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Original Article

Predictors of early mortality post transjugular intrahepatic portosystemic shunts and the role of hepatic venous pressure gradient

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A B S T R A C T

Background: This study was conducted to identify factors associated with early mortality (30-day, 60-day) among patients with cirrhosis and portal hypertension who undergo transjugular intrahepatic portosystemic shunts (TIPS).

Methods: Consecutive patients who underwent TIPS between January 1993 and December 2008 were included in the study. Clinical, laboratory, and procedural data were collected for all patients by retrospective chart review. Qualitative variables were compared by chi square test and quantitative variables by Student's *t*-test. Multinomial logistic regression was used for multivariate analysis.

Results: A total of 643 patients had complete data and were included in the study. The incidence of 30-day mortality in the study group was 17.4% (112/643), and the incidence of 60-day mortality was 22.6% (145/643). Univariate analysis was carried out comparing these risk factors in patients stratified by 30-day and 60-day mortality. On univariate analysis, pre-TIPS bilirubin >2.0 mg, pre-TIPS albumin <2.5 gm/dL, pre-TIPS international normalized ratio >2, pre-TIPS creatinine >2.0, pre-TIPS MELD (Model for End-stage Liver Disease) score >20, pre-TIPS hepatic venous pressure gradient (HVPG) >20 mmHg, higher pre-TIPS alanine transaminase, and higher pre-TIPS aspartate transaminase were found to be predictors of both 30- and 60-day mortality. Multivariate analysis showed pre-TIPS creatinine >2 mg/dL, pre-TIPS MELD levels >20 and HVPG (hepatic venous portal gradient) >20 mmHg to be independent and significant predictors of both 30- and 60-day mortality. For every 1 mg/dL rise of creatinine exceeding 2 mg/dL, the odds of 30-day mortality increased by 80% [odds ratio = 1.8 (1.3–2.4)]. A pre-TIPS HVPG of more than 20 mmHg was found to be correlated with worsened 30-day and 60-day mortality in patients with variceal bleed but not in patients with ascites or hydrothorax.

Conclusion: Stepwise model selection determined that serum creatinine >2.0 mg/dL, MELD >20, and pre-TIPS HVPG >20 mmHg were independent predictors of early mortality. A pre-TIPS HVPG of more than 20 mmHg was found to be correlated with worsened 30-day and 60-day mortality in patients with variceal bleed but not in patients with ascites or hydrothorax.

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Keywords: TIPS, Portal gradient, Prognosis, Mortality

Introduction

Cirrhosis and its complications are major causes of morbidity and mortality in the US. The National Center for Health Statistics reports chronic liver disease and cirrhosis to be the 12th leading cause of death in the US, causing around 27,000 deaths per year.[1] When common complications of cirrhosis, like variceal hemorrhage and ascites, fail to respond to standard medical treatment, transjugular intrahepatic portosystemic shunt (TIPS) is being increasingly used in their management.[2,3] The technical refinements introduced since TIPS was first pioneered, in 1969,[4] have improved its efficacy and clinical outcomes.[5,6]

TIPS is a percutaneously created shunt within the liver between the portal and systemic circulations which decompresses the portal system. TIPS can be performed as an elective procedure or on an emergency basis. Morbidity and mortality associated with TIPS placement are much lesser than those associated with alternatives like surgical portosystemic shunting[7,8]; however, TIPS itself may be followed by complications like shunt dysfunction, bleeding, worsening of hepatic encephalopathy, and liver failure.[7,9] The early mortality after TIPS has been reported to be high in various studies, ranging from 25% to 35%.[10–13] It is thus important to identify and optimize preventive measures or exclude patients who are at high risk for complications and mortality after this procedure.

