National Trends and Outcomes of Transjugular Intrahepatic Portosystemic Shunt Creation Using the Nationwide Inpatient Sample

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ABSTRACT

Purpose: To elucidate trends in transjugular intrahepatic portosystemic shunt (TIPS) use and outcomes over the course of a decade, including predictors of inpatient mortality and extended length of hospital stay.

Materials and Methods: The Nationwide Inpatient Sample was interrogated for the most recent 10 years available: 2003–2012. TIPS procedures and associated diagnoses were identified via International Classification of Diseases (version 9) codes, with the latter categorized into primary diagnoses in a hierarchy of disease severity. Linear regression analysis was used to determine trends of TIPS use and outcomes over time. Independent predictors of mortality and extended length of stay were determined by logistic regression.

Results: A total of 55,145 TIPS procedures were captured during the study period. Annual procedural volume did not change significantly (5,979 in 2003, 5,880 in 2012). The majority of TIPSs were created for ascites and/or varices (84%). Inpatient mortality (12.5% in 2003, 10.6% in 2012; $P < .05$) decreased but varied considerably by diagnosis (from 3.7% to 59.3%), with a disparity between bleeding and nonbleeding varices (18.7% vs 3.8%; $P < .01$). Multivariate predictors of mortality ($P < .001$ for all) included primary diagnoses (bleeding varices, hepatorenal and abdominal compartment syndromes), patient characteristics (age $>$ 80 y, black race), and sequelae of advanced cirrhosis (comorbid hepatocellular carcinoma, spontaneous bacterial peritonitis, encephalopathy, and coagulopathy).

Conclusions: National TIPS inpatient mortality has decreased since 2003 while procedural volume has not changed. Postprocedural outcome is a function of patient demographic and socioeconomic factors and associated diagnoses. Independent predictors of poor outcome identified in this large national population study may aid clinicians in better assessing preprocedural risk.

ABBREVIATIONS

BCS = Budd–Chiari syndrome, eLOS = extended length of stay, HRS = hepatorenal syndrome, ICD-9 = International Classification of Diseases, version 9, NIS = Nationwide Inpatient Sample, TIPS = transjugular intrahepatic portosystemic shunt

Transjugular intrahepatic portosystemic shunt (TIPS) creation plays an important role in treatment of patients with chronic liver disease and portal hypertension. Since the procedure first entered the clinical domain in 1988 (1), thousands of patients worldwide have been treated with TIPS creation (2). National procedural volume and outcomes are not known. Published TIPS data largely emanate from academic centers and reflect a selected patient population, typically with defined inclusion and exclusion criteria. Current TIPS literature therefore may not fully encapsulate practice patterns or outcomes within the larger community of interventionalists treating a broader patient population.

We sought to evaluate national trends in TIPS use and postprocedural outcomes within a representative nonselected national cohort. The major objectives of the study were to determine (*i*) whether procedural volume has increased, (*ii*) whether diagnoses have changed,

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(*iii*) if inpatient mortality has improved, and (*iv*) whether there are predictors of poor outcome.

MATERIALS AND METHODS

Data Source

The Nationwide Inpatient Sample (NIS) is the largest inpatient database in the United States and is a 20% stratified sample originating from all hospitals participating in the Healthcare Cost and Utilization Project, which encompasses more than 95% of the US population. The deidentified administrative discharge dataset is available publicly for purchase from the Agency for Healthcare Research and Quality and contains no patient-level identifiers. Its use for the present study did not meet criteria for human subjects research per institutional review board guidelines and did not undergo review.

Study Population

TIPS procedures were retrospectively extracted from the NIS by their corresponding International Classification of Diseases, version 9 (ICD-9), code, 39.1, for the most recent 10 years available: 2003–2012. No demographic or clinical exclusion criteria were applied. A total of 55,145 TIPS procedures were identified during the study period. Of those, 4,280 (7.8%) did not have a relevant listed diagnosis and were therefore excluded from further analysis, leaving 50,868 in the study group.

