Transplant International ISSN 0934-0874

ORIGINAL ARTICLE

Is MELD score sufficient to predict not only death on waiting list, but also post-transplant survival?

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Keywords
liver transplantation, MELD score, risk factors, waiting list.

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Received: 28 June 2005
Revision requested: 22 July 2005
Accepted: 24 October 2005

doi:10.1111/j.1432-2277.2006.00250.x

Summary

Model for end-stage liver disease (MELD) score has emerged as a useful tool in predicting mortality in patients awaiting liver transplantation. There is still, however, discussion as to whether further parameters could improve the sensitivity and specificity of the MELD score. From 1997 to 2003, 621 adult patients with end-stage liver disease were listed for orthotopic liver transplantation (OLT). Patients suffering from hepatoma were excluded from analysis (113 patients). The MELD score was investigated at the time of listing (MELD ON) and of coming off the list (MELD OFF). Patients who died while on the waiting list showed a significant increase in their MELD score during the waiting time (MELD ON: 21 ± 7 vs. MELD OFF: 28 ± 9) as well as a significantly higher MELD ON compared with patients who were transplanted (MELD ON: 16 ± 5 vs. MELD OFF: 17 ± 7) or removed from the waiting list (MELD ON: 16 ± 6 vs. MELD OFF: 12 ± 3). Multivariate analysis identified MELD ON, ascites and recurrent infection as independent risk factors for death on the waiting list ($P < 0.01$). MELD score was not identified as a predictor for the post-transplant survival rate. MELD score is a strong predictor for death on the waiting list, but refractory ascites and recurrent infection are independent risk factors, too.

Introduction

In times of organ shortage and increasing numbers of patients on the waiting lists for orthotopic liver transplantation (OLT), different strategies have been developed to make organ allocation more effective [1]. In the past, the available grafts were allocated based on the ABO blood type compatibility and waiting time. At present, the allocation policy tends to de-emphasize waiting time and favour disease severity [2].

Originally, the MELD score was designed to assess short-term prognosis in patients undergoing transjugular intrahepatic portosystemic shunt (TIPS) [3]. The MELD score is based on three biochemical parameters: total serum bilirubin, international normalized ratio (INR) of prothrombin time and creatinine:

$$\begin{aligned}\text{MELD} = {} & 9.57 \times \ln(\text{creatinine mg/dl}) \\ & + 3.78 \times \ln(\text{bilirubin mg/dl}) \\ & + 11.2 \times \ln(\text{INR}) + 6.43 \text{ range } 6\text{–}40\end{aligned}$$

This risk model was validated to predict the mortality rate of different groups of patients with various types and stages of chronic liver disease and especially in candidates on the waiting list for OLT [4–7]. Finally, it was identified as a scale for determining the medical urgency for transplantation, as recent studies have shown that prolonged waiting time is not associated with an

increased risk of mortality [8,9]. In February 2002, the United Network for Organ Sharing (UNOS) established the Model for end-stage liver disease (MELD) as an evidence-based scale for organ allocation [10].

Early reports indicated that this new allocation system would reduce the number of deaths on the waiting list [5]. Unfortunately, the MELD score is not adequate for all indications for transplantation as, for example, hepatocellular carcinoma (HCC) [11,12].

Although its value for predicting pretransplant survival has been established, the impact on post-transplant outcome is still a matter of controversy. The relative risk of mortality within 30 days of liver transplantation is increased for patients with MELD scores higher than 25 [12,13]. The capacity of the MELD score to predict patient and graft survival appears to be relatively poor. Only creatinine was found to be an independent predictor for survival. It is also important to mention that patients in the highest MELD quintile were hospitalized for prolonged periods post-transplantation [14].

The aim of the study was to find other risk factors not directly reflected by the MELD score. Therefore, we analysed the effect of therapy refractory ascites, recurrent infection, encephalopathy, or other comorbidities on the death rate of patients on the waiting list. The impact of the MELD score on long-term post-transplant survival was also analysed.

