Ethnoracial Disparity in Hospital Survival following Transjugular Intrahepatic Portosystemic Shunt Creation for Acute Variceal Bleeding in the United States

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ABSTRACT

Purpose: To investigate the magnitude of racial/ethnic differences in hospital mortality after transjugular intrahepatic portosystemic shunt (TIPS) creation for acute variceal bleeding and whether hospital care processes contribute to them.

Methods: Patients aged ≥18 years undergoing TIPS creation for acute variceal bleeding in the United States (n = 10,331) were identified from 10 years (2007–2016) available in the National Inpatient Sample. Hierarchical logistic regression was used to examine the relationship between patient race and inpatient mortality, controlling for disease severity, treatment utilization, and hospital characteristics.

Results: A total of 6,350 (62%) patients were White, 1,780 (17%) were Hispanic, and 482 (5%) were Black. A greater proportion of Black patients were admitted to urban teaching hospitals (Black, n = 409 (85%); Hispanic, n = 1,310 (74%); and White, n = 4,802 (76%); $P < .001$) and liver transplant centers (Black, n = 215 (45%); Hispanic, n = 401 (23%); and White, n = 2,267 (36%); $P < .001$). Being Black was strongly associated with mortality (Black, 32% vs non-Black, 15%; odds ratio, 3.0 [95% confidence interval, 1.6–5.8]; $P = .001$), as assessed using the risk-adjusted regression model. This racial disparity disappeared in a sensitivity analysis including only patients with a maximum Child-Pugh score of 13 (odds ratio 1.2 [95% confidence interval, 0.4–3.6]; $P = .68$), performed to compensate for the absence of Model for End-stage Liver Disease scores. Ethnoracial differences in access to teaching hospitals, liver transplant centers, first-line endoscopy, and transfusion did not significantly contribute ($P > .05$) to risk-adjusted mortality.

Conclusions: Black patients have a 2-fold higher inpatient mortality than non-Black patients following TIPS creation for acute variceal bleeding, possibly related to greater disease severity before the procedure.

ABBREVIATIONS

APR-DRG = All Patients Refined Diagnosis Related Groups, CI = confidence interval, HCUP = Healthcare Cost and Utilization Project, ICD = International Classification of Diseases, NIS = National Inpatient Sample, TIPS = transjugular intrahepatic portosystemic shunt

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Tables E1-E3 and Figure E1 can be found by accessing the online version of this article on *www.jvir.org* and selecting the Supplemental Material tab.

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RESEARCH HIGHLIGHTS

- In this cross-sectional study of 10,331 hospitalizations for transjugular intrahepatic portosystemic shunt (TIPS) creation for acute variceal bleeding, the effect of racial/ethnic differences on risk-adjusted hospital mortality was quantified.
- Patient factors (socioeconomic status, comorbidities), hospital structures (teaching hospitals, liver transplant centers), and processes of care (endoscopic management, transfusion) were assessed for their association with mortality.
- Black patients had 3-fold higher mortality, but not in the subset with maximal Child-Pugh score.
- Variations in care processes were not associated with mortality.
- Black patients have worse survival after TIPS creation for acute variceal bleeding, possibly reflecting greater severity of disease at the time of the procedure.

STUDY DETAILS

Study type: retrospective, observational, cross-sectional

American and European guidelines currently recommend transjugular intrahepatic portosystemic shunt (TIPS) creation in patients with variceal bleeding that cannot be controlled endoscopically and in those at high risk of rebleeding (1,2). Randomized controlled trial data have indicated that TIPS creation reduces rebleeding and offers a significant survival advantage over endoscopic management in high-risk patients with variceal bleeding (3–6). However, in a prior observational study reporting the real-world outcomes of TIPS creation in the United States, being classified as black was strongly predictive of mortality (7). With increasing awareness of the intrinsic biases and social determinants of health impacting patient outcomes, race-based inequities require a focused study.

The objective of this study was to, first, quantify the magnitude of racial/ethnic inequity in survival following TIPS creation for variceal bleeding and, second, analyze whether hospital care processes or structures of care are associated with it. Specifically, 3 study questions were considered. First, are there racial/ethnic differences in hospital characteristics for TIPS admissions? Second, are Black and/or minority patients less likely to receive first-line treatment with endoscopy and blood product repletion prior to TIPS, and, if so, to what extent does that contribute to a mortality gap? Finally, is all-cause inpatient mortality after TIPS creation for variceal bleeding higher for Black and/or minority patients than for White patients, adjusting for demographics, comorbid risk factors, and disease severity?

MATERIALS AND METHODS

Data Source

This study was deemed exempt by our institutional review board. Discharge data from the National Inpatient Sample (NIS) of the Healthcare Cost and Utilization Project (HCUP) (8,9), created by the Agency for Healthcare Research and Quality, were used as the data source. The NIS is a 20% stratified sample of all nonfederal hospitals in 44 participating states, encompassing >95% of the U.S. population. Clinical, resource use, and billing data submitted to statewide agencies by hospitals are aggregated in a survey-weighted national sample.

Study Cohort

All patients aged ≥18 years admitted with a principal diagnosis of acute variceal bleeding treated with TIPS creation in the last 10 years (2007–2016) available in the NIS (n = 10,331) were included. White patients accounted for 62% (n = 6,350), Hispanic patients for 17% (n = 1,780), and Black patients for 5% (n = 482) of these admissions. Asian (n = 153, 1.5%), Native American (n = 153, 1.5%), and other races (n = 333, 3.2%) constituted a smaller proportion of the population. Race/ethnicity information was missing in 10% of records (n = 1,079). Overall, 71% of the patients (n = 7,334) were men (**Table 1**). Compared with White patients, Black and Hispanic patients had a higher proportion of encounters belonging to the lowest income quartile (Black, n = 282 (59%); Hispanic, n = 809 (45%); and White, n = 1,837 (29%)), had Medicaid as their payer (Black, n = 164 (34%); Hispanic, n = 616 (35%); and White, n = 1,339 (21%)), and presented to a densely populated (>1 million) metropolitan hospital (Black, n = 206 (43%); Hispanic, n = 892 (50%); and White, n = 1,619 (25%)).

