TIPS in Florida: Is Its Application a Result of Evidence-Based Medicine?

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BACKGROUND: The typical resident in surgery in the US will not care for a patient with advanced portal hypertension and will not participate in a portacaval shunt. The aim of this study is to compare the number of transjugular intrahepatic portasystemic stent shunts (TIPS) with the number of surgical shunts undertaken in the State of Florida and to assess whether these numbers are consistent with today's evidence-based medicine.

METHODS: We examined the database of the Agency for Health Care Administration of the State of Florida from January 1, 2002, through September 30, 2005, for "intraabdominal venous shunt" (ICD-9 code, 39.1). Data collected include "case mix," "case severity," length of stay, total gross charges, and discharge status. Conclusions about longterm survival from a prospective randomized clinical trial comparing TIPS to surgical shunting were applied to this dataset to determine if the relative frequency of TIPS application in Florida was supported by evidence-based medicine.

RESULTS: TIPS was undertaken more than 12 times as often as surgical shunting (860 patients versus 70 patients). After TIPS versus surgical shunts, average length of stay and hospital charges were less, but case mix, case severity, and in-hospital mortality (11.4% for each) were not different. Applying survival data from a randomized trial comparing TIPS with surgical shunting to the State of Florida database, 129 more people ($p < 0.0001$) would be alive at 2 years and 137 more ($p < 0.0001$) would be alive at 5 years after shunting if surgical shunts had been used in lieu of TIPS.

CONCLUSIONS: TIPS leads to shorter hospitalizations and reduced hospital charges and is applied in numbers much greater than surgical shunts, despite evidence that suggests inferior longterm efficacy and survival. Current application of TIPS is not a result of evidence-based medicine, and application of surgical shunting is encouraged. (J Am Coll Surg 2007;204:794–802. © 2007 by the American College of Surgeons)

The typical surgeon-in-training in the US will not participate in a portacaval shunt during residency. During residency the typical surgeon-in-training will not care for a patient with complications from advanced portal hypertension, including variceal hemorrhage. Discussions of portal hypertension and variceal bleeding among surgeons are now either profoundly superfluous or more important than ever.

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Transjugular intrahepatic portasystemic stent shunt (TIPS) has achieved widespread acceptance among nonsurgeons for control of variceal hemorrhage from cirrhosis. Notably, acceptance of TIPS has occurred without clinical trials documenting outcomes superior to outcomes after surgical shunting. TIPS has seemingly gained acceptance because of its easy availability, ability to provide immediate portal decompression (and thereby palliate complications of portal hypertension), and its inherent avoidance of an intraabdominal operation. Although issues of shunt stenosis and occlusion after TIPS are well recognized, loss of shunt function has been marginalized by promoting the role of TIPS in providing a "bridge" to transplantation. Hepatic dysfunction and progressive deterioration after TIPS seem uniformly attributed to the underlying cirrhosis and its cause. Attributing liver failure after TIPS to underlying cirrhosis without considering the portal hemodynamic changes brought about by TIPS seems shortsighted.

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Table 1. Comparisons of Patients Undergoing TIPS or Surgical Shunts in Florida from January 1, 2003, through September 30, 2005

	TIPS	Surgical shunt
n	860	70
Case mix	3.968 (4.017 ± 1.087)	3.968 (5.183 ± 4.254)
Case severity	4 (3.54 ± 0.61)	4 (3.43 ± 0.87)
Length of stay (d)	7 (8.98 ± 9.4)*	11.5 (19.41 ± 26.2)
Hospital charges ($US)	53,461 (74,170 ± 71,103)*	103,036 (208,946 ± 292,148)
In-hospital deaths, n (%)	98 (11.4)	8 (11.4)

Values are median (mean ± SD) except where indicated.
*Less than after surgical shunts, $p < 0.01$, Mann-Whitney U test.
TIPS, transjugular intrahepatic portasystemic stent shunt.

