S Afr J Surg. 2024;62:161-168. Online first
https://doi.org/10.36303/SAJS.00199

S Afr J Surg
ISSN 038-2361

HPB SURGERY

Intermediate and long-term survival prediction using prognostic scores in patients undergoing salvage TIPS for uncontrolled variceal bleeding

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Background: This study investigated the value of prognostic scores to predict 90-day, 1-, 3- and 5-year survival after salvage TIPS (sTIPS) in patients with exsanguinating variceal bleeding who failed endoscopic intervention.
Methods: The Model for End-Stage Liver Disease (MELD), Model for End-Stage Liver Disease Sodium (MELD-Na), Acute Physiology and Chronic Health Evaluation II (APACHE II) and Child-Pugh (C-P) grades and scores were calculated using Kaplan-Meier curves and Cox proportional hazards models in sTIPS patients treated between August 1991 and November 2020.
Results: Thirty-four patients (29 men, 5 women), mean age 52 years, SD ± 11.6 underwent sTIPS which controlled bleeding in 32 (94%) patients. Ten (29.4%) patients died in hospital at a median of 4.8 (range 1–10) days. On bivariate analysis, C-P score ≥ 10 ($p = 0.017$), high C-P grade ($p = 0.048$), MELD ≥ 15 ($p = 0.010$), MELD-Na score ≥ 22 ($p < 0.001$) and APACHE II score ≥ 15 ($p < 0.001$) predicted 90-day mortality. Individual clinical characteristics associated with 90-day mortality were grade 3 ascites ($p = 0.029$), > 10 units of blood transfused ($p = 0.004$), balloon tube placement ($p < 0.001$), endotracheal intubation (< 0.001) and inotrope support ($p < 0.001$).
The overall 90-day, 1-, 3- and 5-year survival rates were 67.6%, 55.9%, 26.5% and 20.6% respectively. Nine patients (26.5%) were alive at a median of two years (range 1–18 years) post-TIPS. Patients with C-P grade A, C-P score < 10, MELD score < 15, MELD-Na score < 22 and APACHE II score < 15 had significantly better 90-day, 1-, 3- and 5-year survival rates.
Conclusion: Although sTIPS controlled variceal bleeding in 94% of patients after failed endoscopic therapy, in-hospital mortality was 29% and less than one quarter were alive after five years. The selected cut-off values for the nominated scoring systems accurately predicted 90-day mortality and long-term survival.
Keywords: portal hypertension, variceal bleeding, transjugular intrahepatic portosystemic shunt, salvage TIPS, rebleeding, survival.

Introduction

Acute variceal bleeding (AVB) remains a serious complication in patients with portal hypertension and hepatic decompensation.[1] Achieving survival in this high-risk group requires astute multidisciplinary management with urgent control of variceal bleeding, prevention of subsequent rebleeding and support of deteriorating liver function.[2] Standard of care treatment including fluid and blood resuscitation, vasoactive drugs, prophylactic antibiotics, and endoscopic intervention is effective in controlling bleeding in over 90% of patients. However, despite optimal management, up to 10% of patients fail initial endoscopic control and over 20% rebleed within six weeks after control of the initial bleed.[3]

Salvage options when initial endoscopic treatment fails include balloon or oesophageal stent tamponade to temporarily contain bleeding before further attempts at endoscopic control. In patients who do not respond to this approach, mortality rates increase inexorably and the need for a definitive rescue procedure becomes imperative.[4] Transjugular intrahepatic portosystemic shunt (TIPS) has become the preferred salvage intervention in this situation and has largely replaced surgical options.[5] While the success rate of salvage transjugular intrahepatic portosystemic shunt (sTIPS) in arresting bleeding is over 90%, this outcome is negated by mortality rates that can exceed 30% and may approach 100% in patients with associated sepsis, prolonged hypotension, deteriorating liver and renal function and who require inotropic support and mechanical ventilation.[6] Accurate patient selection is therefore vital and several prognostic scores, including Child-Pugh (C-P), Acute Physiology and Chronic Health Evaluation II (APACHE II), Model for End-Stage Liver Disease (MELD), and later MELD-Sodium (MELD-Na) have been developed.[7] The

widely used MELD score was originally designed to predict outcome in patients undergoing only elective TIPS and not emergency or rescue TIPS.