Primary discharge diagnosis, procedure codes, and complications were identified using the International Classification of Diseases, ninth (ICD-9) and 10th (ICD-10) revision codes, summarized in **Table E1** (available online on the article's Supplemental Material page at *www.jvir.org*).

Patient Characteristics and Clinical Severity

Data on patient age, sex, race, primary payer, and median annual household income were extracted from the NIS. Patient race was self-reported and provided by most participating hospitals in the discharge survey. ICD-9/10 codes were used to identify clinical risk factors (10–16) associated with increased mortality in patients receiving TIPS: congestive heart failure, chronic pulmonary disease, pulmonary hypertension, coagulopathy, alcohol abuse, hepatocellular carcinoma, spontaneous bacterial peritonitis, hepatic encephalopathy, ascites, sarcopenia, and portal vein thrombus. The Agency for Healthcare Research and Quality's comorbidity software provided by the HCUP (17) was

Table 1. Demographics, Income Level, Payer Information, Comorbid Risk Factors, and Disease Severity Scores Stratified by the Race of Patients Undergoing TIPS Creation for Acute Variceal Bleeding in the United States between 2007 and 2016.

Patient characteristics	Overall (n = 10,331)	White (n = 6,350)	Black (n = 482)	Hispanic (n = 1,780)	*P* value
Age (median, range) (y)					<.001
18–40	825 (8.0%)	414 (6.5%)	38 (7.9%)	215 (12.1%)	
40–60	6,218 (60.2%)	3,770 (59.4%)	338 (70.1%)	1,114 (62.6%)	
60–80	3,127 (30.3%)	2,059 (32.4%)	106 (21.9%)	426 (23.9%)	
>80	161 (1.6%)	107 (1.7%)	NA	25 (1.4%)	
Sex					.640
Male	7,334 (71.0%)	4,547 (71.6%)	338 (70.2%)	1,259 (70.7%)	
Female	2,997 (29.0%)	1,803 (28.4%)	144 (29.8%)	521 (29.3%)	
Median zip code income					<.001
Quartile 1 (lowest)	3,435 (33.3%)	1,837 (28.9%)	282 (58.5%)	808 (45.4%)	
Quartile 2	2,861 (27.7%)	1,849 (29.1%)	87 (18.1%)	520 (29.2%)	
Quartile 3	2,216 (21.5%)	1,406 (22.1%)	74 (15.3%)	297 (16.7%)	
Quartile 4 (highest)	1,521 (14.7%)	1,088 (17.1%)	34 (7.1%)	131 (7.3%)	
Missing	289 (2.8%)	170 (2.7%)	X* (X.X%)*	24 (1.4%)	
Expected primary payer					<.001
Private	2,959 (38.6%)	1,989 (31.3%)	103 (21.3%)	349 (19.6%)	
Medicare	3,106 (30.1%)	2,007 (31.6%)	134 (27.8%)	432 (24.3%)	
Medicaid	2,541 (24.6%)	1,339 (21.1%)	164 (34.1%)	616 (34.6%)	
Self-pay	981 (9.5%)	532 (8.4%)	52 (10.7%)	253 (14.2%)	
No charge	107 (1.0%)	50 (0.8%)	29 (6.1%)	48 (2.7%)	
Other	612 (5.9%)	413 (6.5%)	NA	77 (4.3%)	
Missing	25 (0.2%)	20 (0.3%)	NA	X* (X.X%)*	
Comorbid risk factors					
Ascites	4,302 (41.6%)	2,843 (44.8%)	196 (40.6%)	629 (35.3%)	.005
Portal vein thrombus	692 (6.7%)	427 (6.7%)	50 (10.3%)	64 (3.6%)	.023
Spontaneous bacterial peritonitis	280 (2.7%)	186 (2.9%)	25 (5.1%)	40 (2.3%)	.331
Hepatic encephalopathy	2,395 (23.2%)	1,518 (23.9%)	97 (20.0%)	356 (20.0%)	.228
Hepatorenal syndrome	333 (3.2%)	208 (3.3%)	20 (4.1%)	45 (2.5%)	.664
Hepatocellular carcinoma	284 (2.8%)	147 (2.3%)	44 (9.2%)	54 (3.0%)	<.001
Sarcopenia	15 (0.1%)	10 (0.2%)	NA	NA	.698
Congestive heart failure	432 (4.8%)	287 (5.2%)	X* (X.X%)*	66 (4.5%)	.410
Pulmonary circulation disease	268 (3.0%)	161 (2.9%)	15 (3.3%)	54 (3.7%)	.014
Chronic pulmonary disease	1,233 (13.8%)	880 (16.0%)	48 (11.1%)	140 (9.6%)	.766
Coagulopathy	4,788 (53.7%)	2,694 (53.9%)	205 (46.8%)	841 (57.8%)	.165
Alcohol abuse	5,151 (57.8%)	3,172 (57.7%)	264 (60.3%)	895 (61.5%)	.467
Drug abuse	574 (6.4%)	333 (6.1%)	49 (11.2%)	119 (8.2%)	.102
Deyo-Charlson score*	4 [4–5]	5 [4–5]	4 [4–6]	5 [4–5]	.184
APR-DRG mortality risk					<.001
Minor	NA	NA	NA	NA	
Moderate	793 (7.7%)	456 (7.2%)	43 (8.9%)	157 (8.8%)	
Major	3,986 (38.6%)	2,434 (38.3%)	149 (30.9%)	744 (41.8%)	
Extreme	4,503 (43.6%)	2,721 (42.9%)	235 (48.8%)	729 (41.0%)	
Missing	1,050 (10.2%)	740 (11.6%)	55 (11.4%)	150 (8.4%)	
APR-DRG severity of illness					<.001
Minor	NA	NA	NA	NA	
Moderate	392 (3.8%)	245 (3.9%)	29 (6.0%)	69 (3.9%)	
Major	3,498 (33.9%)	2,099 (33.1%)	128 (26.6%)	702 (39.4%)	
Extreme	5,391 (52.2%)	3,266 (51.4%)	270 (55.9%)	860 (48.3%)	
Missing	1,050 (10.2%)	740 (11.6%)	55 (11.4%)	150 (7.4%)	

