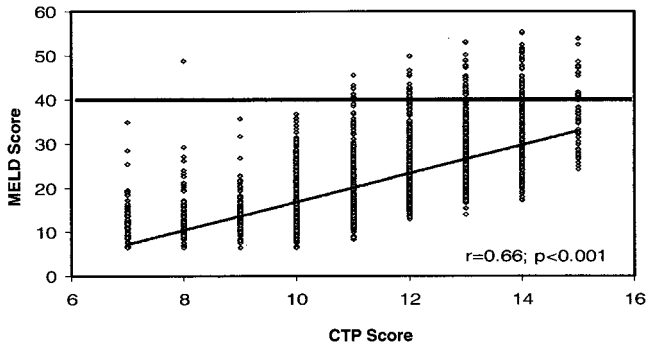

Figure 1. The relationship between the MELD score and CTP at time of listing on the OPTN waiting list. Patients with hepatocellular cancer or metabolic liver disease with a Child-Pugh score of less than 7 were excluded in the analysis.

Discussion

The major findings of this prospective study are that the MELD score, which is based on 3 simple variables (serum bilirubin, serum creatinine, and INR) is able to accurately estimate 3-month mortality in patients with chronic end-stage liver disease. These findings are consistent with a number of retrospective studies, which were used to validate the MELD score as a liver disease severity index.[8,9] Our results demonstrate that the MELD score is superior to the CTP score in ranking patients according to severity of their liver disease and risk of dying, yet is free of subjective parameters such as ascites and portosystemic encephalopathy, which have plagued the use of the CTP score by lack of uniform definitions. This is further illustrated by the fact that only 26.9% of 2A patients died within 3 months of follow-up when the expected survival of the group of patients by definition was to be less than 7 days. Finally, the MELD is free of variables such as age, gender, race,

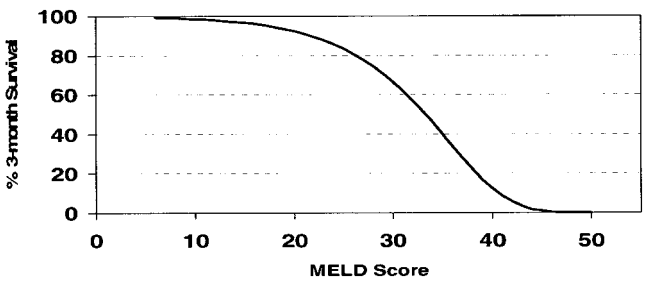

Figure 2. Estimated 3-month survival as a function of the MELD score.

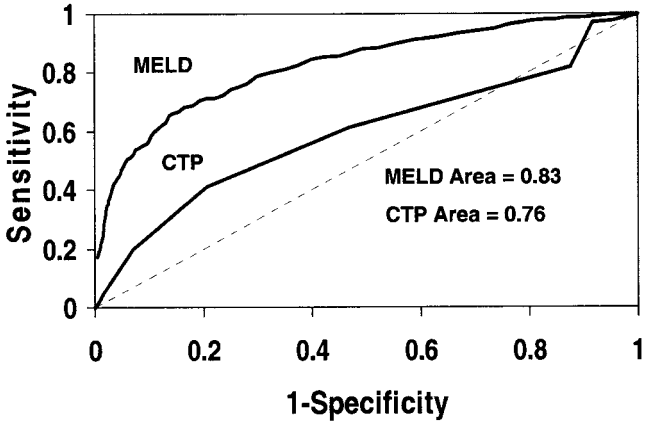

Figure 3. The area under the receiving operating curve for the MELD score and CTP score with 3-month mortality as the end point. The difference was significant ($P < 0.001$). *Dotted line* represents the ROC based on chance alone and has a c-statistic of 0.5.

