MELD 3.0 Score for Predicting Survival in Patients with Cirrhosis After Transjugular Intrahepatic Portosystemic Shunt Creation

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Abstract

Background and aims The selection of appropriate candidates for transjugular intrahepatic portosystemic shunt (TIPS) is important and challenging. To validate the Model for End-Stage Liver Disease (MELD) 3.0 in predicting mortality in patients with cirrhosis after TIPS creation.

Methods A total of 855 consecutive patients with cirrhosis from December 2011 to October 2019 who underwent TIPS placement were retrospectively reviewed. The prognostic value of the MELD 3.0, MELD, MELD-Na, Child–Pugh and FIPS score was assessed using Harrell’s C concordance index (c-index). The Hosmer–Lemeshow test was used to test the goodness of fit of all models and the calibration plot was drawn.

Results The c-index of the MELD 3.0 in predicting 3-month mortality was 0.727 (0.645–0.808), which were significantly superior to the MELD (0.663 [0.565–0.761]; P = 0.015), MELD-Na (0.672 [0.577–0.768]; P = 0.008) and FIPS (0.582 [0.477–0.687]; P = 0.015). The Child–Pugh score reached c-indices of 0.754 (0.673–0.835), 0.720 (0.649–0.792), 0.705 (0.643–0.766) and 0.665 (0.614–0.716) for 3-month, 6-month, 1-year, and 2-year mortality, respectively, which seems comparable to MELD 3.0. A MELD 3.0 of 14 could be used as a cut-off point for discriminating between high- and low-risk patients. The MELD 3.0 could stratify patients with Child–Pugh grade B (log-rank P < 0.001). The Child–Pugh score could stratify patients defined as low risk by MELD 3.0 (log-rank P < 0.001).

Conclusions The MELD 3.0 was significantly superior to the MELD, MELD-Na and FIPS scores in predicting mortality in patients with cirrhosis after TIPS creation.

Keywords Transjugular intrahepatic portosystemic shunt (TIPS) · Liver cirrhosis · Portal hypertension · MELD 3.0 · Survival
is objective, verifiable, and auditable for policy implementation [9]. The new score is more predictive, reclassifying approximately 9% of patients on the liver transplant waiting list to have a greater chance of receiving a liver transplant and reducing waiting list deaths by at least 20 per year. At the same time, Bettinger et al. proposed the Freiburg index of post-TIPS survival (FIPS) score to evaluate 6-month post-TIPS survival and it showed good results [10]. Given that MELD 3.0 is such an excellent prognostic tool, the purpose of this study is to explore MELD 3.0 for predicting survival in patients with cirrhosis after TIPS creation and to compare it with FIPS and conventional prognostic models.

**Patients and Methods**

**Patients**

An electronic inpatient case database was searched and a total of 935 patients who received de novo TIPS implantation between December 2011 and October 2019 were reviewed. Patient data from December 2011 to July 2018 have previously been used to compare FIPS score, MELD score, Child–Pugh score, and Chronic Liver Failure Consortium Acute Decompensation (CLIF-C AD) score [11]. Patients with technical failure (n = 25) and complete lack of laboratory or non-existent follow-up data (n = 55) were excluded. Eventually, 855 patients were enrolled in the study. A flow chart of case selection is shown in Fig. 1. Pre-procedure laboratory parameters, image information, and operation notes were systematically sorted through the medical record system, while the date of death, liver transplantation, or the last follow-up was determined. The primary outcome was 3-month mortality after TIPS creation. The second outcomes were 6-month, 1-year and 2-year mortality after TIPS implantation.