APR-DRG = All Patients Refined Diagnosis Related Groups; HCUP = Healthcare Cost and Utilization Project; NA = not applicable.
*Small cell counts (n $\leq$ 10) have been suppressed from presentation in compliance with the HCUP data use agreement.

used to identify 29 Elixhauser comorbidities using ICD-9-CM codes, 17 of which were also used to calculate the Charlson comorbidity index (18), summarized in **Table E2** (available online at *www.jvir.org*). Finally, the All Patients Refined Diagnosis Related Groups (APR-DRG) severity of illness and mortality risk scores were extracted from the NIS severity files for the adjustment of mortality risk. The APR-DRG is a proprietary formula developed by 3M for severity adjustment in the NIS and has specifically been validated as the best predictor of in-hospital mortality among cirrhotic patients (19). The 3M formula stratifies mortality risk into 4 categories (I–IV): minor, moderate, major, and extreme risk of dying. Important to note, the risk score is a reflection of the patient's disease process (interaction between diagnoses) and is independent of treatments employed during hospitalization (20).

Hospital Characteristics and Treatment Utilization

The hospital characteristics of interest extracted from the NIS included hospital bed size, location and teaching status (urban/rural and teaching/nonteaching), and admission to a liver transplant center. Transplant centers were identified by searching the entire NIS database for the presence of a liver transplant code (ICD-9 50.51 and 50.59, ICD-10 0FY00Z0) billed by the hospital at any time in each calendar year. Additional hospital characteristics of census-designated regions (northeast, midwest, south, and west) and county population size were also extracted and used for risk adjustment in regression models.

The hospital processes of interest included first-line treatments for variceal bleeding (endoscopy and blood transfusions) and the timing of TIPS creation after admission. The use of endoscopy and blood transfusions was identified using the ICD-9/10 codes detailed in **Table E1** (available online at *www.jvir.org*). Each procedure has a corresponding day of performance codified in the NIS. This variable (PRDay) was used to calculate the timing of TIPS creation, in days, from the time of admission.

Mortality

The primary outcome was in-hospital mortality after TIPS creation for acute variceal bleeding. Procedural complications were secondarily identified using the ICD-9/10 codes detailed in **Table E1** (available online at *www.jvir.org*).

Statistics and Sensitivity Analysis

The structure of the dataset, distribution of data values, presence of outliers, and relationships between different variables were explored using data visualization techniques to ensure data integrity prior to analysis. Continuous variables were reported as means and standard deviation and compared using survey-weighted *t* tests or analysis of variance. Categorical variables were reported as number and percentages and compared using survey-weighted chi-squared or Fisher exact tests. To test the association between patient's race and inpatient mortality, hierarchical logistic regression, controlling for baseline differences in the patient demographics, comorbid risk factors, APR-DRG mortality risk, Charlson score, and treatment utilization metrics (number of endoscopies and number of transfusions) were used, while accounting for clustering at the hospital level. The SAS PROC GLIMMIX procedure was used, with adaptive quadrature to fit the true log-likelihood function, with 10 quadrature points and standard errors calculated empirically. Based on the report titled "HCUP Methods Series – Hierarchical Modeling using HCUP Data" (21), sampling weights were not incorporated into this longitudinal analysis. Because of the observation of a nonlinear relationship between the number of blood transfusions and mortality in patients with variceal bleeding, both linear and quadratic terms for the blood transfusion variable were included in the model. Next, a sensitivity analysis was performed to assess the dependence of mortality after the procedure on unmeasured disease severity because the primary methodological limitation of the study is the absence of a patient-specific model for end-stage liver disease or Child-Pugh severity scores for risk adjustment before the procedure. For this secondary analysis, all patients with ascites were excluded, limiting the possible Child-Pugh score to 13 (22). The remaining patients, therefore, fell within the ideal guideline-recommended range for TIPS creation (2).

The association between mortality and race, stratified by the time to TIPS creation was analyzed using the Cochran-Mantel-Haenszel test. Finally, to assess the contribution of baseline racial/ethnic differences to the processes of care or of the hospital characteristics to mortality after TIPS creation, interaction terms between race and the variables of interest were analyzed using the aforementioned regression model. However, these interaction terms were only included in the final model if they were statistically significant. SAS, version 9.4 (SAS Institute, Cary, North Carolina), and R 3.6.0 (R Foundation for Statistical Coding, Vienna, Austria) were used for data management, analysis, and visualization. Results were considered statistically significant if they met a P value threshold of $<.05$.

RESULTS

Clinical Severity

The most common comorbid risk factors were alcohol abuse (n = 5,151, 58% overall), coagulopathy (n = 4,788, 54% overall), ascites (n = 4,302, 42%), and hepatic encephalopathy (n = 2,395, 23%). Black and Hispanic patients were slightly less likely to have ascites (Black, n = 196 (41%); Hispanic, n = 629 (35%); and White, n = 2,843 (45%); P = .005) and hepatic encephalopathy (Black, n = 97 (20%); Hispanic, n = 356 (20%); and White, n = 1,518 (24%); P = .228) and more likely to have documented alcohol abuse (Black, n = 264 (60%); Hispanic, n = 895 (62%); and White, n = 3,172 (58%); P = .467) than White patients. Hepatocellular carcinoma, a relative contraindication to TIPS creation, was an uncommon comorbidity overall but more frequently seen among Black patients (Black, n = 44

Table 2. Hospital Characteristics—Bed Size, Location/Teaching Status, Geographic Census Region, Population Size of County Served by the Hospital, and Liver Transplant Center Status—Stratified Here by the Race of Patients Undergoing Transjugular Intrahepatic Portosystemic Shunt Creation for Acute Variceal Bleeding in the United States between 2007 and 2016.