Patient demographic characteristics of age, sex, race, and ZIP code income quartile were evaluated (Table 1). ZIP code income quartile, an indirect indicator of economic status, codifies the median household income within the patient's residence ZIP code into four national quartiles, the absolute income ranges for which are updated annually. Hospital characteristics of bed size category, teaching status, and location were evaluated. Hospital location is defined as urban or rural, with the designation determined by the Core Based Statistical Area. Hospital bed size reflects the number of short-term acute-care beds and is adjusted for rural versus urban location. The designation of teaching hospital implies that the hospital has an American Medical Association–approved residency program, is a member of the Council of Teaching Hospitals, or has a ratio of full-time equivalent interns and residents to beds of 0.25 or higher.

Underlying clinical diagnoses were identified by searching the database diagnosis fields for the ICD-9 codes corresponding to the following: gastrointestinal bleeding, bleeding esophageal varices, nonbleeding esophageal varices, ascites, abdominal compartment syndrome, hepatorenal syndrome (HRS), Budd–Chiari syndrome (BCS), portal vein thrombosis, portal hypertension, and hydrothorax. To better ascertain trends over time and the individual contribution of each diagnosis toward inpatient mortality, the following hierarchy of clinical severity was used to assign procedures to a primary diagnosis when more than one pertinent diagnosis code was present: bleeding esophageal varices, gastrointestinal bleeding, HRS, abdominal compartment syndrome, BCS, nonbleeding esophageal varices, hepatic hydrothorax, ascites, portal vein thrombosis, and finally portal hypertension. This hierarchic allocation was developed via author consensus before outcomes analysis was performed.

Pertinent comorbidities among those recorded in the database and the following additional codiagnoses were evaluated: hepatocellular carcinoma (ICD-9 code 155.0), encephalopathy (ICD-9 code 572.2), and spontaneous bacterial peritonitis (ICD-9 code 567.23; Table 2).

Outcome Analysis

Primary outcomes of inpatient mortality and length of stay are reported in the database. Extended length of stay (eLOS) was defined to further evaluate the outlier group requiring greater than 2 standard deviations longer than the median length of stay, which equated to at least 20 days of hospitalization. Variables impacting mortality and eLOS were identified, including those of patient demographics, hospital characteristics, primary diagnosis, and comorbidities.

Statistical Analysis

All statistical analysis was performed with SAS (version 9; SAS, Cary, North Carolina) and STATA (version 11; StataCorp, College Station, Texas) software packages. Trends over time were evaluated by a generalized linear regression model. Categorical variables were compared by Wilcoxon rank-sum test. Multivariate models to identify independent clinical predictors of death and eLOS were developed by backward selection of univariate predictors meeting the threshold of $P < .10$. Results were considered statistically significant if they met the P value threshold of $< .05$.

RESULTS

Study Population

Median age within the TIPS population was 55 years, with 89% of cases in patients between 40 and 80 years of age (Table 1). Men constituted the majority of the TIPS population (65% overall), with the exception of BCS and portal vein thrombosis groups, which were composed of 58% and 52% women, respectively. Racial distribution of patients was similar across primary diagnoses, with white patients accounting for 71% of the TIPS population overall, and Hispanic patients, the second major racial subgroup, accounting for 17%.

There was a negative correlation between average income within patient residential ZIP code and TIPS creation overall (27.6% within the lowest income quartile, 21.8% within the highest income quartile; $P < .001$), primarily because of considerable discrepancy in income

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Table 1. Patient Demographics and Hospital Characteristics for Aggregate TIPS Population and Stratified by Primary Diagnosis