In sum, in the US, TIPS is popular, despite real limitations in patency and preservation of liver function. Is TIPS's frequent application an appropriate use of a new and evolving technology or an assault on evidence-based medicine? To address this question in a scholarly manner, we determined TIPS application in Florida through a prospectively collected statewide database and, using data and conclusions from trials comparing TIPS with surgical shunts for control of variceal hemorrhage, predicted longterm survival after TIPS and after surgical shunting, with considerations of shunt function and efficacy. Our hypotheses in undertaking this study were that TIPS is applied in numbers considerably greater than surgical shunts and that considerably more patients would be alive at 2 and 5 years after shunting if surgical shunting were used in lieu of TIPS.

METHODS

The US National Library of Medicine's search service (PubMed, available at: http://www.ncbi.nlm.nih.gov/entrez) was searched for prospective trials of TIPS and for trials comparing TIPS and surgical shunts. Search words of "TIPS," "portacaval shunts," "portocaval shunts," "operative surgical shunts," "variceal bleeding," and "portal decompression" were used alone and in combination. This search led to 160 prospective studies of TIPS. Studies published before 1999 were excluded to allow for the "learning curve" with TIPS. Four reports of trials comparing TIPS with surgical shunts were identified.[1-4] One such trial came from our institution.[3]

Concurrently, the database for the Agency for Health Care Administration of the State of Florida was queried to determine the number of patients undergoing portal decompression from January 1, 2003, through September 30, 2005. September 30, 2005, was the last date for which data were available when the database was queried. Specifically, the database was queried for patients using IDC-9 code 39.1 (ie, intraabdominal venous shunt).

Data collected included admitting and treating physicians and their respective specialties, treating hospital, case mix, case severity, length of stay, patient age, total gross charges, and discharge status (ie, alive or dead). TIPS was designated the shunt undertaken by treating physicians specializing in radiology, interventional radiology, or internal medicine, although surgical shunts were assigned when the treating physician was a surgeon. When questions arose, treating physicians were contacted by telephone. If an admitting physician and physician undertaking the decompressive procedure jointly cared for more than one patient, data were available only in summary form, precluding specific evaluation of each patient treated and limiting some data presentation and statistical analyses. Case mix was defined as the relative amount of resources that were needed to treat the patient by the hospital. Case severity was defined as the relative extent of complexity in treatment and diagnosis of a patient and was codified as 1 (minor), 2 (moderate), 3 (major), or 4 (extreme). Survival beyond hospital discharge was not available from the Agency for Health Care Administration database.

Given the unavailability of longterm survival from the Agency for Health Care Administration's database, longterm survival data were projected using a prospective randomized trial undertaken in Florida that compared TIPS with an operatively constructed small-diameter prosthetic H-graft portacaval shunt in patients with generally severe hepatic impairment.[3] Ultimately, with considerations of shunt patency and efficacy, conclusions from randomized trials comparing TIPS with operatively constructed shunts were applied to the dataset available from the Agency for Health Care Administration to ascertain if application of TIPS in Florida was a result of evidenced-based medicine.

Data, where appropriate, are presented as median (mean ± SD). Data were stored on a spreadsheet registry (Microsoft Excel). Statistical comparisons were undertaken with Tru Epistat (Epistat Services). Statistical significance was assigned with 95% probability.

Table 2. Predicted and Actual Survival after TIPS or Small-Diameter Prosthetic H-Graft Portacaval Shunts[1]

	3 months (%)	6 months (%)	12 months (%)	24 months (%)	60 months (%)
TIPS					
Predicted*	67	59	52	41	—
Actual†	77	71	64	53	31
HGPCS					
Predicted†	68	60	54	43	—
Actual†‡	79	79	74	68	47

*Predicted survival after Model End-Stage Liver Disease score can be modeled for up to 2 years.
†Actual survival is better than predicted survival, $p < 0.001$, Mantel-Haenszel chi-square.
‡Actual survival after HGPCS is superior to actual survival after TIPS, $p < 0.001$, Mantel-Haenszel chi-square.
HGPCS, H-graft portacaval shunts; TIPS, transjugular intrahepatic portasystemic stent shunt.