In the absence of a dedicated and specifically developed prognostic score for patients undergoing sTIPS, this study compared the efficacy of current prognostic scoring models to predict 90-day, 1-, 3- and 5-year survival after sTIPS when endoscopic control of variceal bleeding had failed.

Methods

All adult patients (≥ 18 years) undergoing sTIPS for uncontrolled or refractory variceal bleeding in the surgical gastroenterology unit (SGU) at Groote Schuur Hospital and the University of Cape Town Private Academic Hospital between August 1991 and November 2020 were included in the study. The study followed the "Strengthening The Reporting of Observational Studies in Epidemiology" (STROBE) guidelines for reporting observational studies, and final data analysis was on 30 September 2022.[8] Using de-identified data from a prospectively maintained faculty ethics-approved oesophageal variceal registry, baseline demographic, clinical and endoscopic data and biochemical variables were collected.

Details of the acute bleeding management protocol, endoscopic interventional techniques and TIPS method used have been published previously.[9-11] In patients with exsanguinating bleeding, a balloon tube (Sengstaken or Minnesota tube) or temporary oesophageal stent (Danis stent, Ella-CS, Hradec Kralove, Czech Republic) was inserted for tamponade. In patients receiving a balloon tube, endotracheal intubation was used for airway protection. TIPS was performed under general anaesthesia as soon as logistically possible. Other than two covered stents, expandable 10 mm diameter uncovered metal Wallstents (Boston Scientific, Marlborough, MA, USA) varying in length from 49 to 90 mm were placed to maintain patency of the shunt between the portal and hepatic veins.[11] All patients had regular Doppler ultrasound assessments after the procedure to assess patency of the TIPS and portal and hepatic veins.

Survival was calculated at 90-days, 1, 3, and 5 years after TIPS and compared for dichotomised groups according to C-P grades (A, B, or C), and MELD, MELD-Na, APACHE II, and C-P scores.

Statistical analysis

Normally distributed variables were expressed as mean ± standard deviation (SD) and compared with Student's t-tests. Non-normally distributed variables were expressed as the medians with ranges and compared with the Mann-Whitney U-test. Categorical variables were expressed as counts and percentages and compared with the χ^2 or Fisher's exact tests. Survival analysis was performed by the Kaplan-Meier method. Patients who died or were lost to follow-up were censored at the corresponding time point. Comparisons between cohorts were performed with the log-rank test. The Cox proportional hazards model was used to compute hazard ratios, with corresponding 95% confidence intervals. Statistical significance was established at $p < 0.05$ for all analyses. Data were analysed using Stata software version 16 (Stata Corp LP, College Station, Texas, USA).

Results

Five hundred and sixty-four patients with variceal bleeding were treated during the study period. In 530 patients (94%), acute bleeding was controlled by medical treatment and endoscopic intervention. In 34 patients (6%) in whom endoscopic treatment failed, urgent TIPS was used. Eleven of the 34 patients had endoscopically uncontrollable variceal bleeding and 23 had life-threatening recurrent bleeding.

Demographic details and clinical data are summarised in Table I. The causes of portal hypertension were alcohol (n = 24), haemochromatosis (2), chronic hepatitis B

Table I: Bivariate analysis of risk factors associated with 90-day survival post sTIPS

Risk factor	Total cohort (n = 34)	Survived > 90-days (n = 23)	Died < 90-days (n = 11)	p-value
Age				
Mean	52	49	57	0.052
SD	± 11.6	± 10.4	± 12.4	
	n	*n*	*n*	
Gender				
Male	29	21	8	0.152
Female	5	2	3	
CP Grade				
A	3	3	0	0.048
B	19	15	4	
C	12	5	7	
CP Score				
< 10	22	18	4	0.017
≥ 10	12	5	7	
MELD score				
> 22	17	15	2	0.010
≥ 22	17	8	9	
MELD-Na score				
< 22	24	21	3	< 0.001
≥ 22	10	2	8	
APACHE II score				
< 15	22	21	1	< 0.001
≥ 15	12	2	10	
Ascites				
1	13	11	2	0.029
2	10	8	2	
3	11	4	7	
Balloon tamponade				
Yes	14	5	9	< 0.001
No	20	18	2	
Endotracheal intubation				
Yes	11	2	9	< 0.001
No	23	21	2	
Inotrope use				
Yes	9	0	9	<0.001
No	25	23	2	
Blood units transfused				
Median	6	4	10	0.004
Range	(3–13)	(3–12)	(4–13)	