**TIPS Procedures**

TIPS procedures were performed by two experienced interventional radiologists using the conventional techniques of general anesthesia. From the right jugular vein approach, the liver set (RUPS-100, Cook, Bloomington, USA) was introduced into the right hepatic vein. Once the portal vein access was established, portography was performed to show the entire portal system. An 8 × 60 mm balloon catheter (Cordis, Roden, the Netherlands) was used to dilate the intrahepatic tract. Eight-millimeter polytetrafluoroethylene (PTFE) coated stents (Fluency Plus, Bard & BD, Murray Hill, USA) were placed with or without the use of an 8-mm bare stent (Cordis, Roden, the Netherlands). The portosystemic pressure gradient (PSG) pre-and post-procedure was measured.

**Scores and Statistical Analyses**

The MELD score was calculated as 6.43 + 9.57* log e creatinine (mg/dL) + 3.78 * log e bilirubin (mg/dL) + 11.2 × log e INR. Values of creatinine, bilirubin, or International normalized ratio (INR) less than 1 were set to 1 [12]. The MELD-Na score was given by MELD + 1.32 × (137-Na)−[0.033 × MELD × (137-Na)]. The upper and lower limits of Na are 137 and 125 mmol/L, respectively [13]. The MELD 3.0 was defined as 1.33 (if female) + 4.56 × log e bilirubin + 0.82 × (137-Na)−0.24 × (137-Na) × log e bilirubin + 9.09 × log e INR + 11.14 × log e creatinine + 1.85 × (3.5-albumin)−1.83 × (3.5-albumin) × log e creatinine + 6, which is rounded to the nearest integer. Consistent with prior versions of MELD, bilirubin, INR, and creatinine values below 1.0 were set to 1.0. The lower and upper bounds of Na values were the same as MELD-Na. For serum albumin, lower and upper bounds of 1.5 g/dL and 3.5 g/dL, respectively, were selected [8]. The FIPS score was defined as 1.43 × log 10 (bilirubin)−1.71 × 1/creatinine + 0.02 × age −0.02 × albumin + 0.81 [bilirubin in mg/dl; creatinine in mg/dl; albumin in g/L and age in years]. Patients with FIPS scores ≥ 0.92 were defined as the high-risk group [10]. Continuous variables are expressed as mean with SD. Categorical variables were expressed as frequencies and percentages. The discriminatory performance of the MELD 3.0 in comparison to the MELD, MELD-Na, Child–Pugh and FIPS scores was assessed using Harrell’s C concordance index (c-index). Statistical comparison of the c-indices was performed using STATA’s Somers’ D package. The Hosmer–Lemeshow test was used to test the goodness of

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**Fig. 1** Flow chart of case selection
fit of all models and the calibration plot was drawn. The Kaplan–Meier method was used to assess the ability of risk stratification for each score. Differences in survival were assessed using log-rank tests. In the subgroup analysis, the c-index of each prognostic score was compared in females, patients with viral, non-viral cirrhosis, and patients without hepatocellular carcinoma, and in patients whose TIPS were created for variceal bleeding. Statistical calculations were performed using SPSS (Version 25.0; IBM, New York, NY), STATA (Version 15.0; StataCorp, College Station, TX), and GraphPad Prism (Version 8; GraphPad Software, San Diego, CA). *P* values less than 0.05 were considered statistically significant.

**Results**

**Baseline Characteristics**

A total of 855 patients with cirrhosis who received TIPS in our hospital from December 2011 to October 2019 were included. The main causes of chronic liver disease were hepatitis B virus (HBV) infection (535 cases, 62.6%), alcoholic liver disease (108 cases, 12.6%), autoimmune liver disease (89 cases, 10.4%), and hepatitis C virus (HCV) infection (36 cases, 4.2%). In addition to TIPS, all patients were also treated for underlying etiologies, such as antiviral or alcohol withdrawal. The indications for TIPS treatment were secondary prevention of variceal hemorrhage (bleeding episode > 72 h before TIPS implantation) in 791 cases (92.5%) and refractory ascites in 49 cases (5.7%), and others such as hepatic pleural effusion, portal venous thrombosis and hepatorenal syndrome in 15 cases (1.8%). Hepatocellular carcinoma was found in 36 of 855 patients (4.2%). All patients were diagnosed and treated according to the guidelines for the management of primary hepatocellular carcinoma [14]. The mean follow-up time was 49.5 ± 29.1 months, during which 235 patients died. The main causes of death were massive gastrointestinal hemorrhage (*n* = 70), liver failure (*n* = 75), hepatocellular carcinoma (*n* = 32), hepatic encephalopathy (*n* = 9), hepatorenal syndrome (*n* = 2), multiple organ failure (*n* = 19), severe pneumonia (*n* = 8), sepsis (*n* = 7), cerebral hemorrhage (*n* = 6), heart failure, and unknown cause of death (*n* = 7).