RESULTS

Over 33 months, ending September 30, 2005, a total of 930 patients in Florida underwent portal decompression: 860 (92%) underwent TIPS and 70 (8%) underwent surgical shunting. Case mix and case severity were not different for patients undergoing TIPS or surgical shunting (Table 1). Average length of hospitalization was longer after surgical shunting than after TIPS (Table 1). Consistent with length of stay data, average cost of in-hospital care was greater after surgical shunting than after TIPS (Table 1). Conversely, in-hospital mortality was identical after either surgical shunting or TIPS (Table 1).

In a trial undertaken at our institution in Florida, TIPS was compared with small-diameter (ie, 8 mm) prosthetic H-graft portacaval shunt for its ability to palliate variceal bleeding from portal hypertension and cirrhosis.[3] This was a trial of "all comers" or, stated differently, a trial of very unselected patients, half of whom were of Child's class C. Additionally, the average Model End-Stage Liver Disease (MELD) score was 14 in each arm of the trial. The small-diameter prosthetic H-graft portacaval shunt led to improved survival compared with TIPS (Table 2), even though patients undergoing either shunt survived better than predicted by MELD (Table 2).

If survival in the State of Florida after TIPS is predicted using MELD and the data from this trial are extrapolated to the dataset from the Agency for Health Care Administration of the State of Florida, several survival predictions can be made. Using MELD, of 860 patients undergoing TIPS in Florida, 352 (41% of 860 patients) would be expected to be alive at 2 years (Table 3). Using actual survival data from the randomized trial, after TIPS 456 patients (53% of 860 patients) would be predicted to be alive at 2 years, and 267 patients (31% of 860 patients) would be predicted to be alive at 5 years (Table 3). If patients undergoing TIPS had undergone small-diameter prosthetic H-graft portacaval shunts instead, 585 patients (68% of 860 patients) would be predicted to be alive at 2 years, and 404 patients (47% of 860 patients) would be predicted to be alive at 5 years (Table 3). Small-diameter prosthetic H-graft portacaval shunts would result in significantly more patients surviving at 2 ($p < 0.0001$) and 5 ($p < 0.0001$) years after shunting: 129 more patients at 2 years and 137 more patients at 5 years. Small-diameter prosthetic H-graft portacaval shunts would improve survival by 28% at 2 years and by 51% at 5 years.

DISCUSSION

Application and refinement of TIPS has changed treatment paradigms for variceal bleeding, which results from portal hypertension and cirrhosis. TIPS is not viewed as an insular therapy by most. TIPS is generally applied with the intention of transplantation as later definitive therapy. Unfortunately, this intention is too often an illusion. Many, if not most, patients with variceal bleeding from portal hypertension and cirrhosis are not candidates for hepatic transplantation, nor will they ever be. Economic forces, sociopsychologic forces, and the realities of recidivism preclude many, if not most, patients with variceal bleeding from undergoing transplantation. There are real issues with organ availability and best application of those organs available. As well, issues with TIPS's durability and efficacy impugn its application. This study begins to gauge the disparity in application of TIPS vis-à-vis surgical shunting and begins to gauge the inappropriateness of this disparity.