Methods and patients

Between 1997 and 2003, we listed 621 adult patients suffering end-stage liver disease for OLT. Patients suffering from hepatocellular or cholangiocellular carcinoma (hepatoma) were excluded from analysis (113 patients), because of the discrepancy of awarding extrapoints. Three patients did not undergo transplantation because of technical reasons. Therefore, the study population consisted of 505 patients (mean age: 52.3 ± 9.2 years; median: 53.6 years, range 19–69; 158 female and 347 male patients). The indications for transplantation were mainly alcoholic and virus-induced cirrhosis, details being listed in Table 1.

All patients were evaluated for transplantation at departments of hepatology or special internal medicine wards. In addition, all patients were evaluated for patient-related risk factors including cardiac, pulmonary and metabolic diseases, renal dysfunction, gastrointestinal bleeding, encephalopathy, refractory ascites and spontaneous bacterial infection. Ascites was defined as therapy refractory when it recurred after large volume paracentesis (with adequate albumin substitution) despite sufficient antidiuretic therapy (maximum 400 mg spironolactone and 160 mg furosemide per day) and dietary sodium restriction [15]. Spontaneous bacterial infection was defined as the need for hospitalization because of increased infection parameters combined with leucocyte positive ascites. Renal dysfunction was defined as serum creatinine > 2.0 mg/dl (only set for the evaluation of patient-related risk factors, without influence on the MELD score calculation). Complete laboratory investigations were performed in all patients at the time of listing in order to evaluate the MELD score as well as the CHILD PUGH score [16,17]. MELD ON is defined as the MELD score at time of listing. MELD OFF is the last available MELD score before transplantation, removal or death on the waiting list.

Table 1. Indications for liver transplantation.

Disease	Patients
Alcoholic cirrhosis	256
Virus-induced cirrhosis	135
Cholangiocellular CA	5
Hepatocellular CA	108
Unknown cirrhosis	37
Primary biliary cirrhosis	18
Sclerosing cholangitis	18
Autoimmune cirrhosis	14
Hemochromatosis	9
Others	21
Total	621

After a careful evaluation and psychological examination, these patients were discussed in detail and listed, based on the consensus of a multidisciplinary conference held every week by hepatologists, transplant surgeons, anaesthesiologists and psychologists. During waiting time, all patients had to attend our outpatient clinic once a month and undergo laboratory testing for the MELD score calculation. On this basis, a re-evaluation for transplantation was performed monthly. Patients who where considered too sick or too healthy for transplantation were removed from the waiting list, but remained in contact with our outpatient clinic.

Austria is part of Eurotransplant, Leiden, the Netherlands, and the available organs are allocated depending on local regulations. Patients suffering from end-stage liver disease were ranked on the waiting list according to blood group, weight classification (organ/patient-size compatibility) and waiting time.

All patients underwent transplantation using the same technique by the same team of surgeons and anaesthesiologists. Following the transplantation, the patients were transferred to a specific intensive care unit run by the department of transplantation and thereafter to a special ward for transplanted patients. Follow-up investigations were also performed in the outpatient clinic of the department of transplantation.

Statistical methods

Overall survival was defined as time between the date of listing until death or end of follow-up. Transplanted patients were censored at the time of transplantation. Post-transplant survival was assessed as time from grafting to death for all transplanted patients.

Differences between MELD scores at the time of listing (MELD ON) regarding the overall survival were examined with univariate and multiple Cox proportional hazards models, implying constant hazard ratios between consecutive variable values [18]. MELD ON was modelled as linear factor in the model, all other scrutinized factors having been taken into account as categorical variables. Differences between MELD ON scores were also analyzed in terms of the patient-related risk factors. Patients were divided into two groups, '< 2 risk factors' and '2 or more risk factors', with the former serving as the reference group.

All analyses regarding post-transplant survival were conducted for the MELD scores at the time of listing (MELD ON) and for the MELD scores at the time of removal from the waiting list because of transplantation (MELD OFF). Post-transplant survival was estimated and graphically presented according to the method of Kaplan and Meier [19]. Differences between curves were assessed by the Mantel log-rank test for censored survival data [20]. Differences between MELD scores regarding the post-transplant survival were also analyzed by univariate Cox proportional hazards models, in which case the scores were divided into four groups: '< 11', '11–18', '19–24' and '> 24'. The first served as the reference category [18].