Characteristic	TIPS (Total)	BV	GIB	HRS	COM	BCS	NBV	HHT	Ascites	PVT	pHTN
No. of pts.	50,868	14,999 (29%)	8,690 (17%)	2,132 (4%)	57 (< 1%)	545 (1%)	5,240 (10%)	1,874 (4%)	13,786 (27%)	849 (2%)	2,696 (5%)
Patient demographics											
Age (y)											
Median	55	54	54	57	55	45	56	58	57	50	55
Range	0–101	1–92	0–91	11–83	23–68	0–86	1–90	2–96	0–90	0–80	0–87
Age group (%)											
Age 0–20 y	2.0	1.9	1.4	0.7	0	3.6	3.1	0.2	0.5	24.2	3.5
Age 20–40 y	6.8	7.6	6.8	5.7	32.9	42.3	5.4	3.9	4.2	13.6	8.7
Age 40–60 y	58.8	63.9	62.2	58.7	58.8	33.5	56.4	57.8	59.0	39.6	54.4
Age 60–80 y	30	25.2	27.4	34.0	8.3	16.3	33.2	34.9	33.5	21.4	31.4
Age > 80 y	2.2	1.4	2.0	0.9	0	3.4	1.9	3.2	2.7	0	1.5
Missing data	0.2	0	0.2	0	0	0.9	0	0	0.1	1.2	0.5
Male sex (%)	65.1	71.2	63.7	65.5	65.5	42.4	65.5	53.0	65.2	48.2	64.0
Race (%)											
White	70.6	65.6	70.3	74.2	66.4	70.8	72.6	75.2	74.9	68.4	68.0
Black	5.6	6.2	4.4	6.2	0	7.1	3.9	6.2	5.8	7.2	5.9
Hispanic	17.1	21.2	16.7	14.4	22.1	12.7	16.5	13.4	13.9	19.8	17.5
Asian	2.1	2.4	2.8	1.1	0	2.5	1.7	1.3	1.6	0.8	3.1
Other	4.6	4.6	5.8	4.1	11.5	6.9	5.3	3.9	3.8	3.8	5.5
National ZIP income quartile (%)											
Quartile 1	28.3	30.3	29.3	23.9	27.6	23.5	26.5	28.9	27.6	27.6	25.2
Quartile 2	26.5	27.4	27.5	24.9	27.4	18.8	26.0	33.5	25.9	22.7	25.6
Quartile 3	24.7	24.4	23.8	25.6	45.0	26.2	25.8	21.0	25.1	21.1	26.0
Quartile 4	20.5	17.9	19.4	25.6	0	31.5	21.7	16.6	21.4	28.6	23.2
Hospital characteristic											
Hospital bedsize (%)											
Small	3.9	4.0	3.1	2.8	0	0.9	3.9	3.8	4.2	6.8	4.6
Medium	17.0	18.6	16.9	12.8	8.7	13.7	15.8	12.8	17.5	10.5	16.7
Large	79.1	77.4	80	84.4	91.3	85.4	80.3	83.4	78.3	82.7	78.7
Teaching hospital (%)	75.0	71.6	73.6	78.4	90.5	91.3	79.7	81.9	73.6	92.7	77.6
Urban location (%)	97.9	98.6	97.1	98.3	100	100	98.0	95.6	97.9	99.3	98.2

BCS = Budd–Chiari syndrome; BV = bleeding esophageal varices; COM = abdominal compartment syndrome; GIB = gastrointestinal bleeding; HHT = hepatic hydrothorax; HRS = hepatorenal syndrome; NBV = nonbleeding esophageal varices; pHTN = portal hypertension; PVT = portal vein thrombosis; TIPS = transjugular intrahepatic portosystemic shunt.

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quartile distribution of patients with high-prevalence indications of bleeding varices (30% among the lowest income quartile vs 18% among the highest; $P < .05$) and gastrointestinal bleeding (30% among the lowest income quartile vs 19% among the highest; $P < .05$). The majority of cases were in large (79%) urban (98%) teaching (75%) hospitals. Primary diagnoses of BCS (91%), abdominal compartment syndrome (91%), and portal vein thrombosis (93%) were seen almost exclusively in teaching hospitals.

Coagulopathy (35%) and alcohol abuse (32%) were the most common comorbidities (Table 2). Chronic pulmonary disease (7%), congestive heart failure (5%), renal failure (10%), and diabetes (3%) were comparatively infrequent.