Table II: Survival after salvage TIPS in relation to scoring systems

Risk factor	*n*	90-day survival		1-year survival		3-year survival		5-year survival	
		n	%	*n*	%	*n*	%	*n*	%
Total	34	23	67.6	19	55.9	9	26.5	7	20.6
Child-Pugh grade									
A	3	3	100	3	100	2	67.8	2	67.8
B	19	15	78.9	12	63.1	5	26.3	4	21.1
C	12	5	41	4	33.0	2	16.7	1	8.3
Child Pugh score									
< 10	22	18	81.8	15	68.2	7	31.8	6	27.3
≥ 10	12	5	41.7	4	33.3	2	16.7	1	8.3
MELD score									
<15	17	15	88.2	14	82.4	7	41.2	6	35.3
≥15	17	8	47	5	29.4	2	11.8	1	5.9
MELD-Na score									
< 22	24	21	87.5	18	75	8	33.3	6	25
≥ 22	10	2	20.0	1	10	1	10.0	1	10
APACHE score									
< 15	22	21	95.5	18	81.8	8	36.4	6	27.3
≥ 15	12	2	16.7	1	8.3	1	8.3	1	8.3

infection (2), chronic hepatitis C infection (1), NASH (2), drug-induced (2), or sarcoid-related cirrhosis (1). Mean (SD) Child-Pugh score for the cohort was 8.9 (± 1.8). Median (range) Na, creatinine and INR values were 136 (126–140), 95 (49–326) and 1.4 (1–4.1). Median (range) MELD was 14.5 (7–29), MELD-Na was 15.5 (± 7–33) and bilirubin was 31 (8–409). Mean (SD) albumin was 30.7 (± 5.8).

Before sTIPS, 19 patients had a median of three (range 1–9) injection sclerotherapy (IST) sessions, 20 had a median of two (range 1–6) endoscopic variceal ligation (EVL) sessions, with a median of 10 bands placed per session. Five patients had both IST and EVL. Median units of blood transfused before sTIPS was six (range 3–12), and 14 patients required either balloon tamponade (n = 12) or placement of a Danis stent (n = 2). Twelve patients required endotracheal intubation and ventilation, and nine required inotropic support.

TIPS was placed successfully in all patients and bleeding was controlled in 32 of the 34 (94%) patients. Bleeding persisted in two patients (6%) despite a patent TIPS on repeat US-Doppler examination. A further patient developed recurrent bleeding in hospital during the index admission after initial control of bleeding by TIPS, resulting in overall control of bleeding in 91% of patients.

Ten patients (29.4%) died in hospital (median 4.8, range 1–10 days) of progressive liver failure (4), multi-organ failure (MOF) (2), alcoholic cardiomyopathy (2) and uncontrolled gastric (1) or oesophageal (1) variceal bleeding. When stratified according to C-P grade, 90-day mortality in C-P grade A was 0%, for C-P grade B, 21%, and for C-P grade C, 58%. On bivariate analysis, factors associated with 90-day mortality were C-P grade C (p = 0.048), C-P score ≥ 10 (p = 0.017), MELD ≥ 15 (p = 0.010), MELD-Na ≥ 22 (p < 0.001), APACHE II score ≥ 15 (p < 0.001). For C-P grade C patients, mortality was 58.3%, for a C-P score > 10, 58.3%, for a MELD score > 15, 53%, for a MELD-Na score > 22, 80%, and for an APACHE II score > 15, 83% (Table II). Individual clinical characteristics associated with 90-day mortality were grade 3 ascites (p = 0.029), > 10 units of blood transfused (p = 0.004), balloon tube placement (p < 0.001), endotracheal intubation (< 0.001) and inotropic support (p < 0.001).

Long term follow-up showed substantial morbidity and mortality in survivors. Two of 24 patients developed TIPS stent occlusion and required new stent placement, one of whom also underwent coiling of a patent left gastric vein. Three patients required endoscopic treatment for varices. One underwent EVL for oesophageal varices and two with gastric varices underwent endoscopic *monomeric n-butyl-2-cyanoacrylate* injection and surgical gastric devascularisation respectively. Eight of 24 patients had symptomatic and clinically evident encephalopathy which responded to medical treatment without requiring revision of the TIPS stent. Four of the 24 surviving patients developed secondary bacterial peritonitis, three of whom responded to medical treatment and one patient who had resistant Acinetobacter sepsis died.