In patients with complications of portal hypertension, TIPS has been proven as one of the most effective palliative therapies. The purpose of identifying these risk factors is not to deny patients a potentially life-saving procedure, but to enable us to discuss

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expected outcomes with patients, family members, and referring physicians, and ultimately, to make reasonable decisions in the best interest of patients. Several authors have described high risk factors associated with early mortality after TIPS.[14–16] In spite of a few proposed prognostic indices, a consensus on the high risk factors which mandate exclusion from therapy has not been reached. In this study, we have explored predictors of 30-day and 60-day mortality among a large cohort of patients who underwent TIPS at a single institution over a 15-year period.

Methods

Study population

This retrospective study was approved by the institutional review board. All patients with end-stage liver disease who underwent TIPS between 1993 and 2008 were included in our study group. Right heart failure, pulmonary hypertension, severe infection, severe hepatic encephalopathy, and multiple hepatic cysts were considered to be absolute contraindications and portal vein thrombosis was considered to be a relative contraindication for TIPS. Patients were stratified into two groups based on their mortality status at 30 or 60 days after performance of TIPS procedure.

Data collection

Retrospective chart review was used to collect demographic, clinical, laboratory, radiologic, and procedure-related data. Clinical features recorded include age, gender, race, etiology of cirrhosis, and indication for TIPS. Pre-TIPS laboratory values noted include serum bilirubin, creatinine, albumin, platelet count, aspartate transaminase (AST), alanine transaminase (ALT), and international normalized ratio (INR). MELD (Model for End-stage Liver Disease) scores were calculated from the laboratory values. Procedure-related data collected include date of TIPS, pre- and post-TIPS hepatic venous pressure gradient (HVPG), number of revisions, patency rates, types of stent, and size of TIPS stent.

TIPS procedure

The TIPS procedure has been described numerous times elsewhere.[17] The majority of our TIPS procedures were performed under general anesthesia according to operator and/or patient preference using either the Ring or Haskal Transjugular Intrahepatic Access Sets (Cook Medical Inc., Bloomington, IN). Right atrial, wedge hepatic, and portal vein pressures were recorded before balloon dilatation and stenting. Portal vein, hepatic vein, right atrial pressures, and a portal venogram were recorded following shunt placement. To attain a goal of a post-TIPS portosystemic gradient of 10 mmHg or less, the TIPS tract and stent were usually dilated to a 10-or 12-mm diameter. Uncovered stents, primarily the Wallstent® (Boston Scientific, Natick, MA), were used until the Viatorr® ePTFE-coated stent-graft (W.L. Gore and Associates, Flagstaff, AZ) became available in 2000; this stent was used almost exclusively since that time. Shunt gradient was recorded after the procedure.

Statistics

Patients were stratified into those who suffered mortality within 30 and 60 days, and those who survived beyond these periods. Pearson chi square test and Fisher exact probability were used to compare the distribution of categorical variables. Independent *t*-tests were used to compare means of continuous variables. Statistical tests of association were two-sided. Multinomial logistic regression technique was applied in a stepwise manner to identify risk factors independently associated with early death. All patients were followed up until death, until they were lost to follow up, or until study closure. The software SPSS 16.0 (SPSS Inc., Chicago, IL) was used for all statistical analyses.

Results

A total of 643 consecutive patients underwent the TIPS procedure between 1993 and 2008 and were included in the study. The mean age of the study group was 54.56 years (range 17–87); 62.1% (399/643) were male and 87.9% (565/643) were Caucasian. Table 1 describes the demographic, clinical, and procedure-related data of the study group. The incidence of 30-day mortality in the study group was 17.4% (112/643), and the incidence of 60-day mortality was 22.6% (145/643). TIPS was performed on an emergent basis for management of acutely bleeding esophageal varices refractory to medical treatment in 10.4% (67/643) of patients, and on an elective basis in the remaining 89.6% (576/643) of patients. The most common cause of death in patients who suffered 30-day mortality was liver failure, which was seen in 26.8% (30/112) of patients. The other causes of death were massive gastrointestinal bleed in 17.9% (20/112), renal failure in 15.2% (17/112), sepsis with multiorgan failure in 11.6% (13/112), TIPS procedure-related bleeding 3.6% (4/112), and other causes in 12.5% (14/112). The cause of death could not be discerned in 12.5% (14/112) of patients.