All analyses were carried out using the statistical software package SAS (Version 8.02, SAS Institute, Cary, NC, USA), *P*-values are two-sided and $P < 0.05$ was considered statistically significant.

Results

Out of the 505 analysed patients, 300 (59.4%) have already undergone transplantation surgery. One hundred and twenty-three patients (24.4%) died while on the waiting list. A total of 49 patients were removed from the waiting list because of recovery (43 patients, 8.5%) and poor physical condition for transplantation (six patients, 1.2%) (aetiology of endstage liver disease are listed in Table 2a and b). Thirty-three patients (6.5%) are still waiting for transplantation.

The mean waiting time for transplantation was 3.5 ± 2.9 months (median: 2.7 months, range: 0.1–81). The mean time to death while awaiting a graft was 2.8 ± 2.5 months (median 2.1 months, range: 0–26). Patients removed from the waiting list were listed for 7.0 ± 3.9 months (median 6.0 months, range: 1–68).

Table 2. Aetiology of endstage liver disease in patients who were removed because of being considered too healthy (a) and too sick (b) healthy for transplantation.

Disease	Patients
(a)	
Alcoholic cirrhosis	24
Virus-induced cirrhosis	6
Unknown cirrhosis	4
Primary biliary cirrhosis	1
Sclerosing cholangitis	4
Autoimmune cirrhosis	3
Hemochromatosis	1
Total	43
(b)	
Alcoholic cirrhosis	3
Virus-induced cirrhosis	2
Sclerosing cholangitis	1
Total	6

In the analyses, the patients were allotted to 4 MELD score categories at the time of listing (Table 3a) and at the time they were removed from the waiting list (Table 3b). None of the patients with a MELD score below 11 died. The 43 patients who were removed because of being considered too healthy for transplantation had a mean MELD OFF of 12 ± 3. Five out of 63 patients had a MELD ON higher than 24 and were removed because of recovery. All these patients were listed at the times of decompensation.

Transplanted patients had a significantly lower MELD ON ($P < 0.01$) than the patients who died while on the waiting list, but were comparable with patients who were removed because of recovery ($P =$ NS). Patients who died while on the waiting list had a significantly higher MELD ON than the patients who did not need a graft ($P < 0.01$), and showed a significant increase in the MELD score during waiting time ($P < 0.01$). Patients who underwent transplantation showed a stable MELD score during their waiting time, patients who were removed because of being considered too healthy for transplantation showed a significant decrease ($P < 0.01$) (Table 4).

The mean follow-up time was 35.2 ± 24.1 months (median 33.6 months, range: 0–86). The overall survival rates depending on MELD classification are shown in Figs 1 and 2. Patients with a MELD OFF higher than 24 at the time of transplantation showed a trend towards a worse post-transplant survival than patients in the other groups ($P = 0.06$). MELD ON had no impact on the post-transplant survival rate ($P = 0.07$), either.

Table 3. Classification of patients according to the MELD score at time of listing.

	Patients (%)	DOL (%)	TX (%)	REM good (%)	REM poor (%)
(a) MELD ON					
MELD < 11	27 (5.7)	0	20 (74.1)	7 (25.9)	0
MELD 11–18	259 (54.9)	45 (17.4)	181 (69.9)	29 (11.2)	4 (1.5)
MELD 19–24	123 (26.1)	39 (31.7)	81 (65.9)	2 (1.6)	1 (0.8)
MELD > 24	63 (13.3)	39 (61.9)	18 (28.6)	5 (7.9)	1 (1.6)
Total	472 (100%)	123 (26.1)	300 (63.6)	43 (9.1)	6 (1.2)
(b) MELD OFF					
Meld < 11	34 (7.2)	0	20 (58.8)	14 (41.2)	0
Meld 11 – 18	230 (48.7)	20 (8.7)	176 (76.5)	29 (12.6)	5 (2.2)
Meld 19 – 24	93 (19.7)	22 (23.7)	71 (76.3)	0	0
Meld > 24	115 (24.4)	81 (70.4)	33 (28.7)	0	1 (0.9)
Total	472 (100%)	123 (26.1)	300 (63.6)	43 (9.1)	6 (1.2)

MELD ON = MELD score at time of listing; DOL = Died on list; TX = transplanted; REM good = patients removed because of recovery; REM poor = patients removed because of poor conditions; MELD OFF = MELD score at death, transplantation or removal.

