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A Prospective Trial of Transjugular Intrahepatic Portasystemic Stent Shunts *Versus* Small-Diameter Prosthetic H-Graft Portacaval Shunts in the Treatment of Bleeding Varices

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Objective

The authors compare transjugular intrahepatic portasystemic stent shunts (TIPS) to small-diameter prosthetic H-graft portacaval shunts (HGPCS).

Summary Background Data

Transjugular intrahepatic portasystemic stent shunts have been embraced as a first-line therapy in the treatment of bleeding varices due to portal hypertension, although they have not been compared to operatively placed shunts in a prospective trial.

Methods

In 1993, the authors began a prospective, randomized trial to compare TIPS with HGPCSs. All patients had bleeding varices and had failed nonoperative management. Shunting was undertaken as definitive therapy in all. Failure of shunting was defined as an inability to accomplish shunting despite repeated attempts, unexpected liver failure leading to transplantation, irreversible shunt occlusion, major variceal rehemorrhage, or death. Mortality and failure rates were analyzed at 30 days (early) and after 30 days (late) using Fischer's exact test.

Results

There were 35 patients in each group, with no difference in age, gender, Child's class, etiology of cirrhosis, urgency of shunting, or incidence of ascites or encephalopathy between groups. In two patients, TIPS could not be placed despite repeated attempts. Transjugular intrahepatic portasystemic stent shunts reduced portal pressures from 32 ± 7.5 mmHg (standard deviation) to 25 ± 7.5 mmHg ($p < 0.01$), whereas HGPCS reduced them from 30 ± 4.6 mmHg to 19 ± 5.3 mmHg ($p < 0.01$; paired Student's t test). Irreversible occlusion occurred in three patients after placement of TIPS. Total failure rate after TIPS placement was 57%; after HGPCS placement, it was 26% ($p < 0.02$).

Conclusions

Both TIPS and HGPCS reduce portal pressure. Placement of TIPS resulted in more deaths, more rebleeding, and more than twice the treatment failures. Mortality and failure rates promote the application of HGPCS over TIPS.

More than 10 years ago, partial portal decompression in the successful treatment of portal hypertension was reported.[1] Since then, other authors[2–4] have corroborated Sarfeh's early work with small-diameter prosthetic H-graft portacaval shunts and partial portal decompression. A low incidence of rebleeding with a low incidence of encephalopathy and liver failure have characterized Sarfeh's work[5] and the later reports.

Beginning in 1991, placement of transjugular intrahepatic portasystemic stent shunts (TIPS) was reported to achieve partial portal decompression.[6] Proponents were attracted to TIPS placement because it avoided a surgical procedure and perceived attendant risks. Although TIPS and small-diameter H-graft portacaval shunts have been reported to achieve similar—although not identical—degrees of portal decompression, different complications are believed to occur with the two procedures. In general, patients undergoing H-graft shunt placement face risks of a major operation in the setting of complicated cirrhosis, whereas patients undergoing TIPS placement face risks related to the transhepatic prosthesis, namely thrombosis, migration, and procedurally related bleeding.[7–10]

The superiority of operatively achieved (H-graft shunts) *versus* radiologically achieved (TIPS) partial portal decompression has been argued in many ways on countless occasions. Each is favored by many, but without the aid of a head-to-head comparative trial, no definitive positions have been possible. To address this void, this trial was undertaken to prospectively compare placement of TIPS *versus* small-diameter prosthetic H-graft portacaval shunts in the treatment of variceal bleeding due to cirrhosis and portal hypertension. Our hypothesis in undertaking this trial was that TIPS and small-diameter H-graft shunts would be equally efficacious and equally safe in the treatment of bleeding due to portal hypertension.

MATERIALS AND METHODS

This trial comparing TIPS to small-diameter prosthetic H-graft portacaval shunts began in 1993, with full Institutional Review Board approval. All patients had cirrhosis and portal hypertension with bleeding esphagogastric varices or hypertensive gastropathy. All patients had failed sclerotherapy (esophageal varices) or were not candidates for sclerotherapy (gastric varices or hypertensive gastropathy). Shunting was undertaken as definitive therapy, never as a bridge to transplantation.

On presentation, all patients underwent appropriate resuscitation. Patients were assigned a Child's class. Endoscopy was undertaken with sclerotherapy, when indicated. Color-flow Doppler ultrasound (Acuson 128 with linear array 5-MHz probe, Acuson Corp., Mountain View, CA) was used to determine hepatic vein and portal vein patency and the direction and velocity of portal vein flow. Visceral angiography was undertaken for set indications—possible portal vein thrombosis or uncertain portal vein anatomy.

Patients were randomized, once they were believed to be candidates for partial portal decompression, to either TIPS or H-graft shunts. Patients were not candidates for randomization if portal vein thrombosis had occurred or anticipated chances of survival were hopeless because of profound ill health.

After obtaining informed consent, patients were randomized in pairs to allow for sequential analysis by pair differences. The first of a pair underwent TIPS or H-graft shunt placement and the second of the pair underwent the other shunt. The physicians obtaining consent for the protocol and caring for the patient did not know which procedure was next to be assigned.