Univariate analysis was carried out comparing these risk factors in patients stratified by 30-day and 60-day mortality (Table 2). On

Table 1 Demographic and Clinical Characteristics of Patients

Factor	Categories	All patients ($n = 643$)
Age	< 59 y	581 (90.4%)
	> 60 y	62 (9.6%)
Sex	Male	399 (62.1%)
	Female	244 (37.9%)
Race	Caucasian	565 (87.9%)
	African American	53 (8.2%)
	Other	25 (3.9%)
MELD score	< 15	426 (80.2%)
	≥ 15	105 (19.8%)
Pre-TIPS creatinine	≤ 2.0 mg/dL	555 (86.3%)
	> 2.0 mg/dL	88 (13.7%)
Pre-TIPS bilirubin	< 2 mg/dL	353 (54.9%)
	≥ 2.0 mg/dL	290 (45.1%)
Pre-TIPS INR	< 2.0	557 (86.6%)
	≥ 2.0	86 (13.4%)
Pre-TIPS albumin	< 2.5 gm/dL	257 (40.0%)
	≥ 2.5 gm/dL	386 (60.0%)
HCV	Positive	189 (29.4%)
	Negative	436 (67.8%)
Indication for TIPS	Elective	576 (89.6%)
	Emergent	67 (10.4%)
Clinical indication	Variceal bleed	250 (38.9%)
	Refractory ascites	309 (48.1%)
	Refractory hydrothorax	68 (10.6%)
	Portal vein thrombosis	8 (1.2%)
	Others	8 (1.2%)
Type of TIPS stent	Covered	207 (32.2%)
	Uncovered	436 (67.8%)
Size of stent	< 10 mm	127 (19.8%)
	> 12 mm	516 (80.2%)
Pre-TIPS ALT (IU/L)	Mean (range)	51 (6–911)
Pre-TIPS AST (IU/L)	Mean (range)	77 (5–2344)
Pre-TIPS platelet count (cells/mm^3)	Mean (range)	116 (15–779)
Pre-TIPS HVPG	mmHg	17.4 (2–70)
Post-TIPS HVPG	mmHg	5.5 (0–21)

ALT, alanine transaminase; AST, aspartate transaminase; HCV, hepatitis C virus; HVPG, hepatic venous pressure gradient; INR, international normalized ratio; MELD, Model for End-stage Liver Disease; TIPS, transjugular intrahepatic portosystemic shunt.

Table 2 Univariate Analysis of Factors Predicting 30-day and 60-day Mortality

Factor	Categories	Survived beyond 30 d ($n = 531$)	30-d mortality ($n = 112$)	P	Survived beyond 60 d ($n = 498$)	60-d mortality ($n = 145$)	P
Age	< 59 y	477	104	0.212	450	131	0.552
	> 60 y	54	8		48	14	
Sex	Male	333	66	0.259	317	82	0.074
	Female	198	46		181	63	
Race	Caucasian	465	100	0.753	434	131	0.310
	African American	46	7		46	7	
	Other	20	5		18	7	
MELD score	< 20	426	61	< 0.001	405	82	< 0.001
	≥ 20	105	51		93	63	
Pre-TIPS creatinine	≤ 2.0 mg/dL	471	84	< 0.001	447	108	< 0.001
	> 2.0 mg/dL	60	28		51	37	
Pre-TIPS bilirubin	< 2.0 mg/dL	310	43	< 0.001	291	62	0.001
	≥ 2.0 mg/dL	221	69		207	83	
Pre-TIPS INR	< 2.0	469	88	0.006	442	115	0.003
	≥ 2.0	62	24		56	30	
Pre-TIPS albumin	< 2.5 gm/dL	307	79	0.008	211	46	0.013
	≥ 2.5 gm/dL	224	33		287	99	
HCV	Positive	153	36	0.191	144	45	0.301
	Negative	367	69		342	94	
Clinical indication	Variceal bleed	250	59	0.243	241	68	0.549
	Refractory ascites	214	36		194	56	
	Hydrothorax	55	13		53	15	
Type of TIPS stent	Covered	171	36	0.957	148	39	0.790
	Uncovered	360	76		350	106	
Size of stent	< 10 mm	107	20	0.959	99	117	0.603
	> 12 mm	424	92		399	28	
Pre-TIPS HVPG	< 20 mmHg	347	59	0.010	328	78	0.009
	> 20 mmHg	106	33		97	42	
Pre-TIPS ALT (IU/L)	Mean (range)	84 (8–911)	45 (6–494)	< 0.001	43.7 (6–494)	77.8 (8–911)	< 0.001
Pre-TIPS AST (IU/L)	Mean (range)	139 (12–2344)	64 (5–601)	< 0.001	62.9 (5–601)	124.4 (12–2344)	< 0.001
Pre-TIPS platelet count (cells/mm^3)	Mean (range)	107 (11–613)	118 (15–779)	0.746	119.7 (10–779)	105.9 (11–613)	0.852