Trends over Time

Annual TIPS volume (5,979 cases in 2003, 5,880 cases in 2012) did not significantly change over time (Fig 1). Ascites and portal hypertension were the most common individual diagnoses (28% each). Following allocation, the most common primary diagnoses were those of bleeding esophageal varices (29%) followed closely by ascites (27%). The majority of TIPSs were created in patients with ascites and/or varices (84%), the latter defined here as primary diagnoses of bleeding esophageal varices, gastrointestinal bleeding, or nonbleeding esophageal varices. The prevalences of gastrointestinal bleeding, HRS, and nonbleeding esophageal varices (all $P < .01$) increased over time before and after allocation into primary diagnoses (Fig 2). Although the annual prevalence of ascites did not significantly change before allocation, it decreased as a primary diagnosis following allocation ($P < .01$). The remaining primary diagnoses did not significantly change over time.

Table 2. Prevalence of Coded Chronic Comorbidities and Codiagnoses within NIS TIPS Population

Comorbidity	Incidence (%)
Coagulopathy	34.9
Alcohol abuse	31.7
Renal failure	9.7
Chronic pulmonary disease	7.3
Depression	6.1
Congestive heart failure	5.2
Diabetes with complications	2.7
Codiagnosis	
Encephalopathy	19.9
Hepatocellular carcinoma	2.7
Spontaneous bacterial peritonitis	2.0

NIS = Nationwide Inpatient Sample; TIPS = transjugular intrahepatic portosystemic shunt.

Outcomes

There was a small but statistically significant decrease in aggregate inpatient mortality rate (12.5% in 2003, 10.6% in 2012; $P < .05$) during the study period (Fig 3). Mortality did not differ by hospital teaching status (11.9% for teaching and nonteaching hospitals) or by location (12.0% urban, 12.5% rural). However, mortality did vary by primary diagnosis (Fig 4), reaching 59% for abdominal compartment syndrome compared with 3.7% for BCS ($P < .001$). Of note, inpatient mortality was markedly different for those with bleeding versus nonbleeding esophageal varices (bleeding varices, 18.7%; nonbleeding varices, 3.8%; $P < .01$).

Median length of stay remained constant at 7 days for all study years, with a wide range of 0–240 days for the aggregate TIPS population. Median length of stay varied considerably by primary diagnosis, at 16 days for HRS compared with 6 days for ascites (Fig 5).

Multivariate predictors of postprocedural inpatient mortality (Table 3) included primary diagnoses (bleeding esophageal varices, HRS, abdominal compartment syndrome) and patient demographics (age > 80 y, black race). Complications of advanced liver disease (hepatocellular carcinoma, encephalopathy, spontaneous bacterial peritonitis, and coagulopathy) were predictive of inpatient mortality and eLOS (Table 3 and 4). Patient age younger than 40 years and residence within the highest-income ZIP codes also predicted eLOS (all $P < .05$; Table 4).

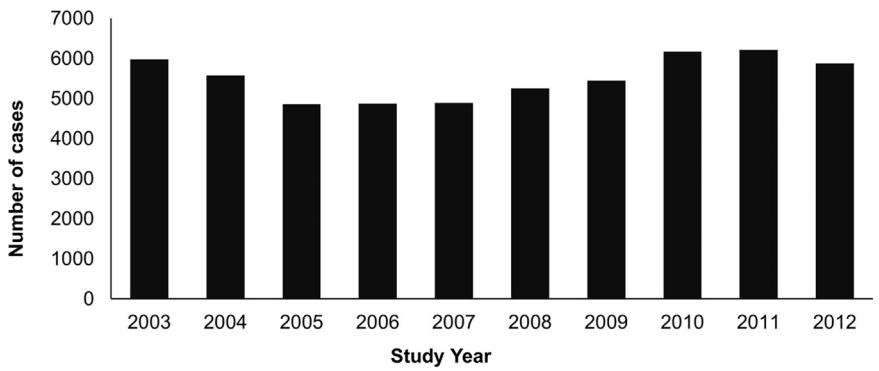

Figure 1. Total number of TIPS procedures identified within the NIS database by study year.