and transplant center, all of which might potentially have an impact on the outcome of chronic liver disease patients but which would be difficult to use in formulating a national organ allocation policy. The major advantage of MELD is that it gives the liver transplant community a continuous liver disease severity score that can be easily applied to rank patients on the OPTN waiting list according to their risk of dying over a defined period of time. The model clearly fulfills many of the criteria outlined in the OPTN Final Rule that stipulates that organ allocation should be based primarily on medical need. Furthermore, the MELD score, applied as a continuous scale, will rank patients more specifically according to their severity of disease, negating the need to heavily rely on waiting time to further segregate patients. Finally, using the MELD for liver allocation could level the playing field for many underprivileged patients who do not have ready access to health care. These patients previously were often listed late for liver transplantation, and are thus less likely, compared with patients with more regular access to health care, to receive a donor organ using the old, waiting time-based allocation scheme. Based on these considerations, the OPTN Board of Directors approved a policy using the MELD for adult liver allocation that was implemented on February 27, 2002.

Although the MELD model appears to be a distinct improvement over the past allocation policy, a number of concerns have been raised regarding its applicability for all liver transplantation candidates. One concern is whether the MELD model accounts for complications of portal hypertension such as esophageal variceal bleeding, spontaneous bacterial peritonitis, ascites, and portosystemic encephalopathy. Previous studies have addressed this concern in a retrospective fashion and have shown convincingly that adding the complication of portal hypertension to the MELD does little to improve the ability of the model to predict survival.[9,10] It appears that a patient's risk of death is determined by his or her overall severity of liver disease and is less influenced by development of a complication related to portal hypertension.

A second concern relates to how patients with hepatocellular cancer who often have less severe intrinsic liver disease will be incorporated into the new allocation scheme. Under the prior policy, patients with cirrhosis and hepatocellular cancer were given 2B status if their cancers meet the following criteria: (1) 1 lesion less than 5 cm or (2) 2 to 3 lesions less than 3 cm without evidence of metastatic disease. Because the outcome of liver transplantation in these patients with hepatocellular cancer is similar to that of patients undergoing liver transplantation for other chronic liver diseases, discrimination against these patients regarding organ allocation does not appear to be justified.[12] At the initial implementation of the MELD system, chronic liver disease patients with qualifying hepatocellular cancers may be assigned a MELD score reflecting a 30% probability of dying in 3 months if there are 2 or 3 lesions or if a single lesion is greater than 2 cm and a 15% probability of dying in 3 months if the lesion is less than 2 cm. This policy will be closely monitored to determine its overall impact on outcomes in liver transplant recipients.

A third concern is that using MELD would provide too much advantage to sicker patients, which could potentially lead to an increase in early posttransplant deaths resulting in a fear that donor livers might be wasted. Indeed, under the past allocation system, survival following liver transplantation has been excellent. However, the impact of the MELD system on liver transplantation outcome cannot be adequately assessed until the new organ allocation policy has been implemented. Preliminary data from an OPTN Region 1 study in which a continuous liver disease severity model has been applied suggest there may be a significant reduction in the number of deaths of patients on the waiting list and that the number of patients undergoing transplantation in the previous 2A category will be significantly reduced.[13] The result was that patients undergoing transplantation were in a less sick state. Thus, in a liver allocation system using a continuous disease severity scale that significantly de-emphasizes waiting time, patients are more likely to receive organ offers earlier in the course of their disease because they are never superseded by less ill patients with more waiting time. This leads to improved overall resource utilization

and should not significantly impact survival after transplantation. Results from the pilot study in OPTN Region 1 demonstrated that the incidence of early death following liver transplantation was not altered when the continuous severity score was used to allocate organs.[13]

In summary, our analysis supports the use of MELD to define the most seriously ill patients on the waiting list for liver transplantation. Use of MELD is also supported by the current emphasis to allocate donor livers to the most seriously ill. The impetus for such a change was driven by accumulating experience using the past system and dramatic changes in waiting list volume and dynamics. However, the organ allocation policy has always evolved over time to better meet changing conditions. Therefore, application of the MELD-based allocation system will and must also evolve. Basing organ allocation on a system that has been derived from a much more evidence-based approach, however, will make it possible to scrutinize more rigorously the results of the system and more precisely apply appropriate changes. Further prospective studies will be required to determine whether use of MELD for organ allocation results in reduction in mortality for patients on the transplantation waiting list.

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