Table 4. Mean MELD scores (median; range) depending on final outcome at time of listing and at off list date.

MELD	DOL	TX	REM good
ON LIST	21 ± 7 (20.0;10–53)	16 ± 5 (15.0; 6–57)	16 ± 6 (16; 6–30)
OFF LIST	28 ± 9 (27.5; 11–54)	17 ± 6 (15.6; 6–53)	12 ± 3 (11.8; 6–24)

ON LIST = time of listing; OFF LIST = time of death (DOL); transplantation (TX) or removal because of recovery (REM good).

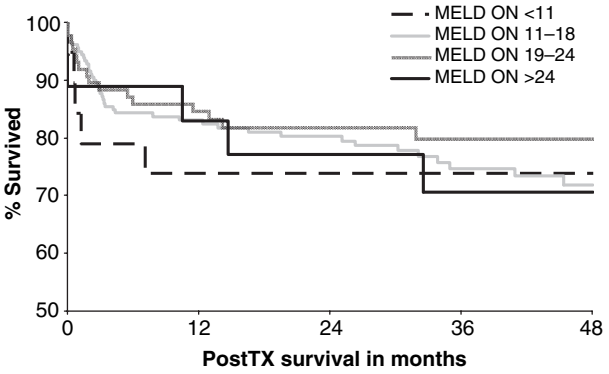

Figure 1 Post-transplantation survival depending on the MELD score at time of listing.

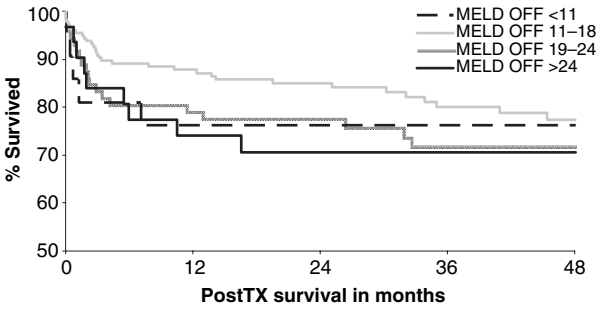

Figure 2 Post-transplant survival depending on the MELD score at time of transplantation.

Table 5. Multivariate risk factor analysis for death on waiting list.

	Probability > chi-square	Hazard	95%
MELD ON	0.001	2.548	2.053/3.161
Infection	0.021	1.594	1.074/2.366
Ascites	0.025	1.581	1.058/2.363
Comorbidity	0.031	1.799	1.055/3.069
Bleeding	0.251	0.787	0.522/1.185
Encephalopathy	0.589	1.077	0.822/1.412

In the univariate analysis MELD ON ($P < 0.01$), refractory ascites ($P < 0.01$), spontaneous bacterial infection ($P < 0.01$) and the comorbidity score ($P < 0.01$) were highly significant for death on the waiting list. Gastrointestinal bleeding ($P = 0.03$) and encephalopathy ($P = 0.04$) were also identified as significant factors.

The multivariate analysis of risk factors for death on the waiting list is shown in Table 5. Refractory ascites and spontaneous bacterial infection remained independent risk factors for death on the waiting list as well as the MELD ON. Additionally, patients with two or more patient-related risk factors had also a significantly higher risk of dying while on the waiting list.

In contrast, gastrointestinal bleeding ($P = 0.25$) and encephalopathy ($P = 0.60$) were not identified as independent risk factors. A total of 47.2% of the patients (58 of 123 patients) who died on the waiting list were suffering from ascites, in contrast to only 28.7% of the

transplanted patients (86 of 300 patients). There was no significant difference in the mean MELD ON between the patients who were suffering from ascites and those who were not ($P = 0.72$). Nor was any significant difference found in the MELD OFF ($P = 0.77$).