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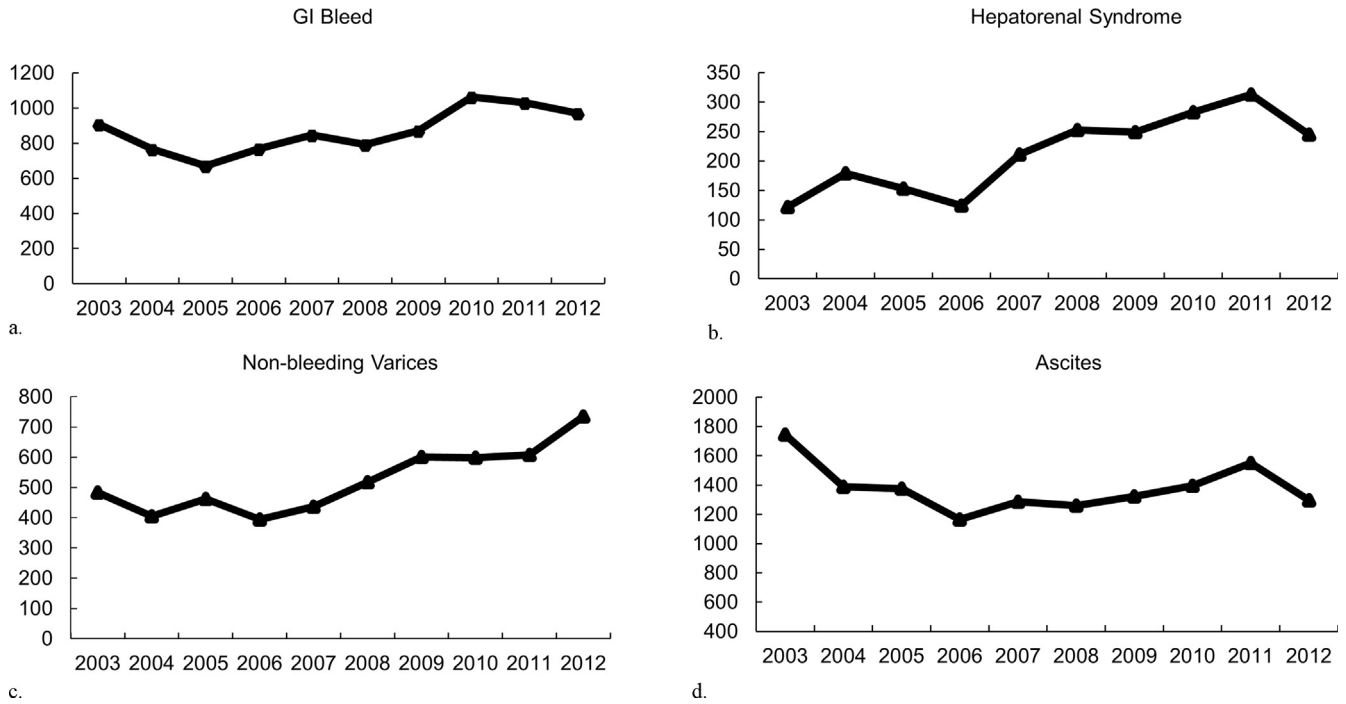

Figure 2. Primary diagnoses show a significant change in prevalence during the study period.

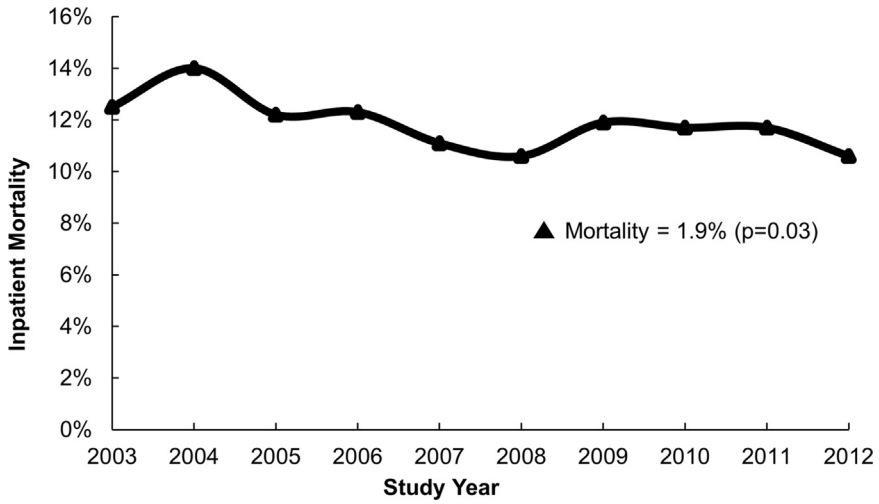

Figure 3. In-hospital mortality following TIPS creation stratified by study year.