Hospital characteristics	Overall (n = 10,331)	White (n = 6,350)	Black (n = 482)	Hispanic (n = 1,780)	*P* value
Bed size					<.001
Small bed size	496 (4.8%)	318 (5.0%)	37 (7.6%)	103 (5.8%)	
Medium bed size	2,142 (20.7%)	1,172 (18.5%)	109 (22.3%)	525 (29.5%)	
Large bed size	7,657 (74.1%)	4,832 (76.1%)	333 (68.9%)	1,152 (64.7%)	
Missing	36 (0.4%)	27 (0.4%)	X* (X.X%)*	NA	
Location/teaching status					<.001
Rural	101 (1.0%)	81 (1.3%)	NA	NA	
Urban nonteaching	2,206 (21.3%)	1,440 (22.7%)	69 (14.4%)	470 (26.4%)	
Urban teaching	7,989 (77.3%)	4,802 (75.6%)	409 (84.7%)	1,310 (73.6%)	
Missing	36 (0.3%)	27 (0.4%)	X* (X.X%)*	NA	
Census region					<.001
Northeast	2,038 (19.7%)	1,156 (18.2%)	101 (20.9%)	104 (5.8%)	
Midwest	1,759 (17.0%)	1,242 (19.6%)	104 (21.5%)	194 (10.9%)	
South	4,504 (43.6%)	2,867 (45.1%)	234 (48.4%)	943 (53.0%)	
West	2,030 (19.7%)	1,085 (17.1%)	44 (9.1%)	539 (30.3%)	
County population					<.001
Central, >1 million	3,189 (30.9%)	1,619 (25.5%)	206 (42.7%)	892 (50.1%)	
Fringe, >1 million	2,025 (19.6%)	1,344 (21.2%)	126 (26.0%)	210 (11.8%)	
Metro, 250k–499k	2,405 (23.3%)	1,527 (24.0%)	101 (20.9%)	430 (24.2%)	
Metro, 50k–249k	820 (7.9%)	577 (9.1%)	20 (4.2%)	94 (5.3%)	
Micro	1,018 (9.9%)	715 (11.3%)	19 (3.9%)	98 (5.5%)	
Not metro/micro	669 (6.8%)	452 (7.1%)	X* (X.X%)*	44 (2.5%)	
Missing	174 (1.7%)	117 (1.8%)	X* (X.X%)*	12 (0.7%)	
Transplant center					<.001
No	6,701 (64.9%)	4,083 (64.3%)	267 (55.5%)	1,380 (77.5%)	
Yes	3,630 (35.1%)	2,267 (35.7%)	215 (44.5%)	401 (22.5%)	

HCUP = Healthcare Cost and Utilization Project.
*Small cell counts (n ≤ 10) have been suppressed from presentation in compliance with the HCUP data use agreement.

(9%); Hispanic, n = 54 (3%); and White, n = 147 (2%); $P < .001$). With respect to mortality risk scores, a greater proportion of Black patients belonged to the highest "extreme" categories of disease severity (Black, n = 270 (63%); Hispanic, n = 860 (53%); and White, n = 3,266 (58%); $P < .001$) and mortality risk (Black, n = 235 (55%); Hispanic, n = 729 (45%); and White, n = 2,721 (49%); $P < .001$), as assessed by the NIS-specific APR-DRG.

Hospital Characteristics

The hospital characteristics are summarized based on patient's race in Table 2. A greater proportion of Black patients were admitted to urban teaching hospitals (Black, n = 409 (85%); Hispanic, n = 1,310 (74%); and White, n = 4,802 (76%); $P < .001$) and liver transplant centers (Black, n = 215 (45%); Hispanic, n = 401 (23%); and White, n = 2,267 (36%); $P < .001$).

Hospital Processes of Care

There were small, albeit statistically significant, differences in the use of first-line endoscopy and blood transfusion across the race groups (Table 3). Most patients underwent a single endoscopy prior to TIPS creation (Black, n = 229 (50%); Hispanic, n = 1,018 (59%); and White, n = 2,925 (48%)), and a relative minority underwent ≥2 endoscopies (Black, n = 68 (15%); Hispanic, n = 144 (8%); and White, n = 707 (12%)). The time to TIPS creation was longer for Black patients than for all the other races (a mean of 4.1 days for Black, 2.8 days for White, and 2.5 days for Hispanic patients; $P = .09$).

Mortality Based on Race

Black patients had >2-fold higher mortality following TIPS creation for acute variceal bleeding than all the other races (Black, n = 142/462 (30%); Hispanic, n = 266/1,737 (15%); and White, n = 857/6,039 (14%); Fig). Liver failure was the most common procedural complication (n = 564, 5.5% overall) and was seen more frequently among Black patients (Black, n = 44 (9%); Hispanic, n = 70 (4%); and White, n = 342 (5%); $P = .113$). Procedural hemorrhage occurred in 1% of the patients overall and did not significantly vary by race (Black, n = 0 (0%); Hispanic, n = 19 (1%); and White,

Table 3. Treatment Utilization Metrics of Interest—Number of Endoscopies, Number of Blood Transfusions, and Timing of TIPS Creation—Stratified by the Race of Patients Undergoing Transjugular Intrahepatic Portosystemic Shunt Creation for Acute Variceal Bleeding in the United States between 2007 and 2016.