ALT, alanine transaminase; AST, aspartate transaminase; HCV hepatitis C virus; HVPG, hepatic venous pressure gradient; INR, international normalized ratio; MELD Model for End-stage Liver Disease; TIPS, transjugular intrahepatic portosystemic shunt. P values are statistically significant.

univariate analysis, pre-TIPS bilirubin >2.0 mg, pre-TIPS albumin <2.5 gm/dL, pre-TIPS INR >2, pre-TIPS creatinine >2.0, pre-TIPS MELD score >20, pre-TIPS HVPG >20 mmHg, higher pre-TIPS ALT, and higher pre-TIPS AST were found to be predictors of both 30-day and 60-day mortality. Age, gender, ethnicity, HCV positivity, indication for TIPS, type of stent (covered vs. uncovered), and size of stent were not found to predict early mortality. Multivariate analysis was carried out using logistic regression model. A significance level of 0.10 in the univariate analysis was used as a cutoff to include a variable in multivariate analysis. The results of multivariate analysis are given in Table 3. Multivariate analysis showed higher pre-TIPS creatinine levels, higher pre-TIPS MELD score, and higher pre-TIPS HVPG to be independent and significant predictors of 30-day and 60-day mortality.

We evaluated the relationship between creatinine and 30-day mortality and found that for every 1 mg rise in creatinine (above 2 mg/dL) the risks of 30-day mortality increased by 80% [odds ratio (OR) 1.8; 1.3–2.4]. The 30-day and 60-day mortality rate in patients who underwent emergent TIPS was high, at 41.8% (28/67) and 58.2% (39/67), respectively. But the mean pre-TIPS MELD score in patients who underwent TIPS on an emergent basis was higher (19.2) than that of patients who underwent elective TIPS (16.7) ($P = 0.012$). We divided the patient population into those who underwent TIPS before and after 2000. The 30-day mortality in patients underwent TIPS before 2000 was 18.7% (68/364), and in those who underwent TIPS after 2001 it was 15.8% (44/279) ($P = 0.347$). The 60-day mortality in patients underwent TIPS before 2000 was 25.0% (91/364), and in those who underwent TIPS after 2001 it was 19.4% (54/279) ($P = 0.105$). We performed a substratification analyses to evaluate the effect of pre-TIPS HVPG on early mortality based on the clinical indication for TIPS placement (Table 4). A pre-TIPS HVPG of more than 20 mmHg was found to be correlated with worsened 30-day and 60-day mortality in patients with variceal bleed. However, such a correlation was not found in patients with refractory ascites or refractory hydrothorax.