DISCUSSION

Annual TIPS volume did not change during the study period, and the majority of shunts were created for patients with the two best-studied indications: ascites and varices.

The increasing prevalence of gastrointestinal bleeding and nonbleeding varices may reflect greater awareness of the benefit of TIPS creation in patients with variceal bleeding who are at high risk of recurrent bleeding (3,4). Similarly, the increase in TIPS creation for HRS is substantiated by studies demonstrating efficacy of the intervention in this high-risk population (5,6). The decrease in the primary diagnosis of ascites is unexpected given that several studies in the past decade have demonstrated superiority of TIPS over repeated large-volume paracentesis for control of chronic ascites (7,8). However, the trend was noted in the present study only after allocation into primary diagnoses and is a consequence of the concomitant increase in gastrointestinal bleeding, nonbleeding varices, and HRS over the same time period rather than a true decrease in disease prevalence.

The hospital mortality rate decreased slightly between 2003 and 2012 (12.5% vs 10.6%; $P < .05$). The major procedural advancements since 2003 include US Food and Drug Administration approval of the polytetrafluoroethylene-covered stent in 2004 (9) and increasing ability to treat patients with previously unfavorable anatomy (10), neither of which are expected to yield

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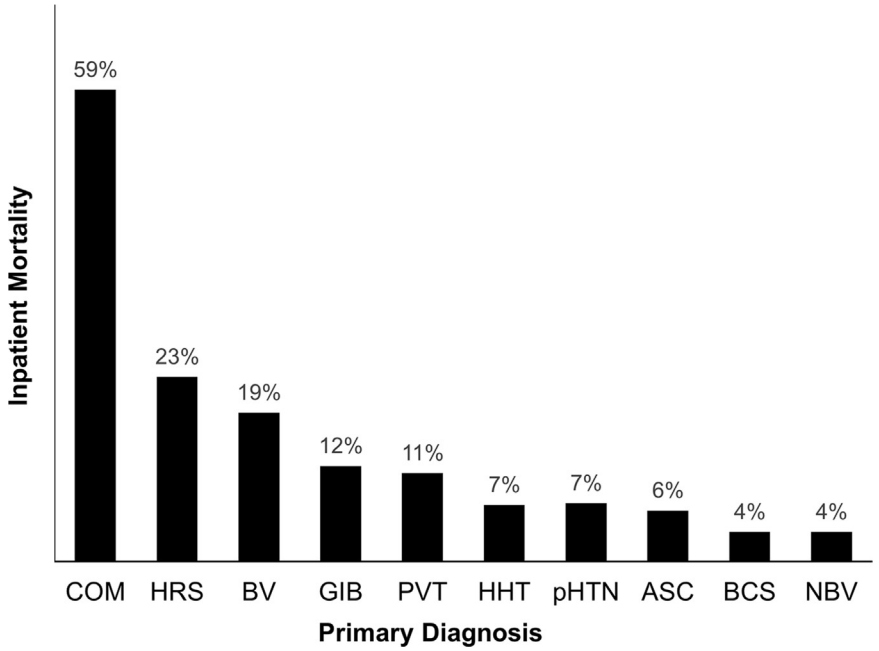

Figure 4. In-hospital mortality following TIPS creation stratified by primary diagnosis.