Treatment utilization	Overall (n = 10,331)	White (n = 6,350)	Black (n = 482)	Hispanic (n = 1,780)	*P* value
No. of endoscopies					<.001
0	3,638 (38.6%)	2,408 (39.9%)	165 (35.8%)	576 (33.1%)	
1	4,714 (50.0%)	2,925 (48.4%)	229 (49.6%)	1,018 (58.6%)	
2	905 (9.6%)	593 (9.8%)	58 (12.6%)	120 (6.9%)	
3	126 (1.3%)	79 (1.3%)	X* (X.X%)*	24 (1.4%)	
>4	45 (0.5%)	35 (0.6%)	X* (X.X%)*	NA	
No. of blood transfusions					<.001
0	4,732 (50.2%)	3,190 (52.8%)	224 (48.4%)	657 (37.8%)	
1	2,185 (23.2%)	1,355 (22.4%)	96 (20.7%)	449 (25.9%)	
2	1,602 (17.0%)	981 (16.2%)	88 (19.0%)	396 (22.8%)	
3	785 (8.3%)	439 (7.3%)	50 (10.7%)	220 (12.7%)	
>4	125 (1.3%)	75 (1.2%)	X* (X.X%)*	14 (0.8%)	
Time to TIPS (d)[†]	2.9 [4.2]	2.8 [4.2]	4.1 [5.4]	2.5 [2.6]	.09

Note–Categorical data presented as n (%).
HCUP = Healthcare Cost and Utilization Project; TIPS = transjugular intrahepatic portosystemic shunt.
*Small cell counts (n ≤ 10) have been suppressed from presentation in compliance with the HCUP data use agreement.
[†]Time to TIPS presented as mean [standard deviation].

n = 67 (1%); *P* = .988). Cardiac arrest during the procedure (n = 48, 0.5% overall), shock (n = 40, 0.4% overall), and infection (n = 16, 0.2% overall) were not common.

In the risk-adjusted hierarchical multivariable logistic regression model (**Table 4**), the Black race was strongly associated with mortality after the procedure (odds ratio, 3.0 [95% confidence interval {CI}, 1.6–5.8]; *P* = .001). No other patient-level factor was predictive of mortality, including age, sex, other races, household income level, or primary payer type. The highest APR-DRG mortality risk category was strongly associated with death (odds ratio, 56.6 [95% CI, 7.7–414.1]; *P* < .001), providing some internal validity for its utility as a risk adjustment tool for this population.

Upon examination of the hospital structures, no significant association was observed between admission to teaching hospitals or liver transplant centers and risk-adjusted mortality after TIPS creation. Additionally, the interaction terms for Black race and nonteaching hospital (odds ratio, 1.6 [95% CI, 0.3–9.0]; *P* = .624) and for Black race and liver transplant center (odds ratio, 0.7 [95% CI, 0.2–3.0]; *P* = .664) did not predict mortality.

Upon examination of the hospital care processes, the number of billed transfusions was found to be quadratically associated with mortality (odds ratio, 1.3 [95% CI, 1.1–1.5]; *P* < .001). Since the time from admission to TIPS creation was significantly longer among Black patients, a secondary analysis was performed to assess the impact of TIPS timing on mortality. Overall, a longer time to TIPS creation was not associated with higher mortality (**Fig E1** [available online at *www.jvir.org*]). Black patients who received TIPS within 72 hours had significantly higher mortality (Black, n = 93 (33%); Hispanic, n = 222 (18%); and White, n = 739

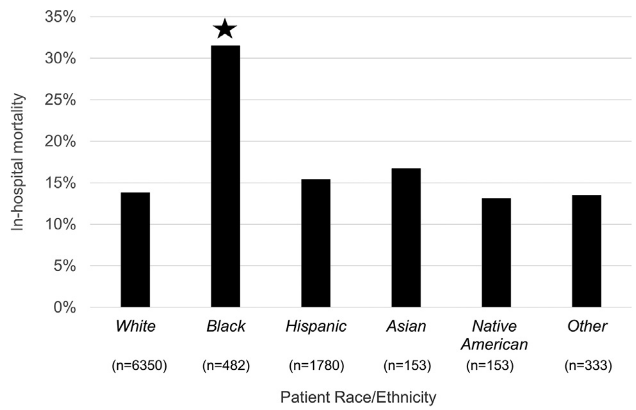

Figure. Unadjusted in-hospital mortality based on the race of patients undergoing transjugular intrahepatic portosystemic shunt creation for acute variceal bleeding in the United States (2007–2016). The total number of encounters for each race/ethnicity category is numerated between brackets. **P* < .001 Black versus non-Black.

(17%); *P* < .001), and there was a general trend towards lower mortality for all patients with TIPS creation *after* 72 hours (**Fig E1** [available online at *www.jvir.org*]). Accordingly, neither increasing the time to TIPS creation (odds ratio, 0.96 [95% CI, 0.92–1.00]; *P* = .097) nor its interaction with the Black race (odds ratio, 0.99 [95% CI, 0.88–1.12]; *P* = .923) was significantly associated with risk-adjusted mortality after the procedure.

Sensitivity Analysis

Among patients without ascites (a maximum possible Child-Pugh score of 13), mortality varied less by race (Black, n =

Table 4. Results of Survey-Weighted Multivariable Logistic Regression Testing the Association between the Covariates of Interest and the Outcome of In-Hospital Mortality for the Study Population.

Covariate	Odds ratio	95% CI	*P* value
Age, centered (y)	0.99	(0.98–1.01)	.621
Reference (male)			
Female	0.87	(0.60–1.27)	.470
Reference (White)			
Black	3.01	(1.55–5.84)	.001
Hispanic	1.41	(0.90–2.21)	.130
Asian or Pacific Islander	0.61	(0.16–2.38)	.480
Native American	0.37	(0.07–2.06)	.258
Other race	0.83	(0.30–2.29)	.722
Missing race	0.83	(0.41–1.68)	.605
Reference (quartile 1)			
Household income quartile 2	1.01	(0.65–1.56)	.965
Household income quartile 3	0.87	(0.55–1.39)	.571
Household income quartile 4	1.09	(0.64–1.85)	.760
Reference (private insurance)			
Medicaid	0.65	(0.42–1.03)	.068
Medicare	0.73	(0.45–1.17)	.190
Other primary payer	0.82	(0.49–1.36)	.436
Reference (urban teaching)			
Urban nonteaching	0.94	(0.60–1.45)	.764
Rural	2.29	(0.53–9.98)	.268
Reference (northeast region)			
Midwest region	1.40	(0.81–2.42)	.235
South region	1.05	(0.65–1.71)	.834
West region	1.36	(0.80–2.32)	.255
Reference (central counties, >1M)			
Fringe counties >1M population	0.98	(0.62–1.57)	.946
Metro counties 250k–499k population	1.01	(0.64–1.60)	.959
Metro counties 50K–249K population	0.68	(0.32–1.43)	.304
Micro counties	0.33	(0.14–0.77)	.010
Not metro or micro	0.80	(0.36–1.75)	.576
Reference (primary admission)			
Transfer into hospital	1.12	(0.74–1.70)	.578
Reference (APR-DRG risk mortality moderate)			
APR-DRG risk mortality major	2.24	(0.29–17.68)	.443
APR-DRG risk mortality extreme	56.58	(7.73–414.06)	<.001
Number of endoscopies	1.02	(0.62–1.69)	.934
Number of endoscopiesˆ2	1.01	(0.82–1.24)	.948
Number of transfusions*	0.5	(0.38–0.91)	.017
Number of transfusionsˆ2*	1.29	(1.12–1.48)	<.001
Day of TIPS procedure	0.96	(0.92–1.01)	.097
Reference (nontransplant center)			
Transplant center	1.43	(0.96–2.13)	.081
Ascites	0.80	(0.57–1.12)	.195
Hepatic encephalopahy	0.77	(0.53–1.10)	.154
Hepatic vein thrombus	0.69	(0.35–1.34)	.270

