Transjugular Intrahepatic Portasystemic Shunt vs Surgical Shunt in Good-Risk Cirrhotic Patients

A Case-Control Comparison

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Hypothesis: In good-risk patients with variceal bleeding undergoing portal decompression, surgical shunt is more effective, more durable, and less costly than angiographic shunt (transjugular intrahepatic portasystemic shunt [TIPS]).

Design: Retrospective case-control study.

Setting: Academic referral center for liver disease.

Patients: Patients with Child-Pugh class A or B cirrhosis with at least 1 prior episode of bleeding from portal hypertension (gastroesophageal varices, portal hypertensive gastropathy).

Intervention: Portal decompression by angiographic (TIPS) or surgical (portacaval, distal splenorenal) shunt.

Main Outcome Measures: Thirty-day and long-term mortality, postintervention diagnostic procedures (endoscopic, ultrasonographic, and angiographic studies), hospital readmissions, variceal rebleeding episodes, blood transfusions, shunt revisions, and hospital and professional charges.

Results: Patients with Child-Pugh class A or B cirrhosis undergoing TIPS (n=20) or surgical shunt (n=20) were followed up for 385 and 456 patient-months, respectively. Thirty-day mortality was greater following TIPS compared with surgical shunt (20% vs 0%; P=.20); long-term mortality did not differ. Significantly more rebleeding episodes (P<.001); rehospitalizations (P<.05); diagnostic studies of all types (P<.001); shunt revisions (P<.001); and hospital (P<.005), professional (P<.05), and total (P<.005) charges occurred following TIPS compared with surgical shunt.

Conclusions: Operative portal decompression is more effective, more durable, and less costly than TIPS in Child-Pugh class A and B cirrhotic patients with variceal bleeding. Good-risk patients with portal hypertensive bleeding should be referred for surgical shunt.

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Bleeding from portal hypertension, primarily from esophagogastric varices, remains a major medical problem, resulting in substantial morbidity and mortality as well as extensive resource expenditures. Numerous treatments for portal hypertensive bleeding are available, each with advantages as well as significant side effects or complications, with the choice of therapy being dependent on the patient’s physiologic status and medical compliance and available medical expertise and local-regional physician prejudice or bias.

Surgical portasystemic shunt (PSS) has been well established as definitive therapy for bleeding esophagogastric varices, with variceal rebleeding being extremely uncommon during extended follow-up in patients who have survived operation. However, PSS can be associated with substantial perioperative morbidity and mortality, and in those who survive operation, the risk of accelerated hepatic decompensation and neuropsychologic deterioration (portasystemic encephalopathy) significantly diminishes the overall benefit of the shunting procedure.

The now well-established technique of catheter-directed angiographic portacaval shunt (transjugular intrahepatic portasystemic shunt [TIPS]) has been demonstrated over the past decade to provide many of the immediate advantages of the PSS without the physiologic and metabolic morbidity that may result from a major abdominal operation in these frequently chronically decompensated patients. TIPS has been found to be particularly advantageous, even lifesaving, in patients with end-stage liver disease listed for orthotopic liver transplantation (OLT), as well as certain other
PATIENTS AND METHODS

For more than 5 years we attempted to interest academic and community internists and gastroenterologists, as well as our interventional radiology colleagues, in a prospective randomized trial comparing TIPS and PSS, without success. Accordingly, we conducted a retrospective case-control comparison of outcomes for these 2 portal decompressive techniques in cirrhotic patients meeting study criteria during 1993 to 1997 in University of Washington Academic Medical Center teaching hospitals (University of Washington Medical Center and Harborview Medical Center) in Seattle. Study design and conduct were approved by the University of Washington institutional review board.

Eligibility criteria included at least 1 prior episode of variceal (or portal hypertensive gastrointestinal) bleeding, management on an elective basis (ie, >48 hours since the last bleeding episode, hematocrit >0.30, normal blood pressure), excellent or good hepatic status (Child-Pugh class A or B), and availability for complete follow-up. Exclusion criteria included poor hepatic risk (Child-Pugh class C), emergency intervention (acute anemia [hematocrit <0.30], most recent bleeding episode <48 hours previously), and unavailability for complete follow-up.

Consecutive patients undergoing TIPS or PSS were matched for Child-Pugh classification, sex, age, and cause of cirrhosis (alcoholic vs nonalcoholic). Patients were followed up for 24 months or until death or OLT. Follow-up for each patient group was calculated in patient-months.

Primary study end points were extracted from case records of patients beginning with the hospitalization for the initial intervention—either TIPS or PSS. These include periprocedural (30-day) and subsequent mortality, episodes of portal hypertensive rebleeding, and shunt revisions. Secondary end points, accrued following the index hospitalization for TIPS or PSS, included additional hospitalizations, total units of blood transfused, diagnostic shunt-surveillance procedures (ultrasonographic, angiographic, and upper endoscopic studies), and hospital charges and professional fees.