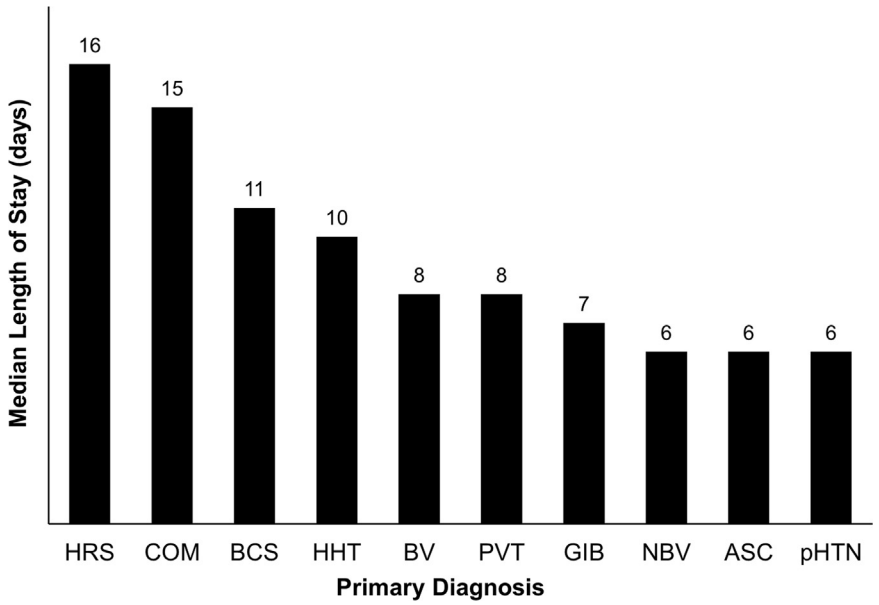

Figure 5. Median length of hospital stay stratified by primary diagnosis.

short-term inpatient mortality improvement. We therefore posit that this decrease reflects improving patient selection and periprocedural management, with the development of procedural guidelines and indications by consensus working groups occurring over the same time period (11,12). That mortality varied considerably by primary diagnosis (**Fig 3**) highlights the heterogeneity of disease severity within this population. Abdominal compartment syndrome, defined as intraperitoneal pressure of greater than 20 mm Hg, was associated with the highest postprocedural mortality rate (59%). Awareness and understanding of this diagnosis is in its infancy, with a consensus definition of it released only recently in 2006 (13) and subsequent ICD-9 code allocation in 2007. Although abdominal compartment syndrome remains a rare clinical diagnosis, prospective single-center screening studies place its prevalence between 19% and 23% among critically ill patients at the time of intensive care unit admission (14). Liver dysfunction, ascites, and gastrointestinal bleeding are independent risk factors for the development of abdominal compartment syndrome (14,15), and it therefore reflects a severe manifestation of these better-understood diagnoses. Importantly, abdominal compartment syndrome is a predictor of poor outcome among critically ill patients, with reported mortality rates as high as 38% in the intensive-care

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Table 3. Independent Predictors of In-Hospital Postprocedural Mortality by Multivariate Logistic Regression Analysis

Predictive Variable	OR (95% CI)	*P* Value
Compartment syndrome	16.7 (5.2–53.5)	< .001
Hepatorenal syndrome	3.1 (2.4–4.0)	< .001
Bleeding varices	2.5 (2.2–2.9)	< .001
Black race	1.8 (1.4–2.3)	< .001
Age > 80 y	1.6 (1.1–2.3)	< .01
Hepatocellular carcinoma	2.3 (1.7–3.0)	< .001
Spontaneous bacterial peritonitis	2.1 (1.5–2.9)	< .001
Encephalopathy	1.7 (1.5–1.9)	< .001
Coagulopathy	1.6 (1.4–1.7)	< .001

CI = confidence interval; OR = odds ratio.

Table 4. Independent Predictors of Extended Hospital Stay by Multivariate Logistic Regression Analysis

Predictive Variable	OD (95% CI)	*P* Value
Hepatorenal syndrome	4.3 (3.2–5.8)	< .001
Hydrothorax	2.3 (1.6–3.4)	< .001
Age < 40 y	1.9 (1.5–2.5)	< .001
Highest ZIP income quartile	1.3 (1.1–1.6)	< .01
Congestive heart failure	1.7 (1.2–2.3)	< .01
Renal failure	1.3 (1.0–1.8)	.03
Spontaneous bacterial peritonitis	2.8 (1.8–4.2)	< .001
Encephalopathy	2.2 (1.8–2.6)	< .001
Hepatocellular carcinoma	1.6 (1.0–2.6)	.04
Coagulopathy	1.3 (1.0–1.5)	.01

CI = confidence interval; OR = odds ratio.

population (14). The inpatient mortality rate of 59% in the present TIPS population is comparatively high, and, in the context of a low relative prevalence of < 1%, suggests underdiagnosis and bias toward recognition of more severe cases.