Discussion

In times of organ shortage, transplant units should aim at optimal organ allocation to lower the death rate on the waiting list and increase the post-transplant survival rate. Objective evaluation of the disease severity of patients awaiting a graft is the main argument for allocating livers based on the MELD score. It is based on a few objective parameters using the standardized tests that are readily available and reproducible. The model does not refer to subjective parameters and has proved to be predictive for death on the waiting list. This model de-emphasizes waiting time and ranks patients depending on disease severity. It was demonstrated that longer waiting time was not associated with an increased risk of death while on the waiting list [8,9]. Further investigations have to show that longer waiting time has no impact on long-term survival after transplantation. The CHILD PUGH score is also predictive for death on the waiting list [21], but does not offer such a precise disease severity differentiation as the MELD score.

In the USA, notable changes were observed with the implementation of the MELD score system. The number of patients listed with a MELD score of <10 dropped significantly in contrast to patients, with a MELD score of over 20, who increased. Overall, significantly fewer patients were listed for liver transplantation. The trend to fewer removals and deaths on the waiting list was also remarkable [22]. This led to the conclusion that patients are registered later in the progression of their liver disease when the mortality risk exceeds the mortality risk of transplantation. In this system, it is not necessary to list patients early to gain waiting time in anticipation of decompensation. Despite a change in the waiting list population, patient and graft survival rates were comparable in short-term follow-up [12]. Additionally, no apparent increase in transplantation costs was reported [22].

Our data prove that the MELD ON is predictive for the death rate of patients on the waiting list, but the risk factors 'spontaneous bacterial infection' and 'therapy refractory ascites' are independent risk factors, too. These findings are supported by the fact that the death rate on the waiting list was high despite an average MELD score on the waiting list that is comparable with that of other transplant units. The impact of these additional risk factors is supported by the high death rate in correlation to the relatively short-waiting time [23].

It has been suggested that the complications of portal hypertension are predictors of mortality for patients suffering end-stage liver disease [24–28]. Nevertheless, these factors were not reflected by the MELD score formula, as only a minimal change was noted in the MELD score's ability to predict 3-month mortality by adding individual complications of portal hypertension [29].

In our experience, refractory ascites and spontaneous bacterial infection should be considered beyond the MELD score. Especially, patients suffering ascites showed no significant difference in their MELD scores compared with patients without ascites, as the MELD scores did not increase until decompensation. The correlation between ascites and hyponatremia is already documented by several reports [25,29–31]. In our opinion, therapy of the refractory ascites with TIPS might be more effective than including hyponatremia in an expended MELD formula. TIPS will permit the reduction of diuretic doses, leading to much less hyponatremia in this fragile patient population.

Patients suffering from two or more patient-related risk factors in addition to their end-stage liver disease have a significant higher risk of dying during waiting time. Therefore, these patients have to be evaluated carefully before they are listed for OLT and adequate treatment of the additional risk factor is necessary. Listed patients should have a realistic chance of surviving the estimated waiting time and of having improved quality of life after transplantation.

The ability of the MELD score to predict post-transplant outcome is still under discussion [22,32]. There have been concerns raised that the trend towards transplantation of the sickest will result in a decrease in overall survival rates and cause prolonged hospitalization and increasing costs [33]. This could result in a cost inefficient use of cadaveric livers. Desai *et al.* found that the MELD score is a poor predictor for post-transplant survival and that only creatinine was an independent predictor. Nevertheless, the longer hospitalization and poorer survival was found in patients with a MELD score higher than 24 [14]. Although the MELD score was not created to predict post-transplant survival, other transplant units could show correlation with post-transplant survival, although long-term outcome is not yet available [13,32,34].

In the analysis presented here, a trend towards poorer survival rates was found for patients with a MELD score higher than 24, although the difference showed no statistical significance.

In conclusion, MELD score is a very good predictor for death on the waiting list. It permits the listing of patients depending on the severity of disease and uses

only routine blood tests without any subjective parameters. Nevertheless, refractory ascites and recurrent infection, two subjective parameters, were evaluated as independent risk factors, as well. These complications of portal hypertension should be treated adequately and rigorously, especially in patients with lower MELD scores.

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