The mean MELD score was 10.6 ± 2.9, and 652 patients (76.3%) had MELD scores ≤ 12. The mean MELD-Na and MELD 3.0 scores were 11.0 ± 3.5 and 10.9 ± 3.8, respectively. The mean Child–Pugh score was 7.3 ± 1.6, 298 (34.9%), 493 (57.7%), and 64 (7.5%) patients were graded as Child–Pugh A, B, and C, respectively. The mean FIPS score was -1.1 ± 1.1, and only 8 patients (0.9%) had FIPS score > 0.92. The pre-TIPS PSG decreased from 17.9 ± 9.8 mm Hg to 7.4 ± 5.1 mm Hg after TIPS placement (*P* < 0.001). The overall mortality at 3-month, 6-month, 1-year, and 2-year was 3.8%, 5.4%, 8.0%, and 14.6%, respectively. The baseline features of the study cohort are summarized in Table 1.

**Table 1 Patient demographics and transjugular intrahepatic portosystemic shunt (TIPS) procedure details**

| Characteristic                      | Value               |
|------------------------------------|---------------------|
| Age, years, mean ± SD              | 51.5 ± 11.4         |
| Gender (%)                         | Male 582 (68.1%)    |
|                                    | Female 273 (31.9%)  |
| Cause of liver disease (%)         | HBV 535 (62.6%)     |
|                                    | HCV 36 (4.2%)       |
|                                    | Alcoholic 108 (12.6%) |
|                                    | PBC/AIH 89 (10.4%)  |
|                                    | Other 87 (10.2%)    |
| Ascites                            | 583 (68.2%)         |
| Hepatic encephalopathy before TIPS| 12 (1.4%)           |
| Hepatocellular carcinoma           | 36 (4.2%)           |
| Laboratory                         |                     |
| Bilirubin (mg/dL)                  | 1.3 ± 0.8           |
| Albumin (g/L)                      | 33.3 ± 5.7          |
| Creatinine (mg/dL)                 | 0.8 ± 0.5           |
| International normalized ratio (INR)| 1.3 ± 0.2          |
| Sodium (mmol/L)                    | 139.7 ± 5.7         |
| Indication for TIPS (%)            | Varices 791 (92.5%) |
|                                    | Ascites 49 (5.7%)    |
|                                    | Others 15 (1.8%)    |
| PSG before TIPS (mmHg)             | 17.9 ± 9.8          |
| PSG after TIPS (mmHg)              | 7.4 ± 5.1           |
| Child–Pugh score                   | 7.3 ± 1.6           |
|                                    | A 298 (34.9%)       |
|                                    | B 493 (57.7%)       |
|                                    | C 64 (7.5%)         |
| FIPS score                         | < 0.92 847 (99.1%)  |
|                                    | ≥ 0.92 8 (0.9%)     |
| MELD                               | 10.6 ± 2.9          |
| ≤ 12                               | 652 (76.3%)         |
| > 12                               | 203 (23.7)          |
| MELD-Na                            | 11.0 ± 3.5          |
| MELD 3.0                           | 10.9 ± 3.8          |
| Follow-up period, months, mean ± SD| 49.5 ± 29.1         |