TIPS is of indisputable value in the treatment of variceal bleeding from portal hypertension and cirrhosis, but it is not a panacea. Many series of TIPS purport encouraging outcomes. Variceal bleeding is quite reliably controlled and variceal rehemorrhage is not common with short-term followup. TIPS has its issues; specifically, stent narrowing with loss of portal decompression is common, and so are stent thrombosis and occlusion. Vigilance is required to maintain patency. Unfortunately, necessary health care and followup is not often available to the medically disenfranchised or patients in rural areas or far from sophisticated (ie, able) health-care providers. Progressive hepatic dys-

Table 3. Number of Patients Predicted to Be Alive after TIPS or if Small-Diameter Prosthetic H-Graft Portacaval Shunt Was Applied versus TIPS*

	TIPS	HGPCS	p
No. of shunts	860	860	—
2-year predicted survival (MELD),† n (%)	352 (41)	370 (43)	NS
2-year predicted survival (actual),‡ n (%)	456 (53)	585 (68)	< 0.0001
5-year predicted survival (actual),‡ n (%)	267 (31)	404 (47)	< 0.0001

*Using predicted and actual survival data from a prospective randomized trial comparing TIPS and HGPCS.[3]
†Predicted survival using MELD and patient data supplied in randomized trial.[3]
‡Predicted survival using actual survival rates in randomized trial.[3]
HGPCS, H-graft portacaval shunts; MELD, Model End-Stage Liver Disease score; TIPS, transjugular intrahepatic portasystemic stent shunt.

function after TIPS is frequently noted and nearly universally ascribed to progression of the underlying cirrhosis without due consideration of how TIPS alters portal hemodynamics and nutrient hepatic blood flow.[5-7]

For patients undergoing portal decompression identified through the database of the Agency for Health Care Administration, TIPS was applied much more often, more than 12 times more often, than surgical shunts and led to shorter and less-expensive hospitalizations.

Case mix and case severity were very similar for patients undergoing TIPS or surgical shunting; in-hospital mortality after TIPS or surgical shunting was identical, although patients were well matched. Identical mortality after shunting is a surprise, given that one of the advantages of TIPS is that it is a less-invasive procedure. In this database, a perceived advantage of TIPS is lost.

Use of survival data from our prospective trial seems fair, given that the trial involved an unselected group of "all comers." The projected increased numbers of patients alive at 2 and, especially, 5 years after surgical shunting is remarkable and cannot be ignored.

There are obviously many holes in the tenet of this report. At this time, better data do not exist. How many of the patients in Florida undergoing TIPS during this time period could have undergone surgical shunting? How many were in extremis and, thereby, were believed not to be candidates for a major intraabdominal operation? How many had access to the surgical expertise to undertake shunting? How many were in need of imminent transplantation? Given the vagaries of this report, no definitive declaration can be given on the appropriateness of the application of TIPS in Florida, only on the relative frequency with which TIPS is applied relative to surgical shunting and how that could impact longterm survival. Discussion and debate can gather and appropriate changes can begin.

Studying the four trials comparing surgical shunting with TIPS, many deductions can be made, some of which have material impact on the implied conclusions of this report. The first, published in 2000, compares TIPS with distal splenorenal shunts.[1] This prospective controlled trial involved 67 male patients of Child's class A or B, all of whom suffered from alcoholic cirrhosis (Table 4). All patients had experienced variceal bleeding and had failed endoscopic therapy for definitive control. More than one-third of patients had refractory ascites and more than one-third had at least moderate renal dysfunction at the time of shunting. Although there were no patients of Child's class C by description, this was a reasonably unselected group of patients with moderate hepatic dysfunction.

TIPS were placed to achieve a portasystemic gradient of < 12 mmHg. Periprocedural mortality was $< 10\%$ and 2-year survival was quite good (Table 4). In this trial, TIPS was more frequently complicated by shunt occlusion by 2 years after shunting and, as expected, was more often followed by recurrent variceal hemorrhage (Table 4). Notably, encephalopathy was more frequent after TIPS (43% versus 19% at 2 years after shunting, $p < 0.05$). Although with the short-term followup through this trial, survival was not impacted by the mode of shunting, the "Achilles heel" of TIPS was apparent, namely, excessive shunt thrombosis and occlusion with consequent variceal rebleeding. This trial recommends distal splenorenal shunt as a superior therapeutic option.