Table 3 Multivariate Analysis of Factors Predicting 30-day and 60-day Mortality

Factor	30-d mortality		60-d mortality	
	P	OR (95% CI)	P	OR (95% CI)
Pre-TIPS creatinine	0.020	2.2 (1.4–4.4)	0.004	2.5 (1.3–4.7)
Pre-TIPS MELD	0.050	2.0 (0.9–4.0)	0.027	1.8 (1.1–2.7)
Pre-TIPS HVPG	0.040	1.7 (1.0–2.8)	0.025	2.1 (1.1–3.9)
Pre-TIPS bilirubin	0.176	1.4 (0.8–2.5)	0.321	1.2 (0.8–2.0)
Pre-TIPS INR	0.470	0.8 (0.3–1.6)	0.662	0.7 (0.3–1.3)
Pre-TIPS albumin	0.110	1.5 (0.9–2.5)	0.349	1.2 (0.8–2.0)
Pre-TIPS AST	0.208	0.9 (0.9–1.0)	0.267	0.9 (0.9–1.0)
Pre-TIPS ALT	0.959	0.9 (0.9–1.0)	0.642	0.9 (0.9–1.0)

AST, aspartate transaminase; ALT, alanine transaminase; HVPG, hepatic venous pressure gradient; INR, international normalized ratio; MELD, Model for End-stage Liver Disease; TIPS, transjugular intrahepatic portosystemic shunt. P values are statistically significant.

Discussion

In this study, the incidence of 30-day and 60-day mortality was found to be 17.4% and 22.6%, respectively. Pre-TIPS creatinine >2 mg/dL, pre-TIPS MELD >20, and pre-TIPS HVPG >20 mmHg were found to be independent predictors of both 30-day mortality and 60-day mortality (Fig. 1). Though the early mortality rates improved in the current decade compared to the previous, the rates were not statistically different. A pre-TIPS gradient of more than 20 mmHg was found to be correlated with worsened 30-day and

Table 4 Relationship between Pre-TIPS HVPG and Early Mortality

Indication for TIPS	Pre-TIPS HVPG (mmHg)	30-d mortality	*P*	60-d mortality	*P*
Variceal bleed	< 20	15.1%	0.03	17.7%	0.04
	> 20	26.9%		30.1%	
Refractory ascites	< 20	12.8%	0.51	20.7%	0.36
	> 20	16.9%		27.1%	
Refractory hydrothorax	< 20	17.4%	0.27	19.5%	0.30
	> 20	33.3%		33.3%	

HVPG, hepatic venous pressure gradient. *P* values are statistically significant.

60-day mortality in patients with variceal bleed but not in patients with ascites or hydrothorax.

The early mortality rate reported in our study is similar to the rates described in a few other studies analyzing the same data. Table 5 lists a few studies which analyzed factors predicting early mortality after TIPS.[12–16,18] In our study, the common causes of death were liver failure, recurrent variceal bleeding, renal failure, and sepsis. The incidence of procedure related mortality was low. This suggests that the high rate of early mortality in the post-TIPS period is related more to the severity of the underlying liver disease and the indication for TIPS placement rather than the procedure itself. The shunting of blood from the portal to the systemic circulation via the TIPS might compromise the hepatic parenchymal blood flow, thus contributing to the worsening liver function and death.[19–21]

In our study, renal function was found to be an independent predictor of early mortality after TIPS (Fig. 2). Every 1 mg raise in creatinine above 2 mg/dL was associated with an increase in the risk of 30-day mortality by 80% (Fig. 3). Similar results have been published before. Patch et al[22] also found serum creatinine to be one of the six independent factors associated with early mortality after TIPS placement in variceal bleeders. Russo et al even reported elevated serum creatinine level to be the strongest predictor of 30-day mortality after TIPS placement.[23] Acute renal failure has actually been shown to be associated with higher mortality in all patients with end-stage liver disease.[24,25] However, there are some case studies where performance of TIPS was actually associated with a delayed improvement in creatinine clearance, especially in patients with ascites.[26,27] TIPS has even been used as a therapeutic modality in small uncontrolled studies for selected patients with hepatorenal syndrome type 1.[28,29] At this point, TIPS appears to improve renal function in a certain subset of patients but is overall associated with higher early mortality in patients with renal failure. Recently, an interdisciplinary working party proposed a revised classification system of renal dysfunction in patients with cirrhosis.[30] If such systems are used to better classify renal dysfunction in cirrhotics, then we hopefully can identify the subset of patients in whom TIPS might be helpful and the subset in which it would be contraindicated.