Patients with C-P grade A, C-P score < 10, MELD score < 15, MELD-Na score < 22 and APACHE II scores < 15 had significantly better 90-day, 1, 3 and 5-year survival rates (Supplementary file 1). Ninety day, 1-year, 3-year and 5-year survival were 67.6%, 55.9%, 26.5% and 20.6% respectively. Four of the seven 5-year survivors are alive and well, one underwent a liver transplant post-TIPS and is well 18 years later (Table II).

The Cox proportional hazards models showed that at 1, 3 and 5 years the APACHE II score had higher hazard ratios for risk of death post-sTIPS than the other scores: HR = 14.5, 5.6 and 4.8 respectively, with the highest risk overall at 1 year. Conversely, for 90-day survival, MELD was the only score that predicted for death with a HR = 13.5 (p = 0.013), suggesting that the best score to predict post-sTIPS survival at 90 days is the MELD score and at 1 year the APACHE II score (Supplementary file 2).

Discussion

In this observational study the predictive value of clinical scores in survival and long-term outcome was assessed in a defined cohort of cirrhotic patients with life-threatening variceal bleeding who required sTIPS placement. We found two distinct and different temporal mortality periods after TIPS placement. An initial in-hospital peri-procedural period of increased mortality after TIPS stent insertion due to multi-organ failure precipitated by the acute bleeding episode was followed by a longer period of insidious but inexorably progressive liver failure unrelated to bleeding. Although variceal bleeding control was achieved in 91% of patients, overall 90-day mortality was 29.4% and was substantially higher in patients with overt liver decompensation and high-risk scores. Ninety-day mortality increased with C-P scores > 10, MELD scores > 15, MELD-Na scores > 22 and APACHE II scores > 15. Despite the need for a high-risk procedure in a group of seriously ill patients, and although two-thirds of the cohort were alive at 90 days, progressive liver failure resulted in a 20.6% survival rate at 5 years.

Perceived disadvantages of TIPS are the substantial mortality rate following the procedure, the risks of recurrent variceal bleeding and shunt-induced encephalopathy, the need for regular radiological evaluation to confirm stent patency and modest long-term survival rates. Mortality after TIPS placement varies widely due to differing inclusion criteria, timing of TIPS and the severity of underlying liver disease.[1,12] Some reports include haemodynamically unstable patients with active bleeding during TIPS as well as patients undergoing elective TIPS. In our study, only cirrhotic patients with exsanguinating or life-threatening refractory variceal bleeding who underwent sTIPS placement were included; bivariate analysis showed that grade 3 ascites, > 10 units of blood transfused, balloon tube placement, endotracheal intubation and the need for inotropic support were associated with increased mortality at 90-days. Early mortality after sTIPS was 48% in the Patch study,[13] predominantly in patients with C-P scores > 11, and a 63% mortality rate due to aspiration and MOF was reported in a study by Sanyal et al.[14] Independent clinical and biochemical predictors of mortality are crucial in identifying high-risk patients after TIPS insertion.[15] In the Baveno VII report, C-P class C, an increased MELD score and failure to achieve primary bleeding control were found to predict 6-week mortality.[3] Other studies have identified high-risk demographic and clinical factors, including age over 60 years,[16] encephalopathy,[17] haemodynamic instability at the time of the TIPS procedure,[18] use of inotropes,[12,19-21] need for mechanical ventilation,[19] balloon tamponade,[18] comorbidities and sepsis.[18,21,22] Biochemical parameters found to be independent predictors of mortality include hyperbilirubinaemia,[12,15,17] albumin < 2.7g/L, prothrombin activity < 50%, lactate ≥ 12 mmol/L,[20] hyponatraemia[21] and renal failure.[12,19,22-24]

Published long-term survival data following sTIPS are also widely divergent, with survival averaging 60% at 1-year and 30% at 5-years, depending on population selection, emergency versus elective placement and facility experience in the management of critically ill patients with end-stage liver disease.[25] The most common cause of late death after a TIPS procedure in most series is progressive liver failure.[26] The principal determinant of survival in our study was the severity of the underlying liver disease.