*HBV* hepatitis B virus, *HCV* hepatitis C virus, *PBC* primary biliary cholangitis, *AIH* autoimmune hepatitis, *PSG* portosystemic gradient
Prognostic Discrimination

To assess the prognostic discrimination of the different scores, the patients’ Harrell c-indices were calculated. MELD 3.0 reached c-indices of 0.727 (0.645–0.808), 0.715 (0.646–0.783), 0.713 (0.681–0.743) and 0.663 (0.631–0.695) for 3-month, 6-month, 1-year and 2-year mortality, respectively, which were significantly superior to the MELD (0.663 [0.565–0.761]; P = 0.015), (0.657 [0.575–0.738]; P = 0.011), (0.669 [0.601–0.737]; P = 0.011) and (0.618 [0.564–0.673]; P = 0.004) and MELD-Na (0.672 [0.577–0.768]; P = 0.008), (0.665 [0.584–0.745]; P = 0.007), (0.670 [0.602–0.738]; P = 0.003) and (0.616 [0.563–0.670]; P < 0.001). The c-indices of the Child–Pugh score in predicting 3-month, 6-month, 1-year, and 2-year mortality were 0.754 (0.673–0.835), 0.720 (0.649–0.792), 0.705 (0.643–0.766) and 0.665 (0.614–0.716), respectively, which seems comparable to MELD 3.0. However, there was no statistical difference compared with MELD 3.0, MELD and MELD-Na. The FIPS score had the poorest discrimination with c indices of (0.582 [0.477–0.687]; P = 0.015) for 3-month mortality and (0.585 [0.527–0.643]; P = 0.015) for 2-year mortality compared with MELD 3.0. (Table 2).

Sub-analyses revealed that MELD 3.0 yielded higher c-indices in predicting 3-month, 6-month, 1-year, and 2-year mortality (0.774, 0.729, 0.690 and 0.651) in female than either MELD (0.710, 0.657, 0.657 and 0.595) or MELD-Na (0.735, 0.681, 0.667 and 0.600) (Table S1). The same trend was observed in patients with viral or nonviral cirrhosis (Tables S2, S3). MELD 3.0 also yielded higher c-indices in patients without hepatocellular carcinoma (0.755, 0.712, 0.722 and 0.663) than either MELD (0.695, 0.675, 0.682 and 0.619) or MELD-Na (0.708, 0.682, 0.685 and 0.619) (Table S4). MELD 3.0 had better c-indices in patients whose TIPS were created for variceal hemorrhage (0.715, 0.716, 0.699 and 0.656) than either MELD (0.666, 0.673, 0.669 and 0.622) or MELD-Na (0.657, 0.659, 0.654 and 0.614) (Table S5). However, the Child–Pugh score showed similar efficacy to MELD 3.0 in all subgroups, and the FIPS score had the poorest discrimination.

Calibration of Scores for Different Survival Endpoints

Figure 2 demonstrates the scores in terms of calibration, showing the observed and predicted mortality at each survival node. The Hosmer–Lemeshow test confirmed similar observed and predicted 3-month mortality (MELD 3.0 [χ² = 7.276, P = 0.507], MELD [χ² = 8.295, P = 0.405], MELD-Na [χ² = 6.452, P = 0.597], Child–Pugh [χ² = 3.063, P = 0.547], FIPS [χ² = 9.476, P = 0.304]), as well as 6-month and 1-year mortality (Table S6).

Optimal Cut-off Value for Risk Stratification

We used the 85th percentile of our cohort as a cut-off (MELD 3.0 = 14), as done by Bettinger et al. [10]. There was a significant difference in survival between high-risk (> 14) and other patients in our cohort (P < 0.001 for the log-rank test of Kaplan–Meier’s survival curve; Fig. 3A). Similarly, the Child–Pugh score could also achieve effective risk stratification through its grading system (log-rank P < 0.001; Fig. 3B). We attempted to explore whether the MELD 3.0 and Child–Pugh score complement each other for risk stratification in patients. Interestingly, the MELD 3.0 could significantly discriminate patients with high and low risk even if they were classified as intermediate risk groups according to the Child–Pugh score (log-rank P < 0.001; Fig. S1a). Conversely, the Child–Pugh score could also stratify the risk of patients defined as low risk by MELD 3.0 (log-rank P < 0.001; Fig. S1b).