The second published trial comparing TIPS with surgical shunting was published in 2001[2] (Table 4). This retrospective case-controlled trial involved a relatively small number of consecutive patients, of only Child's-Pugh class A or B, undergoing TIPS or 1 of 2 different types of surgical shunts (30% underwent distal splenorenal shunts and 70% underwent partially decompressing portacaval shunts). Patients were matched for Child's-Pugh class, gender, age, and cause of cirrhosis. Child's-Pugh scores averaged just under 8.0 for patients undergoing TIPS or surgical shunting. Cirrhosis was generally not caused by alcohol. All patients had experienced variceal bleeding and underwent intervention electively. Followup was for up to 24 months after shunting (Table 4).

Periprocedural mortality was 20% for patients undergoing TIPS, but no differences in short-term or longterm survival were noted in this small cohort of patients (Table 4). TIPS stent occlusion occurred in 60%, with an average of 2.5 occurrences per patient. Occlusion of TIPS occurred

Table 4. Summary of Results from Four Trials Comparing TIPS with Surgical Shunting

	Khaitiyar et al[1]		Henderson et al[4]		Helton et al[2]		Rosemurgy et al[3]	
	TIPS	DSRS	TIPS	DSRS	TIPS	Shunt	TIPS	HGCPS
n	35	32	67	70	20	20	66	66
Cirrhosis from alcohol (%)	100	100	55	59	30	35	70	76
Class (%)					All A/B			
A	34	31	58	56			18	14
B	66	69	42	44			38	36
C	—	—	—	—	—	—	47	50
Preshunt ascites (%)	40	35	50	52	—	—	70	68
Preshunt encephalopathy (%)	11	15	19	26	—	—	29	18
Followup (mean ± SD or median)	887 ± 189 d		45 mo		19 mo	23 mo	7.7 y	8.7 y
30-day mortality (%)	6	6	1	7	20	0	15	20
2-year survival (%)	80	81	88	81	80	90	53	68*
5-year survival (%)	—	—	61	62	—	—	31	47*
Variceal rehemorrhage (%)	26	6*	11	6	50	5*	30	0*
Shunt stenosis (%)	69	6*	82	11*	60	10*	48	11*

*Better after surgical shunting, $p < 0.05$.
DSRS, distal splenorenal shunt; HGPCS, H-graft portacaval shunts; TIPS, transjugular intrahepatic portasystemic stent shunt.

in more patients and more often than occlusion of the surgical shunts (Table 4). Notably, rehospitalization was significantly more frequent after TIPS (20 rehospitalizations for 9 patients) than after surgical shunts (3 rehospitalizations for 2 patients) ($p < 0.05$). As well, the cost of care with TIPS was greater, nearly double ($111, 573 versus $61,934, $p < 0.005$), and resource consumption (eg, units of red blood cells transfused) after TIPS was substantially greater (55 U blood transfused versus 0 U, $p < 0.001$).

The third published trial comparing TIPS with surgical shunting was published in 2006[4] (Table 4). This was a multicenter randomized trial comparing TIPS with distal splenorenal shunt in patients who had generally experienced variceal hemorrhage. Patients were only of Child's class A or B and were more often of class A. Average MELD score for the patients undergoing either shunt was < 10.0. Cirrhosis was most often a result of alcohol (Table 4). The last patient was entered into the trial 4 years before publication.

Variceal bleeding was well controlled by both shunts. Variceal rehemorrhage occurred in a relatively small number of patients after shunting (Table 4). Periprocedural mortality was not different between the therapies, and 2-year and 5-year survival was similar and admirable (Table 4). Shunt stenosis/occlusion was problematic after TIPS (Table 4). Shunt stenosis and occlusion/thrombosis were considerably more common after TIPS. Although initially limiting costs of care, TIPS became the more expensive therapy with time.