The data presented must be interpreted in the light of several limitations including the retrospective design, lack of a control group, the long duration of the study and the relatively small patient numbers, all but two of whom received uncovered metal stents which have now been superseded by covered metal stents. In addition, there may be a covert selection and referral bias as our unit functions as a tertiary centre for high-risk patients. As sTIPS is not always readily available in some hospitals, the results and implications may not be generally applicable to all units. The intrinsic weakness due to the retrospective study analysis is partially overcome by the fact that data were recorded prospectively, and integrity was maintained in a dedicated unit registry.

Despite these limitations, our study has several strengths. All the patients included in this database were admitted with AVB and decompensated cirrhosis and the analysis encompasses real-world data from an unselected cohort of consecutively treated patients by the same team using specific endpoints.

In conclusion, this study confirms that sTIPS is an effective and lifesaving minimally invasive method of portal decompression that can be performed successfully with low procedural morbidity and mortality in critically ill patients with advanced liver disease and uncontrolled variceal bleeding. Although in the short term sTIPS controlled variceal bleeding in 94% of patients, mortality remained high with 29% in-hospital deaths. Most deaths after sTIPS were the consequence of hepatic or multiorgan failure and sepsis, and seldom due to recurrent variceal bleeding. In this study C-P score ≥ 10, C-P grade, MELD-Na score ≥ 22, and APACHE II score ≥ 15 predicted increased 90-day mortality while C-P grade A, C-P score < 10, MELD score < 15, MELD-Na score < 22 and APACHE II score < 15 predicted long term survival. A caveat, however, is that because this study was based on a small cohort of predominantly alcoholic decompensated cirrhotic patients, the high-risk category identified should not be denied consideration for a sTIPS and each patient should be assessed on a case-by-case basis especially in units where there is available access to liver transplantation after sTIPS.

Conflict of interest

The authors declare no conflict of interest.

Ethical approval

The study protocol was approved by the Human Research Ethics Committee (HREC Ref No. 710/2021) of the University of Cape Town and the research was conducted in accordance with the Declaration of Helsinki.

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S Afr J Surg. 2024;62:161-168. Online first
https://doi.org/10.36303/SAJS.00199