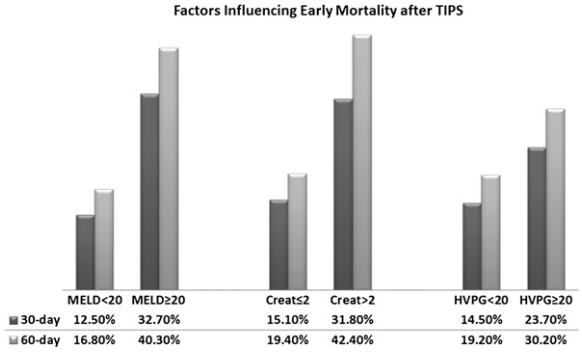

Fig. 1. Bar graph showing 30-day and 60-day mortality (*y*-axis) among patients with high risk factors (*x*-axis).

MELD score > 20 was found to be an independent predictor of both 30-day and 60-day mortality. Several earlier studies have established that MELD score is a useful predictor of both short-term and long-term survival in patients with end-stage liver disease.[23,31,32] It is interesting to note that Malinchoc et al[23] originally developed the MELD score in 2000 as a predictor of 3-month mortality after TIPS, and it has been subsequently used to predict severity of liver disease and for transplant listing.

HVPG is an objective measure of the severity of portal hypertension and usually correlates well with the occurrence of complications like variceal bleeding. Studies have shown that a fall below 12 mmHg or a reduction in HVPG by at least 20% can prevent recurrence of variceal bleed and improve survival.[33] In almost all the patients who underwent TIPS at our center, the post-TIPS HVPG was reduced to less than 12 mmHg and the mean decrease in HVPG from baseline was 67%. We found that pre-TIPS HVPG greater than 20 mmHg was associated with worse short- and intermediate-term mortality in patients with variceal bleed. In an earlier study by Moitinho et al,[33] an initial HVPG of ≥ 20 mmHg was associated with a significantly longer intensive care unit stay, longer hospital stay, greater transfusion requirements, and a worse actuarial probability of survival. This was further validated in a later study which showed that HVPG remained an independent variable in a model adjusted by MELD, ascites, encephalopathy, and age.[34] Endpoints Single Topic Conference on "Portal Hypertension and Variceal Bleeding—Unresolved Issues" took place in Atlanta, GA, in 2007 and was jointly sponsored by the American Association for the Study of Liver

Table 5 Comparison of Studies Analyzing 30-day Mortality

Study	Year	*n*	Indication for TIPS	30-d mortality	Predictive factors
Chalasani et al[15]	2000	129	All indications	–%	Emergent TIPS, Bilirubin > 3 mg/dL
Rajan et al[12]	2002	220	Variceal hemorrhage	26.0%	Bilirubin > 3 mg/dL, Intubated patients, Child Pugh class C
Russo et al[13]	2002	90	All indications	20.0%	Uncontrolled variceal bleeding, coagulopathy, hyperbilirubinemia, and renal insufficiency
Yoon et al[16]	2005	73	Acute variceal bleeding in viral hepatitis	31.5%	Hyperbilirubinemia (> 3 mg/dL); serum creatinine level (> 1.7 mg/dL).
Pan et al[18]	2008	352	All indications	11.9%	Bilirubin level > 2.5 mg/dL and creatinine level > 1.2 mg/dL
Tzeng et al[14]	2009	107	Emergent TIPS	28.0%	Child–Pugh score > 11; MELD^2 score > 20
Current study		643	All indications	17.4%	Emergent TIPS, creatinine > 2 mg/dL and MELD> 20

MELD, Model for End-stage Liver Disease; TIPS, transjugular intrahepatic portosystemic shunt.