Statistical analyses for differences between TIPS and PSS patient groups were performed both for inclusion criteria (age, sex ratio, Child-Pugh hepatic status, and alcoholic vs nonalcoholic cause for cirrhosis) and the primary and secondary study end points. Statistical analysis was performed by using the t test, χ² test, or Fisher exact test. Statistical significance was set at P<.05.

categories of decompensated cirrhotic patients, eg, those with intractable coagulopathies, severe ascites, hypersplenism, and, perhaps, hepatoportal failure.

A more problematic indication for TIPS has been its broad utilization in good-risk cirrhotic patients with portal hypertensive bleeding. The cardinal shortcoming of TIPS is its well-documented lack of durability; TIPS channel stenosis or thrombosis may occur in up to 50% of such patients within 6 to 12 months after installation.2,4 Because, if untreated, this results in a return of portal hypertension and a predictable likelihood of variceal rebleeding, it is not clear whether TIPS is safe or cost-effective in this particular good-risk patient population.

Therefore, we designed a study to compare clinical and resource allocation outcomes in a series of good-risk cirrhotic patients with portal hypertensive bleeding undergoing either TIPS or PSS.

RESULTS

Twenty patients meeting inclusion criteria and undergoing TIPS were compared with 20 matched patients undergoing PSS. All 40 patients underwent initially successful portal decompression. Procedures in PSS patients included 12 small orifice direct portocaval shunts, 6 distal splenorenal shunts, and 2 portocaval H-graft shunts. Follow-up was complete for all 40 patients, 385 patient-months (mean, 19.2 months) for those who underwent TIPS and 456 patient-months (mean, 22.9 months) for patients who underwent PSS. Demographic and outcome data are presented in the Table.

COMPARISON BETWEEN GROUPS

No statistically significant differences between TIPS and PSS groups were found for age, sex ratio, Child-Pugh classification, or alcoholic vs nonalcoholic cause of cirrhosis (Table).
MORTALITY

Four patients receiving TIPS died in the first 30 days, compared with none in the PSS group, a difference that did not achieve statistical significance (P = .20). Two TIPS patients died of recurrent variceal bleeding, 1 from intra-abdominal bleeding following hepatic capsular perforation and the other of progressive hepatorenal failure. During follow-up, 0 TIPS patients and 2 PSS patients died (P > .10). One of the PSS patients died as a consequence of end-stage liver disease; the other died of a cirrhosis-related hepatocellular carcinoma. Overall mortality in this series did not differ.

ORTHOTOPIC LIVER TRANSPLANTATION

No patient in either arm of this study was referred for consideration of, or listed for, OLT. None required consideration of OLT through December 1999 (24 months after this study was completed).

REBLEEDING

Recurrent variceal hemorrhage occurred 23 times in 10 TIPS patients, while a single PSS patient had 1 episode of recurrent portal hypertensive bleeding (P < .001). During follow-up, 55 units of blood were transfused among TIPS patients compared with 0 units in PSS patients (P < .001).

SHUNT REVISIONS

Revision of TIPS, either by balloon angioplasty or repeat stenting of the existing TIPS channel or by placement of a new TIPS stent, was required 30 times in 12 patients. Two shunt revisions were required in 2 PSS patients (P < .001 for numbers of shunt revisions).

OTHER OUTCOMES

Outcome data for hospital readmissions, diagnostic studies, and resource allocation are given in the Table (all significant, P < .005).

Twenty repeated hospitalizations were required among 9 TIPS patients; 3 were required for 2 PSS patients.

During follow-up, a total of 82 and 32 ultrasound, 21 and 10 angiographic, 18 and 2 endoscopic, and 121 and 44 total diagnostic studies were performed in TIPS and PSS patients, respectively. Eight of the 10 angiograms performed in PSS patients were carried out immediately postoperatively to document the trans-shunt portacaval pressure gradient, rather than for therapeutic reasons.

Total hospital charges during follow-up were $91,683 for TIPS patients and $48,589 for PSS patients. Professional fees during follow-up totaled $19,890 for TIPS patients and $13,343 for PSS patients. Total hospital and professional charges during follow-up were $111,573 for TIPS patients and $61,934 for PSS patients.

COMMENT

The TIPS technique is an undeniable advance in the management of patients with chronic liver disease and bleeding from portal hypertension. After its experimental validation by Rosch and colleagues5 in the 1960s, the initial clinical trials of the concept by Colapinto and others7 in the 1970s, and the development of contemporary TIPS technique and technology under the guidance of Ring,7 Rossle,8 and coworkers since the late 1980s, TIPS has been ever more broadly applied, not only in patients with Child-Pugh class C cirrhosis or other poor-risk patients with variceal bleeding but in other disease categories, such as patients with Budd-Chiari syndrome,9 intractable ascites,10,11 hypersplenism,12 and even hepatorenal syndrome.13 The relative ease and noninvasiveness of the procedure and its predictable early success rate have quickly resulted in its broad application to almost all patients with portal hypertensive bleeding, regardless of the status of their underlying chronic liver disease.