The fourth trial comparing TIPS with surgical shunting has been referenced previously.[3] In brief, this trial compared two methods of direct partial portal decompression, namely, TIPS, with small-diameter prosthetic H-graft portacaval shunt. The patients in the trial were unselected. Half of the patients were of Child's class C (Table 4). Cirrhosis was generally from alcohol, and intractable ascites and encephalopathy before shunting were relatively frequent (Table 4). Patients undergoing one shunt or the other were very well matched, and predicted survival up to 2 years after shunting was nearly identical for each shunt (Table 2). Any differences in survival apparent after shunting in this trial could not have been because of a bias in randomization.

After each shunt, patients experienced substantially better survival than predicted by MELD (Table 2). Any differences in survival after shunting should not be a result of poor results associated with either shunt. Actual survival after shunting substantially favored the small-diameter prosthetic H-graft portacaval shunt for patients of Child's class A (53 ± 40.1 months versus 41 ± 39.3 months) and for patients of Child's class B (64 ± 39.1 months versus 36 ± 30.7 months, $p < 0.05$). Patients with MELD scores < 13 lived considerably longer after small-diameter prosthetic H-graft portacaval shunts than after TIPS. Patients in this randomized trial were more likely to experience shunt stenosis/occlusion and variceal rehemorrhage after TIPS (Table 4). Shunt failure, prospectively defined in this trial, occurred sooner after TIPS, particularly for patients of Child's class A or Child's class B. For patients with MELD scores < 14, time to shunt failure was substantially superior after small-diameter prosthetic H-graft portacaval shunts.

Table 5. Representative Reports of Patients Undergoing TIPS

	Zhuang et al[6]	Tripathi et al[15]	Tripathi et al[14]	Membreno et al[16]
n	107	472	292	101
Technical success (%)	96	95	94	—
Class (%)				
A	15	—	—	7
B	33	—	—	49
C	51	52	—	44
Periprocedural 30-day mortality (%)	22	27	14	19
Followup (mo), mean ± SD	20 ± 25.6	33 ± 1.9	< 36	18
Early control of bleeding (%)	96	—	—	—
Rehemorrhage (%)	33	18	15	15
Stenosis/thrombosis (%)	52 (at < 2 y)	74 (at 2 y)	40	37
Interventions per patient	2.04	0.97	—	—
Overall mortality (%)	45	60	54 (at 2 y)	40 (at 18 mo)
Liver transplantation (%)	9	9	8	4

TIPS, transjugular intrahepatic portasystemic stent shunt.

What conclusions can be drawn from these trials? TIPS might or might not negatively impact survival after shunting for patients with moderate hepatic impairment but does not hint at promoting it relative to surgical shunting. TIPS is incontrovertibly plagued by narrowing, stenosis, thrombosis, and occlusion. As an expected result, TIPS is also incontrovertibly associated with shunt failure, namely, control of or relief from variceal rebleeding. Covered stent graphs have not notably impacted the problem of stent patency, and they have not notably improved outcomes after TIPS.[8,9] Shunt dysfunction and rehemorrhage are the causes of relatively increased resource consumption and health-care expenses, which continue to increase disparately with increased duration of followup. Other studies confirm this.[10,11] As well, beyond dollars and cents, there are other real costs attributable to TIPS. Some of these can be measured and quantified, such as number of rehospitalizations, number of ICU days, and units of red blood cells transfused,[2,4,10,11] although others cannot be, such as time and opportunity costs.

Notably, TIPS is often presented as a "bridge" to transplantation. In these trials comparing TIPS with surgical shunting, hepatic transplantation was an uncommon result after shunting, even after TIPS. When it was undertaken, it was often done at a time distant to the time of shunting.[3,4] Others have also noted the uncommon occurrence of hepatic transplantation after surgical shunting.[12,13] Orloff and colleagues[12] noted that only 19 (1.5%) of 1,300 patients after surgical shunting qualified for and underwent hepatic transplantation. An additional 31 (2.4%) patients were proposed for transplantation but were rejected because of concerns about recidivism, infection, IV drug abuse, and other serious comorbidities.[12] As well, transplantation is uncommon after TIPS.[6,14-16] Hence, the appellation of "illusion" to the intimation that TIPS is generally applied as a "bridge" to transplantation. To apply TIPS widely for purposes of possible subsequent transplantation seems almost contrived.