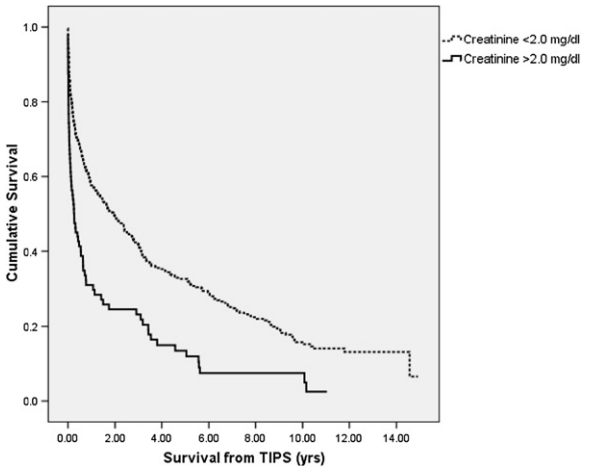

Fig. 2. Kaplan–Meier survival curves comparing survival between patients with serum creatinine, ≤2.0 and >2 mg/dL.

Diseases and the European Association for the Study of the Liver. They reported that in patients with decompensated cirrhosis, an HVPG of 20 mmHg appeared to be the best cutoff for predicting clinical outcome.[35] Earlier studies which have validated this quantitative cutoff have involved very small patient populations. Several other larger studies did not even consider this factor in their analyses. In our large series, we were able to confirm the significance of this cutoff, which further strengthens its clinical relevance.

This study represents one of the largest numbers of patients being analyzed although its retrospective nature can be considered its main limitation. We were unable to use some other prognostic models like APACHE II (Acute Physiology And Chronic Health Evaluation) and Child–Pugh score in the analysis due to the subjective nature of some of the parameters and/or lack of complete laboratory data. Considering that the study spans a duration of 15 years, variation exists in selection criteria used and technique of TIPS performance over the period we have studied. Traditionally, liver function has been considered to be the main determinant of outcome after TIPS. Our study does highlight the role of renal function and the degree of portal hypertension as factors which also play a significant role in determining clinical outcome. A multicenter prospective trial with uniform patient selection criteria will be able to identify these risk factors more accurately.

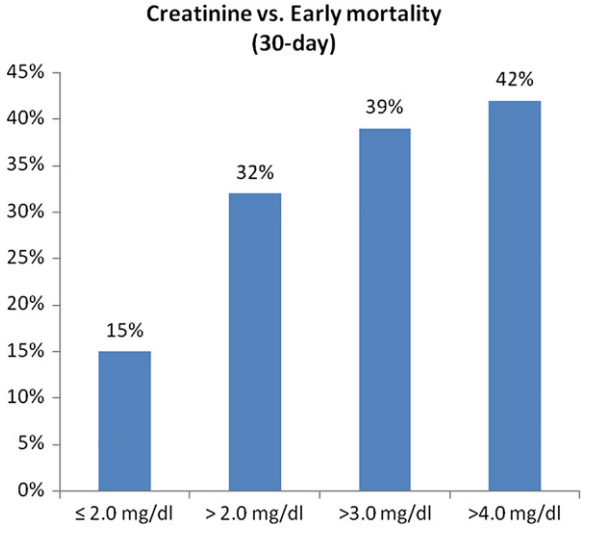

Fig. 3. Bar graph showing incremental 30-day mortality (*y*-axis) with a unit rise in serum creatinine (*x*-axis).

Conclusion

The 30-day and 60-day mortality after TIPS in this study were 17.4% and 22.6%, respectively. Stepwise model selection determined that serum creatinine > 2.0 mg/dL, MELD > 20, and pre-TIPS HVPG > 20 mmHg were independent predictors of early mortality. A pre-TIPS HVPG of more than 20 mmHg was found to be correlated with worsened 30-day and 60-day mortality in patients with variceal bleed but not in patients with ascites or hydrothorax.

Conflict of interest

The author declares that no conflict of interest.

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