Discussion

To the best of our knowledge, our study is the first to investigate the prognostic value of the MELD 3.0 in patients with TIPS creation. In our cohort, MELD 3.0 showed robust effects in predicting short- and medium-term mortality, and was significantly superior to MELD, MELD-Na and FIPS scores.

Table 2  C-indices of scores for prediction of different survival endpoints

| Endpoints   | MELD 3.0 (95% CI) | MELD (95% CI) | MELD-Na (95% CI) | Child–Pugh (95% CI) | FIPS (95% CI) |
|-------------|-------------------|---------------|------------------|---------------------|--------------|
| 3-month     | 0.727 (0.645–0.808) | 0.666 (0.565–0.761) | 0.672 (0.577–0.768) | 0.754 (0.673–0.835) | 0.582 (0.477–0.687) |
| 6-month     | 0.715 (0.646–0.783) | 0.657 (0.575–0.738) | 0.665 (0.584–0.745) | 0.720 (0.649–0.792) | 0.623 (0.538–0.798) |
| 1-year      | 0.713 (0.652–0.773) | 0.669 (0.601–0.737) | 0.670 (0.602–0.738) | 0.705 (0.643–0.766) | 0.644 (0.572–0.716) |
| 2-year      | 0.663 (0.614–0.713) | 0.618 (0.564–0.673) | 0.616 (0.563–0.670) | 0.665 (0.614–0.716) | 0.585 (0.527–0.643) |

*C-index (95% CI) P Value, P value against MELD 3.0 score
Fig. 2  Calibration plot showing the observed vs. predicted mortality for each score at 3-month (A), 6-month (B), 1-year (C), and 2-year (D).

Fig. 3  Freedom from death after TIPS creation stratified by MELD 3.0 score (A) and Child–Pugh grade (B).
It is well known that patients treated with TIPS often have decompensated cirrhosis, and these patients always have very poor liver function and high mortality [15]. Diverting blood from the liver through TIPS creation may further exacerbate liver damage and increase mortality [1]. Careful pre-procedure assessment and risk stratification could tell clinicians which patients need more careful care post-procedure. In 2000, the MELD was first established to predict 3-month mortality in patients with TIPS creation and to assess liver function reserve [12]. MELD has also shown robust efficacy in cirrhotic patients who have not received TIPS placement and was used in liver allocation in 2002 to ensure objectivity and fairness [16]. Data show that serum sodium level is an independent predictor of mortality in cirrhotic patients awaiting transplantation [17]. Therefore, the MELD-Na scoring system was established and used for liver allocation [13]. Recently, the Freiburg index of post-TIPS survival (FIPS) score was proposed to evaluate 6-month post-TIPS survival [10].

However, changes in the epidemiology of liver disease and advances in medical technology require us to re-examine the clinical usefulness of the current score. In addition, women are at a disadvantage in the current system. It has been reported that women with the same MELD score were significantly less likely to receive a transplant than men [18]. This was associated with an overestimation of the glomerular filtration rate (GFR) in serum creatinine, thus underestimating the risk of mortality in women compared to men with the same creatinine [19]. Based on the above reasons, MELD 3.0 was established by Kim et al. to predict 3-month survival [8]. In the new model, sex and albumin levels were taken into account. Impaired liver function is known to lead to reduced albumin synthesis, and hypoproteinemia is associated with prognosis. Renal impairment occurs in 20% of patients with decompensated cirrhosis, and previous studies have shown it to be significantly associated with survival. However, in patients with reduced renal function, the MELD may overestimate the risk of death [20]. In the MELD 3.0, the overestimation of mortality was partially offset by the addition of creatinine and albumin level interaction terms and the reduction of the upper limit of creatinine levels from 4.0 to 3.0 mg/dL. These factors all improved the predictive accuracy of MELD 3.0. In our cohort, the MELD 3.0 was significantly superior to the MELD and MELD-Na in predicting 3-month survival, and it was also found to be significantly superior in predicting middle-term survival. Furthermore, subgroup analyses demonstrated that the discriminant ability of MELD 3.0 was better than that of MELD, MELD-Na and FIPS scores.