Are these trials comparing TIPS with surgical shunting consistent with other reports that document clinical outcomes after TIPS or surgical shunts? There are many such reports documenting clinical outcomes after TIPS from many centers across the world (Table 5). In terms of periprocedural mortality, ability to complete the TIPS procedure, and early control of variceal bleeding, results after TIPS in the trials comparing TIPS to surgical shunts are better than or as good as the voluminous body of work defining outcomes after TIPS. Many measures of longterm outcomes denoted in the referenced trials comparing TIPS with surgical shunting, unfortunately, are generally not often or well denoted in reports of clinical outcomes after TIPS. In these reports, death after TIPS is generally felt to be a result of the progression of the underlying hepatic disease, with minimal consideration to the unique changes of portal hemodynamics brought about by TIPS. Specifically, the relatively excess diversion of portal blood flow and the relatively excess diminution of effective (ie, nutrient) hepatic blood flow after TIPS is barely considered in analyzing death after TIPS. Diversion of nutrient hepatic blood flow[5,7] and propensity for loss of shunt function play roles in the relatively poorer survival after TIPS. Notably, survival after TIPS is often a lesser consideration than other end points. Longterm survival has even been defined by 1 group as survival beyond 30 days after TIPS.[16] The discrepancy between the excellent "success rates" after TIPS and

the relatively high "funeral rates" of the patients being treated has been pointed out.[17]

There are few contemporary series of surgical shunting to compare with the results seen in trials comparing surgical shunting with TIPS. One recent report examined outcomes after distal splenorenal shunts, occasionally (15%) undertaken as salvage therapy for failing TIPS.[13] This trial of 119 Child's class A or B patients documented a 30-day mortality of 6 % and a 1-year survival rate of 86%. Variceal rehemorrhage was uncommon (< 6%) after shunting. Consistent with many other reports of portal decompression, liver transplantations were subsequently undertaken in only 13% of patients, and only then at a mean of 5.1 years after shunting.

Small-diameter prosthetic H-graft portacaval shunts have been studied by others.[18] In a small number of patients, this shunt was associated with a cumulative 1-year survival rate of 82%, with shunt failure leading to variceal rehemorrhage in only 1 (6%) patient. In another similar report, the small-diameter prosthetic H-graft portacaval shunt was associated with a near 10% early mortality.[19] Notably, the shunt universally controlled variceal bleeding longterm (mean 40 months) with survival of all patients after hospital discharge.[19]

The exclusions of surgeons in "state-of-art" care for patients with variceal bleeding because of portal hypertension and cirrhosis are documented by recent practice guidelines from the American Association for the Study of Liver Diseases.[20] These guidelines recommend that "the decision to perform a TIPS, especially in a high-risk patient, should be reached by a team consisting of a gastroenterologist/hepatologist, interventional radiologist, and, where appropriate, a transplant physician." Surgeons are not specifically mentioned in the guidelines and are not even considered in the general text.[20]

In conclusion, is the application of TIPS in Florida a result of evidence-based medicine? The evidence is that TIPS does not seem to have reduced periprocedural mortality, although it avoids an intraabdominal operation and seems to have less "up-front" costs. The evidence is that after hospital discharge, TIPS is irrefutably more often plagued by shunt narrowing, stenosis, thrombosis, and occlusion, and, thereby, variceal rehemorrhage. TIPS requires more vigilance in followup and requires more surveillance. The evidence is that longterm survival after TIPS is negatively impacted by shunt patency, resource consumption, and diversion of nutrient hepatic blood flow. The evidence is that caring for patients after TIPS is more expensive, in measurable and quantifiable parameters (eg, resource consumption and dollars spent on health care) and in more abstract, but no less real, parameters (eg, time and opportunity costs). Because all of this information is widely available, the application of TIPS in Florida seems not a result of evidence-based medicine.