S Afr J Surg
ISSN 038-2361

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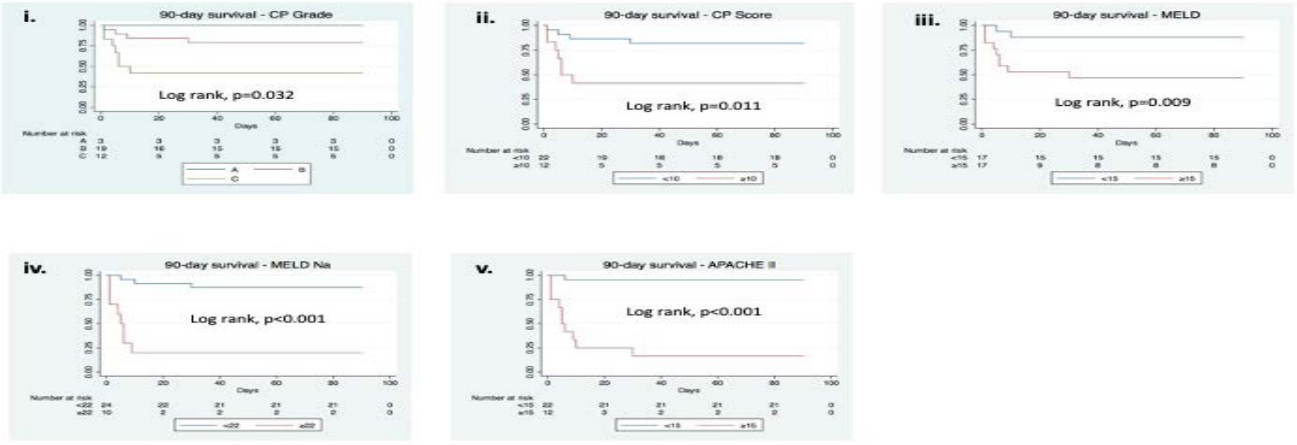
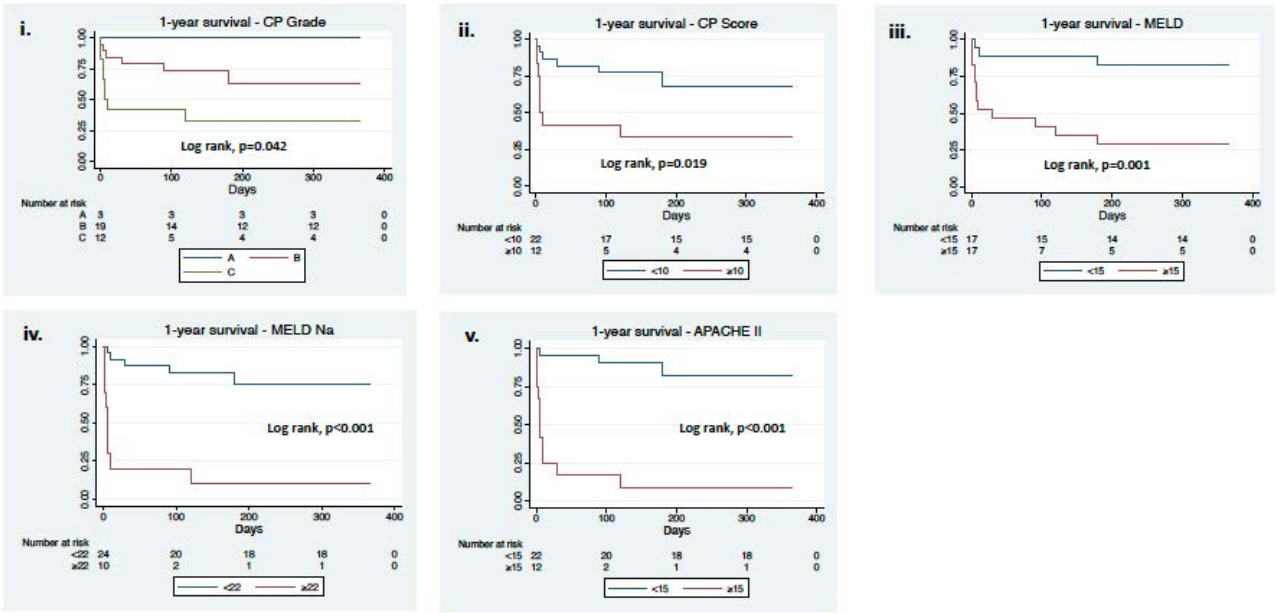
Supplementary file 1: Kaplan Meier survival curves