Although previous studies have shown that MELD was superior to the Child–Pugh score in this setting [12, 21], recent studies by Wang et al. and Kraglund et al. concluded that the Child–Pugh score was superior to MELD [22, 23]. The reasons for that may be due to both MELD and Child–Pugh score having their defects. The Child–Pugh score includes ascites and hepatic encephalopathy, which are greatly influenced by subjective perception. Differences in the INR between laboratories can lead to differences of up to 12 points in MELD scores [24]. In addition, almost 10% of patients with MELD scores less than 12 may still develop early hepatic failure after TIPS creation [25]. Gender and albumin are added to MELD 3.0, which still ensures the objectivity of all elements. At the same time, the more factors required to calculate a score, the more accurate it will be, but the calculation will also become more complicated. In our cohort, MELD 3.0 and Child–Pugh scores showed similar discrimination.

Considering that our cohort was Chinese patients, our cohort had better liver function reserve compared with Kim’s cohort, which can be seen from the MELD score (median 10 vs. 16) and Child–Pugh score (median 7 vs. 9). So based on our cohort, we found that a MELD 3.0 of 14 can be used as a cut-off point for discriminating between high- and low-risk patients. Another interesting finding was that using this cut-off value, MELD 3.0 was able to stratify patients with Child–Pugh grades A and B. Conversely, Child–Pugh score could also stratify the risk of patients with MELD 3.0 ≤ 14. These results suggest that MELD 3.0 and Child–Pugh score are complementary in identifying high-risk patients.

There are obvious advantages to our study. Previous studies have assessed prognostic scores in patients with TIPS creation in a relatively small number of patients. We are a large tertiary center and receive the vast majority of patients from Western China. Results derived from these data are more reliable. However, our study has some limitations that need to be discussed. First, it was a single-center retrospective analysis, which inevitably has information biases. Second, it should be noted that patients with HBV-related cirrhosis accounted for the vast majority of our cohort. In the subgroup analysis of patients with HBV-related cirrhosis, MELD 3.0 still maintained significant superiority. However, this superior performance was reduced in the nonviral cirrhosis subgroup. This may also suggest that these results appear to be more applicable to patients with HBV-related cirrhosis. In addition, the indications for TIPS in our cohort were primarily variceal hemorrhage. Our results may be more likely to reflect the outcome of this population. Larger sample size studies are needed in patients with refractory ascites as an indication for TIPS.

**Conclusion**

In conclusion, our cohort showed that the MELD 3.0 was significantly superior to the MELD, MELD-Na and FIPS scores in predicting short- and medium-term mortality in
patients with TIPS creation. This study also confirms that the scoring system is worthy of clinical application. The MELD 3.0 is suitable for the prognostic assessment of patients with cirrhotic portal hypertension allocated for TIPS implantation. However, since the vast majority of patients treated with TIPS in our cohort were patients with HBV-related cirrhosis and with variceal hemorrhage, the predictive power of this new score for post-TIPS mortality in patients with other etiology and indications need further exploring.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10620-023-07834-3.

Author contributions This study was designed by XL. Material preparation, data collection and analysis were performed by JS, XW, YY and TX. The first draft of the manuscript was written by JS. All authors read and approved the final manuscript.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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