Who should undergo TIPS? Patients needing a "bridge" to imminent transplantation (ie, occurring in the next 6 months), for which they qualify. Patients with substantial aortic valve stenosis and mitral valve regurgitation. Patients who are morbidly obese or have a history of multiple previous celiotomies, particularly involving the right upper quadrant. Patients with severe comorbidities, including cardiorespiratory comorbidities. Otherwise, surgical shunting should be the first-line therapy for patients with or with a history of bleeding varices from portal hypertension and cirrhosis that are not amenable to or have failed endoscopic therapy. Specifically, surgical shunting should not be abandoned by the educators of tomorrow's physicians and surgeons. Educators of tomorrow's physicians and surgeons should not passively abjure surgical shunting and should not abdicate our responsibilities to these patients.

Author Contributions

Study conception and design: Rosemurgy, Cowgill, Zervos
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Discussion

J MICHAEL HENDERSON, MD (Cleveland, OH): Portal hypertension used to be a hot topic at surgical meetings, and many papers have been presented here at the Southern Surgical on this topic. It is rare now that we see a paper on portal hypertension. We had a historic paper from Miami last year, and Dr Rosemurgy puts portal hypertension fair and square on the table today in the context of TIPS versus surgical shunt. I will address three areas: the patient population in this study, the methods and data analysis, and TIPS dysfunction and costs.

The population database used in this study, the Florida Agency for Healthcare Database, is not the same population as the trial group you compare it to. TIPS is often done for intractable ascites, which is a very different patient population from patients with variceal bleeding. My first question is, did you pull out the TIPS patients in the Florida Healthcare Database with a variceal bleeding as opposed to those with more advanced disease who had intractable ascites as an indication for TIPS? I think that is an important issue for the comparison that you have made. What your data does show is that TIPS is being used 12 times more frequently than surgical shunts in Florida for all indications for TIPS use.

Next, about the methods and data analysis, I think we need to be cautious on how you extrapolate data from a single randomized trial into this database. You could take other trials, such as ours, which included Miami, and if you extrapolate from it, come up with the opposite results. The two-year survival in Child's A and B patients in our study was 88% survival for TIPS patients, 81% survival for distal shunt patients, both excellent outcomes, but in fact slightly favoring TIPS. Again, the five-year data from our study showed 61% and 62% survival in the two groups. So indeed for Child's A and B patients using these data, you would come up with no difference if you extrapolate along the same lines you have done in this analysis.

The other comment that I would make is that TIPS has changed a lot in the last five years. Covered stents do better. The multicenter randomized trial out of Europe showed a significant reduction in the rates of stenosis. Rates of stenosis dropped to about a third seen with bare stents. That is the big advantage that covered TIPS is showing in this field.

There is an increased cost with the reintervention of TIPS. But, in our multicenter study we presented a cost-effective analysis at the recent liver meetings that has been submitted for publication. This showed that in the initial couple of years the cost of TIPS was slightly higher than the cost of distal splenorenal shunts, but at no point was there a significant difference between the two groups. In fact, when we did a cost-effective analysis, which includes the survival patterns and quality-of-life data, the incremental cost-effectiveness ratios showed a moderate benefit to TIPS rather than to distal splenal renal shunt.

I would caution you in looking at this type of mixed data set with a large administrative database and comparing it to a single center randomized trial. I think if you took the two randomized trials and applied the data from both of those for this type of analysis, you are not going to come up with the same number of lives saved as you did on the analysis you presented.

I make these comments with some reservations; I love doing shunt surgery. There are some patients who benefit from it. It is very hard to show benefits for the individual patient in these kinds of randomized trials. Patients with excellent liver function, stable disease, with refractive variceal bleeding, are still excellent candidates for decompres-