Among the complications of cirrhosis, HRS is known to carry the worst long-term prognosis. The median survival duration without treatment is poor, at approximately 2 weeks with type 1 disease (16) and 6 months with type 2 disease (17). The HRS definition used here captures both populations, as the ICD-9 code does not differentiate between subtypes. The inpatient mortality rate for the HRS group was 23% in the present study, which is in concordance with the previously reported 3-month mortality rate of 37% for a nondifferentiated type 1 and 2 HRS population treated with TIPS creation (6). HRS was also independently predictive of inpatient mortality and eLOS.

Although TIPS creation is effective as a rescue intervention for patients with refractory bleeding (18), the underlying severity of liver disease and further deterioration in liver function following TIPS creation results in a high 3-month mortality rate of 30% despite intervention (19). Among patients undergoing TIPS creation for varices, the majority presented with bleeding varices, and the mortality rate was substantially higher in this group than in those with nonbleeding varices (18.7% vs 3.8%; $P < .01$) despite the fact that diagnostic coding does not reflect the extent of hemorrhage or the number of previous bleeding episodes or interventions. The diagnosis of bleeding varices was also independently predictive of inpatient mortality. Going forward, a potential avenue of improvement in outcomes therefore lies in shifting the proportion of patients requiring a TIPS toward those with nonbleeding rather than bleeding varices by identifying patients at high risk. This notion is corroborated by two studies (3,4) demonstrating reduction in mortality with early TIPS creation in patients presenting with variceal bleeding who are at high risk for recurrent bleeding.

Most patients who undergo TIPS creation have more than one sequela of liver disease, and, although the procedure serves to address the one that confers greatest immediate morbidity and mortality, data from the present study suggest that postprocedural outcome is a function of patient demographic and socioeconomic characteristics and the collective diagnostic burden. Patients older than 80 years constituted only 2% of the TIPS population and had an expectedly higher risk of mortality. Black race was also independently predictive of mortality, a finding that raises serious concern and is without an obvious clinical explanation. The negative correlation between patient income ZIP code quartile and TIPS creation is a result of the comparatively high incidence of bleeding varices and gastrointestinal bleeding among patients within the lowest income quartile. Analysis of this finding is beyond the scope of the present study, but its economic underpinnings raise the question of disproportionate access to care resulting in delayed or emergent presentation. Residence within the highest income ZIP code quartile predicted eLOS independent of all covariates, including underlying diagnoses. That codiagnoses of hepatocellular carcinoma, coagulopathy, encephalopathy, and spontaneous bacterial peritonitis were all independently predictive of mortality and eLOS indicates the larger role of chronic liver disease and its complications even in early postprocedural prognosis.

The present study has several important limitations. Eight percent of the TIPS population was excluded from analysis because of the absence of a relevant coded diagnosis. To determine the role of individual diagnoses, rather than diagnostic clusters, in postprocedural outcome, a system of allocation into groups of primary diagnoses based on associated clinical severity was developed via author consensus. The allocation system predominantly affects trends for diagnoses lower within the hierarchy, accounting for the relative decrease in prevalence of ascites as a primary diagnosis. Multiple diagnosis codes may be used for a single patient encounter, and which diagnosis was considered the procedure indication cannot be ascertained. The NIS does not quantify disease severity to allow calculation of prognostic indices

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such as Model for End-stage Liver Disease score. Analysis is further limited by possible institutional variation in ICD-9 coding. Because coding within the NIS is used for reimbursement, reporting of higher-severity and higher-reimbursement diagnoses may be favored (20).

In summary, annual TIPS volume did not change between 2003 and 2012. National inpatient mortality decreased slightly and varies considerably by associated diagnoses. Patient demographic characteristics, comorbidities, socioeconomic status, and severity of underlying liver disease all contribute to postprocedural outcome.

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