However, current evidence suggests that, although TIPS may be of immense advantage in poor-risk cirrhotic patients (especially those awaiting OLT), the procedure lacks durability. The TIPS channel rapidly becomes stenotic due to exuberant neointimal hyperplasia.3,4,13 Sanyal and colleagues6 demonstrated shunt stenosis or occlusion and variceal rebleeding in more than 50% of 100 consecutive patients who underwent TIPS during follow-up of less than 1 year. While such stenosis can be detected by serial ultrasonography or angiography, and thrombosis or rebleeding forestalled by repeated balloon angioplasty or stent placement (or insertion of a new TIPS channel),14,15 such management requires significant resource allocation as well as (importantly in this patient population) a compliant patient.

Experimental maneuvers to improve TIPS' durability by the use of graft-covered stents,16 intraluminal irradiation,17 or other novel modalities are under investigation but have not yet found clinical application.

Because of the ever-widening use of TIPS and the maturation of techniques of liver transplantation, a marked reduction in the numbers of PSS procedures for variceal hemorrhage has resulted over the past decade. Moreover, PSS is currently so uncommonly performed that oral examiners for the American Board of Surgery are discouraged from querying candidates for board certification regarding the technical details of PSS (Robert Rhodes, MD, American Board of Surgery, Inc, oral communication, October 1999). Some18 have speculated whether surgical portal decompression is obsolete; others have lamented that this has de facto become the case because so few surgeons have retained the technical and judgment skills involved with PSS (I. James Sarfeh, MD, oral communication, January 2000).

The morbid side effects of the standard surgical portal decompressive procedure are well documented. While the traditional portacaval shunt is extraordinarily effective at achieving its primary goal—permanent elimination of any future portal hypertensive bleeding—the likelihood of subsequent hepatic and neuropsychologic deterioration has discouraged all but the most diehard gastroenterologists and surgeons regarding the use of the “total” PSS.

However, just as for TIPS, technology and technique have advanced apace in surgical portal decompression. Large series of patients undergoing variations of the
standard portacaval shunt, designed either to maintain prograde hepatic portal perfusion or to limit the risk of postoperative portasystemic encephalopathy by producing only “partial” portal decompression, have been reported in the past 2 decades. These studies have demonstrated that “small-stoma” surgical shunts can be performed safely, with durability in protecting against recurrent variceal hemorrhage equivalent to that of the standard portacaval shunt, and with significantly lower risks of subsequent portasystemic encephalopathy—in fact, at rates little different from those resulting from the natural history of cirrhosis in nonshunted patients.

The present study, while retrospective, was designed as a case-control comparison of 2 different therapies for variceal bleeding in a group of relatively good-risk cirrhotic patients matched for age, sex, degree of hepatic decompensation, and cause of chronic liver disease. In this comparison, we demonstrated that, although all TIPS and PSS patients underwent an initially successful portal decompression, patients receiving TIPS had a highly statistically significantly greater likelihood of rebleeding, total units of blood transfused, rehospitalization, and shunt revision during medium-term follow-up. Patients who underwent TIPS required significantly more diagnostic procedures of all types and required resource expenditures during follow-up in almost double those of PSS patients. Follow-up was relatively short among the patients in this study; the advantages we demonstrated in surgically shunted patients would have become even more stark with longer follow-up.

We conclude from this study that, in comparison to surgical portal decompression, TIPS is neither durable nor cost-effective in good-risk cirrhotic patients with portal hypertensive bleeding. On the contrary, such patients are as likely to survive, are much less likely to experience rebleeding, and will consume vastly fewer medical resources if referred for surgical shunt. These results are consonant with those of a small prospective randomized trial of TIPS vs H-graft portacaval shunt by Rosemurgy and colleagues, in which it was demonstrated that deaths, rebleeding, and treatment failures were substantially greater in TIPS patients than in surgically shunted patients. In addition, in a recently published decision analysis in patients with Child-Pugh class A cirrhosis undergoing TIPS or PSS, Zacks et al demonstrated prohibitively greater expenditures—almost $150,000 per life-year saved—for patients undergoing angiographic portacaval shunt.

Cirrhosis ranks 10th among all causes of death in the United States—to a large extent because it commonly results either in end-stage liver disease or bleeding from portal hypertension, or both. Currently, a substantial proportion of good-risk cirrhotic patients treated for variceal hemorrhage in the United States are considered to be candidates for TIPS; our data suggest that this approach in such patients is neither durable nor cost-effective. Two prospective randomized trials of surgical shunt vs TIPS (University of California San Diego [Marshall J. Orloff, MD]; Cleveland [Ohio] Clinic Foundation [J. Michael Henderson, MD]) are in progress and results will likely be reported within the next 2 years. We predict that these studies, like ours, will demonstrate the superiority of surgical over angiographic shunt in good-risk patients with portal hypertensive bleeding.

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REFERENCES