APR-DRG = All Patients Refined Diagnosis Related Groups; CI = confidence interval; TIPS = transjugular intrahepatic portosystemic shunt.

*The linear function of the number of blood transfusions has a negative association with mortality, whereas its quadratic form (tranfusionsˆ2) has a positive association. This is commonly seen with convex quadratic relationships. With respect to interpretation, the linear term is to be ignored. The quadratic term provides a more accurate association between the 2 variables: mortality increases as the number of blood transfusions increases in a convex quadratic fashion.

59 (21%); Hispanic, n = 143 (12%); and White, n = 526 (15%)). The results of the hierarchical logistic regression for the outcome of mortality and covariates of interest in this population subset are presented in **Table E3** (available online at *www.jvir.org*). As such, the Black race was not associated with higher odds of risk-adjusted mortality in this subset (odds ratio, 1.2 [95% CI, 0.4–3.6], P = .68). Conversely, among patients with ascites, Black patients had >2-fold higher mortality (Black, n = 94 (48%); Hispanic, n = 131 (21%); and White, n = 353 (13%)).

DISCUSSION

In this study of adults undergoing TIPS creation for acute variceal bleeding in the United States, Black patients had 3-fold higher adjusted odds of in-hospital mortality than White patients. A possible explanation for this marked racial disparity is that Black patients may have had disproportionately higher disease severity at the time of TIPS creation. This hypothesis is supported by 2 findings. In the sensitivity analysis, a study of the subset of patients with a maximum Child-Pugh score of 13 showed that Black race was not significantly associated with higher mortality. Additionally, Black patients had a significantly higher rate of liver failure after TIPS creation, a complication known to be associated with a degree of an underlying hepatic dysfunction (23,24). Alternatively, it is possible that more severe disease (Child-Pugh score > 13) had a disproportionately negative impact on survival for Black patients as opposed to the impact on survival for White patients undergoing TIPS creation.

A large number of patient-level factors, socioeconomic determinants, hospital characteristics, and care processes were examined to assess whether any of them are associated with a higher death rate among Black patients with severe variceal bleeding. Although Black patients were disproportionately poor and more likely to reside in densely populated urban areas, they were also more frequently admitted to teaching hospitals and liver transplant centers and had similar access to first-line endoscopic intervention and blood transfusion support. A notable exception among the hospital care processes examined was the timing of TIPS creation. The mean time to TIPS creation was 4.1 days for Black patients compared with 2.8 days for White patients. Two randomized controlled trials have shown that TIPS creation within 72 hours of admission in carefully selected high-risk patients is associated with significantly lower treatment failure and mortality rates (4,25). Observational studies have not confirmed a survival benefit with "early" TIPS (within 72 hours) (4,26), and the most recent guidelines from the American Association for the Study of Liver Diseases indicated a need for further studies on the topic (11). Therefore, a rudimentary secondary analysis was performed by calculating mortality across patient races/ethnicities, stratified by the time to TIPS creation. A greater time to TIPS creation was not a contributor to higher mortality among Black patients in this study. In fact, compared with White patients, Black patients who received TIPS within 72 hours had significantly higher mortality, with a general trend towards lower mortality with later TIPS.

These findings have important clinical and policy implications. Although TIPS has been a major medical advancement, in terms of ensuring significant survival benefits for patients with variceal bleeding in multiple randomized controlled trials (3–6), Black patients experience poor outcomes with the procedure in the United States. In fact, the current national in-hospital mortality rate of 32% for Black patients is in line with what was seen with the control (standard management) arms of the aforementioned clinical trials. This may be a result of adverse patient selection, as suggested by the sensitivity analysis. Although access to first-line endoscopy and blood product repletion do not substantially vary by race at the individual hospital encounter level, the fact that Black patients appear to have more advanced disease when TIPS is created speaks about the inequitable management of their disease course preceding it. Racial disparities have previously been documented among patients with chronic liver disease. Black patients are less likely to be screened for hepatitis C in the presence of documented risk factors (27), less likely to be treated for hepatitis C after testing positive (27), and more likely to develop portal hypertension and hepatocellular carcinoma (28) despite exhibiting slower biological progression of the disease (29). However, for examining upstream factors, a couple of focused questions need to be answered next: do Black patients who die despite TIPS creation (*a*) have more bleeding episodes (indicating a higher risk and need for definitive TIPS) in the months preceding it? and/or (*b*) have lower rates of endoscopic screening/ligation for their variceal disease? Answering these questions should help us understand whether this racial disparity can be mitigated by (*a*) considering TIPS earlier in the disease course for Black patients using a simple objective metric of a number of variceal bleeding episodes over time and (*b*) focusing systemic efforts on improving access to endoscopic screening/management. In the meantime, this data should not be used to stop considering TIPS for Black patients with variceal bleeding. Rather, careful patient selection should immediately improve outcomes, as suggested by the sensitivity analysis.