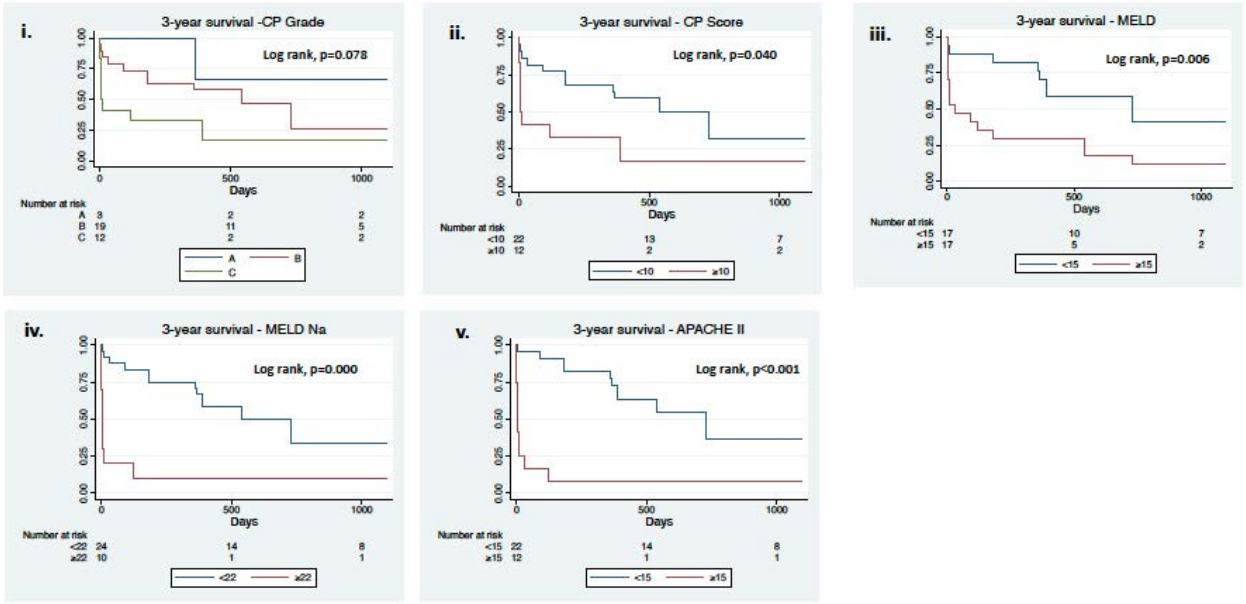
A. 90-day survival



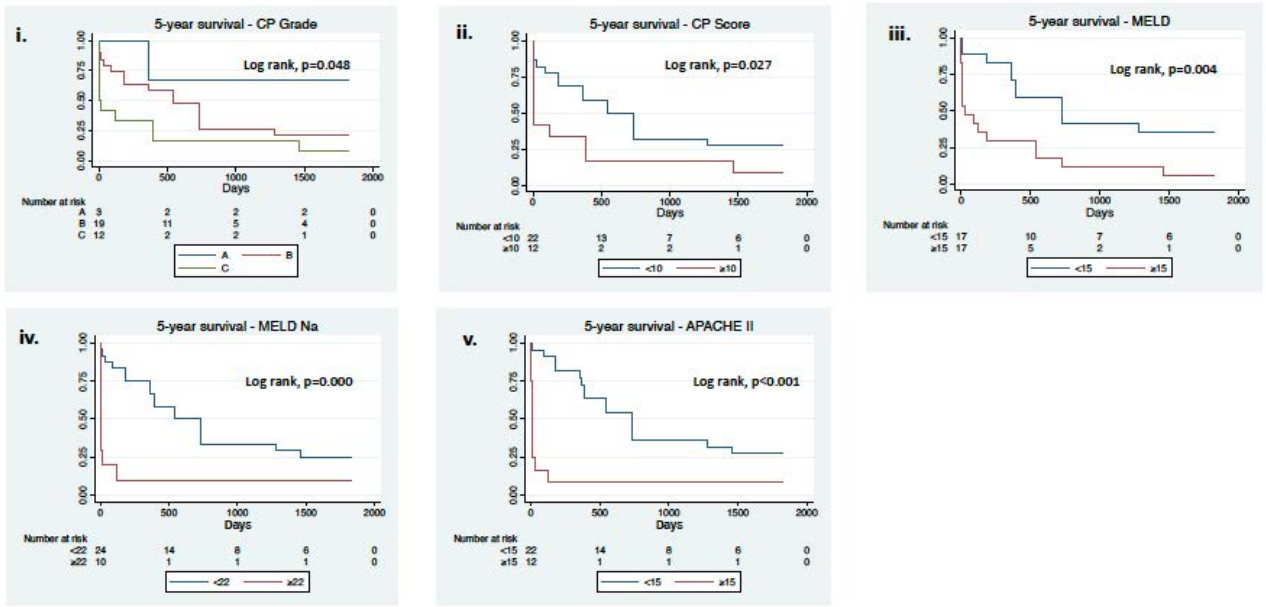
B. 1 year survival



C. 3 year survival



D. 5 year survival



Supplementary file 2: Cox proportional hazards models

Survival Period	Hazard ratio	95% CI	*p*-value
90-day survival			
CP Grade	1.3	0.48-3.3	0.628
CP Score	0.95	0.27-3.2	0.94
MELD	13.5	1.7-105	0.013
MELD Na	2.5	0.74-8.0	0.141
APACHE II	2.8	0.86-9.4	0.08
1-year survival			
CP Grade	3.1	1.2-7.9	0.017
CP Score	3.2	1.1-8.8	0.028
MELD	5.2	1.5-19	0.011
MELD-Na	9.6	3.2-29	0.000
APACHE II	14.5	4.3-49	0.000
3-year survival			
CP Grade	2.1	1.1-4.3	0.032
CP Score	2.2	0.9-6.2	0.052
MELD	2.7	1.2-6.2	0.017
MELD-Na	4.6	1.9-11	0.001
APACHE II	5.6	2.7-13	0.000
5-year survival			
CP Grade	2.2	1.5-4.3	0.019
CP Score	2.3	1.1-5.0	0.036
MELD	2.7	1.3-6.1	0.012
MELD-Na	4.0	1.7-9.3	0.001
APACHE II	4.8	2.1-11	0.000