Several limitations deserve consideration. The Child-Pugh or model for end-stage liver disease score could not be calculated directly because of the absence of laboratory values in the NIS. Although all validated claims-based clinical severity indicators were used to perform risk adjustment (Deyo-Charlson, Elixhauser, APR-DRG, and liver disease complications), the magnitude of unmeasured clinical risk remains unclear. To that end, a sensitivity analysis was performed by excluding all patients with ascites. Therefore, in the remaining cohort, all patients had a maximum Child-Pugh score of 13 for TIPS eligibility. Since the Black patients in this subset did not experience higher mortality, unmeasured clinical risk likely plays a significant role in explaining the observed variance.

Hemodynamic parameters were also not available to gauge the severity of bleeding and associated procedural urgency. Patients may have undergone emergency TIPS creation in the setting of acute variceal bleeding or elective TIPS creation for a history of recurrent variceal bleeding. Since these 2 populations are very different in terms of the procedural risk implied, only patients with a diagnostic code for bleeding varices were included (nonbleeding varices have a separate code). Nonetheless, some crossover related to miscoding in such real-world data captures is expected. Finally, since the data captured from the NIS terminated at the time of discharge, this study only reports in-hospital outcomes. Therefore, follow-up studies evaluating within- and between-hospital variance in the management of variceal bleeding based on patient race over longer follow-up periods are needed.

In conclusion, Black patients undergoing TIPS creation for variceal bleeding experienced 2-fold higher in-hospital mortality than non-Black patients even after accounting for the differences in demographics, socioeconomic determinants, clinical comorbidities, hospital characteristics, and care processes. This racial disparity may be related to higher disease severity at the time of TIPS creation. Being Black was not associated with higher mortality in a subset of patients with a maximum Child-Pugh score of 13, indicating a possible role of adverse patient selection, leading to a lower survival rate after TIPS. Collectively, these findings suggest a need for public health and policy efforts to focus on disparities in the upstream management of decompensated liver disease.

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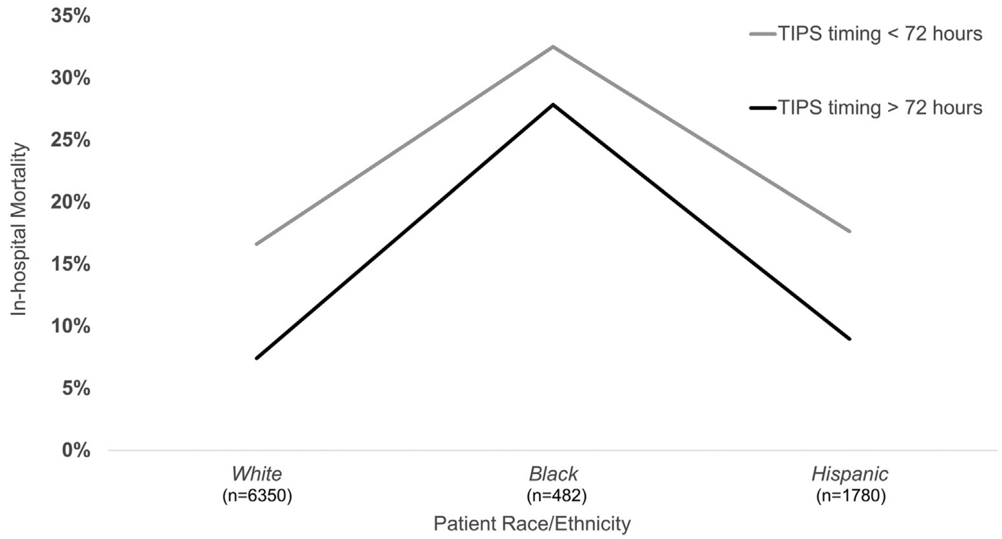

Figure E1. Unadjusted in-hospital mortality based on the race of patients undergoing transjugular intrahepatic portosystemic shunt (TIPS) creation for acute variceal bleeding in the United States (2007–2016) stratified by the time to TIPS creation: <72 hours and >72 hours from the time of admission. The total number of encounters for each race/ethnicity category is numerated between brackets.

Table E1. International Classification of Disease, Version Ninth and 10th, Codes Used to Identify the Variables of Interest for This Study.

Variable	ICD-9 code(s)	ICD-10 code(s)
Diagnosis		
Bleeding esophageal varices	456.00, 456.20	I85.01, I85.11
Procedures		
TIPS	39.1	06183DY, 06183JY, 06183J4, 06184J4
Endoscopy	45.13, 42.33	0DJ08ZZ, 06L34CZ, 0W3P8ZZ
Blood transfusion	99.0	30233N1
Clinical severity codes		
Hepatocellular carcinoma	155.0	C22.0
Sarcopenia	728.2	M62.84
SBP	567.23	K65.2
Hepatic encephalopathy	572.2	K72.91
Ascites	789.5, 789.59	K70.31, R18.8
Portal vein thrombus	452	I81
Hepatorenal syndrome	572.4	K76.7
Complications		
Shock after the procedure	998.0	T81.1, T81.10, T81.11, T81.12, T81.19
Infection after the procedure	998.5	T81.4
Cardiac arrest during the procedure	997.1	I97.711, I97.121

ICD = International Classification of Diseases; SBP = spontaneous bacterial peritonitis; TIPS = transjugular intrahepatic portosystemic shunt.

Table E2. Comorbidities Used to Calculate the Elixhauser and Charlson Comorbidity Indices.

Comorbidity	Overall (n = 10,331)	White (n = 6,350)	Black (n = 482)	Hispanic (n = 1,780)
Congestive heart failure	522 (5.1%)	372 (5.9%)	X* (X.X%)*	71 (4.0%)
Cardiac arrhythmias	1,260 (12.2%)	885 (13.9%)	49 (10.2%)	139 (7.8%)
Valvular disease	211 (2.0%)	163 (2.6%)	NA	29 (1.6%)
Pulmonary circulation disease	308 (3.0%)	191 (3.0%)	15 (3.0%)	59 (3.3%)
Peripheral vascular disorder	207 (2.0%)	149 (2.3%)	14 (2.9%)	29 (1.6%)
Hypertension, uncomplicated	3,241 (31.4%)	1,986 (31.3%)	171 (35.5%)	614 (34.5%)
Hypertension, complicated	484 (4.7%)	311 (4.9%)	45 (9.3%)	44 (2.5%)
Paralysis	44 (0.4%)	30 (0.5%)	NA	X* (X.X%)*
Other neurological disorders	1,162 (11.2%)	766 (12.1%)	44 (9.2%)	186 (10.4%)
Chronic pulmonary disease	1,428 (13.8%)	1,010 (15.9%)	63 (13.2%)	165 (9.3%)
Diabetes without complications	2,742 (26.5%)	1,588 (25.0%)	93 (19.3%)	608 (34.2%)
Diabetes with complications	441 (4.3%)	270 (4.3%)	X* (X.X%)*	93 (5.2%)
Hypothyroidism	822 (8.0%)	612 (9.6%)	X* (X.X%)*	93 (5.2%)
Renal failure	708 (6.9%)	414 (6.5%)	69 (14.3%)	78 (4.4%)
Liver disease	10,331 (100%)	6,350 (100%)	482 (100%)	1,780 (100%)
Peptic ulcer disease, excluding bleeding	284 (2.8%)	178 (2.8%)	19 (4.0%)	53 (3.0%)
AIDS/HIV	58 (0.6%)	35 (0.6%)	19 (4.0%)	X* (X.X%)*
Lymphoma	48 (0.5%)	X* (X.X%)*	NA	X* (X.X%)*
Metastatic cancer	84 (0.8%)	69 (1.1%)	NA	X* (X.X%)*
Solid tumor without metastasis	370 (3.6%)	223 (3.5%)	44 (9.2%)	54 (3.0%)
Rheumatoid arthritis/collagen vascular disease	258 (2.5%)	136 (2.1%)	15 (3.0%)	54 (3.0%)
Coagulopathy	5,583 (54.0%)	3,424 (53.9%)	230 (47.6%)	1,046 (58.8%)
Obesity	760 (7.4%)	442 (7.0%)	15 (3.0%)	172 (9.7%)
Weight loss	1,342 (13.0%)	860 (13.5%)	58 (12.1%)	176 (9.9%)
Fluid and electrolyte disorders	4,870 (47.1%)	3,017 (47.5%)	278 (57.6%)	819 (46.0%)
Blood loss anemia	1,018 (9.9%)	568 (9.0%)	34 (7.0%)	245 (13.8%)
Deficiency anemia	344 (3.3%)	192 (3.0%)	15 (3.0%)	83 (4.7%)
Alcohol abuse	6,036 (58.4%)	3,697 (58.2%)	299 (61.9%)	1,115 (62.6%)
Drug abuse	634 (6.1%)	378 (6.0%)	49 (10.2%)	134 (7.5%)
Psychoses	134 (1.3%)	89 (1.4%)	25 (5.1%)	X* (X.X%)*
Depression	968 (9.4%)	721 (11.3%)	X* (X.X%)*	98 (5.5%)

AIDS = acquired immunodeficiency syndrome; HCUP = Healthcare Cost and Utilization Project; HIV = human immunodeficiency virus; NA = not applicable.
*Small cell counts ($n \leq 10$) have been suppressed from presentation in compliance with the HCUP data use agreement.

Table E3. Results of the Sensitivity Analysis Testing the Multivariable Association between the Covariates of Interest and the Outcome of In-Hospital Mortality for Patients with a Maximum Possible Child-Pugh Score of 13 (No Ascites).

Covariate	Odds ratio	95% CI	*P* value
Age, centered (y)	0.98	(0.96–1.00)	.074
Female	1.17	(0.68–2.01)	.566
Black	1.25	(0.43–3.63)	.682
Hispanic	1.16	(0.62–2.18)	.645
Other race	0.43	(0.15–1.25)	.119
Missing race	0.91	(0.35–2.38)	.846
Household income quartile 2	0.95	(0.51–1.76)	.860
Household income quartile 3	0.68	(0.35–1.33)	.255
Household income quartile 4	1.09	(0.51–2.33)	.829
Medicaid	0.96	(0.50–1.82)	.892
Medicare	0.98	(0.49–1.96)	.946
Other primary payer	0.6	(0.28–1.28)	.185
Urban nonteaching	1.23	(0.67–2.25)	.500
Rural	2.38	(0.40–14.29)	.341
Midwest region	0.97	(0.44–2.16)	.946
South region	0.78	(0.40–1.52)	.465
West region	1.2	(0.57–2.52)	.638
Fringe counties, >1M population	1.38	(0.72–2.63)	.333
Metro counties 250k–499k population	0.87	(0.44–1.75)	.702
Metro counties 50k–249k population	0.99	(0.37–2.67)	.989
Micro counties	0.63	(0.21–1.89)	.409
Not metro or micro	1.02	(0.30–3.50)	.971
Transfer	1.87	(1.04–3.36)	.036
APR-DRG risk mortality major	2.22	(0.26–19.26)	.469
APR-DRG risk mortality extreme	54.14	(6.95–421.96)	<.001
Number of endoscopies	0.94	(0.44–2.01)	.866
Number of endoscopies^2	1.19	(0.85–1.65)	.316
Number of transfusions	0.49	(0.25–0.94)	.031
Number of transfusions^2	1.36	(1.10–1.69)	.005
Day of TIPS procedure	0.85	(0.76–0.95)	.004
Transplant center	1.5	(0.82–2.73)	.187
Hepatic encephalopahy	0.81	(0.48–1.36)	.420
Hepatic vein thrombus	1.39	(0.50–3.89)	.533

APR-DRG = All Patients Refined Diagnosis Related Groups; CI = confidence interval; TIPS = transjugular intrahepatic portosystemic shunt.