All TIPS procedures were undertaken with general anesthesia. Nearly all TIPS were placed using a right internal jugular approach. One TIPS was placed using a left internal jugular approach due to right jugular occlusion. The internal jugular vein was entered with a 21-gauge, single-wall needle from a Coaxial Micropuncture Introducer set (Cook Surgical, Bloomington, IN). Through the 21-gauge needle, an 0.018 wire was introduced into the central venous system and the coaxial dilator system advanced over this wire. With a 5-French dilator in the internal jugular vein, a Wholey guide wire (Mallinckrodt Medical, St. Louis, MO) was directed down the superior vena cava and into the inferior vena cava. After serial dilatation, the 10-French introducer sheath from the Rosch-Uchida Transjugular Liver Access set (Cook Surgical) was advanced over the guide wire into the inferior vena cava. Pressures were obtained in the inferior vena cava using a high-pressure preceptor Morse Manifold (NAMIC, Glens Falls, NY).

Through the 10-French introducer sheath, a 7-French multipurpose catheter (Cordis, Miami, FL) was advanced into the inferior vena cava and used to selectively catheterize the right hepatic vein. Over a guide wire, the catheter was advanced into a wedged position in the right lobe of the liver. Hexabrix contrast (Mallinckrodt Medical) was injected through the wedged catheter with filming in digital mode to fill the portal venous system. If the portal venous system was visualized, it was marked appropriately for eventual transhepatic puncture.

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The 7-French multipurpose catheter was exchanged out over the Wholey guide wire, and the introducer sheath was advanced well into the right hepatic venous system. Through the sheath, a 14-gauge sheathed needle (Rosch-Uchida Transjugular Liver Access set) was advanced into the right hepatic venous system. Under fluoroscopic guidance, the sheathed needle was pulled back into the proximal right hepatic vein and pointed anteriorly. A coaxial 22-gauge sheathed needle then was thrust through the liver parenchyma toward the right portal vein near the bifurcation of the main portal vein. Then the needle itself was removed and the sheath/dilator was connected to a syringe filled with Hexabrix. Then the dilator was pulled back until copious blood flow was obtained. Contrast was injected, confirming the position of the tip of the dilator in the portal venous system.

Once appropriate portal venous access had been obtained, the Wholey wire was advanced onto the main portal vein and down into the superior mesenteric vein. A 7-French multipurpose catheter was advanced over the Wholey wire into the superior mesenteric vein. Pressure monitoring was obtained using the Morse manifold as aforementioned. Portal pressure was measured, and the pressure gradient between the portal vein and the inferior vena cava was calculated. Then contrast was injected through the multipurpose catheter with filming over the abdomen in digital mode to define portal, splenic, and superior mesenteric venous anatomy and portoazygous collaterals.

The transhepatic tract from the right hepatic vein to the portal vein was balloon-dilated using an 8-mm Ultrathin angioplasty balloon (Meditech, Boston Scientific Corp., Watertown, MA). The balloon was exchanged out over a guide wire for the 10-mm × 68-mm Schneider Wallstent (Pfizer, New York, NY). The Wallstent was positioned appropriately under fluoroscopic guidance and then deployed. After successful deployment, the entire stent was balloon dilated to 8 mm.

Then the stent catheter was removed over a guide wire. The 7-French multipurpose catheter was again positioned in the superior mesenteric vein. Contrast was injected, confirming location and patency of the shunt. The presence of hepatopedal or hepatofugal flow in the left-sided portal venous system was documented. Pressures were then measured in the superior mesenteric vein and inferior vena cava, and a pressure gradient was calculated. We strived to obtain pressure gradients in the range of 8 mmHg to 12 mmHg. If the gradient was greater than 12 mmHg, the stent was dilated to a diameter of 10 mm with an Ultrathin balloon (Boston Scientific Corp.). Pressures in the portal/superior mesenteric vein and inferior vena cava were measured again. Then contrast was injected through the catheter to again document portal venous anatomy, collateral filling, and patency of the shunt.

If significant gastric collateral vessels remained after TIPS placement, they were embolized with appropriately sized embolization macro coils (Cook Surgical). At the successful conclusion of the procedure, the 10-French introducer sheath was exchanged out for a short 10-French introducer sheath (Boston Scientific Corp), which was then positioned with its tip in the superior vena cava. This sheath was left in place for 2 to 4 days, at which time the patient was brought back to the angiography suite for trans-shunt venography and venous pressure measurements.

Before trans-shunt venography, all patients underwent duplex ultrasound to document patency of the shunt and to measure flow velocities within the shunt and within the portal venous system. These measurements were used to assess trans-shunt flow and as baseline values to be followed as a noninvasive assessment shunt patency and function of TIPS. Midshunt flow velocities of 100 cm/sec or more were sought. Flow velocities of less than 100 cm/sec generally led to stent dilatation/thrombectomy at the time of trans-shunt venography.

The technique of small-diameter prosthetic H-graft portacaval shunt has been described in detail.[11] Briefly, 8-mm externally reinforced polytetrafluorethylene (W. L. Gore, Flagstaff, AZ) was used. The graft measured 3 cm from toe to toe and 1½ cm from heel to heel, with bevels at each end oriented 90° to each other. A portion of the caudate lobe was excised generally to allow for shunt placement. Portal vein and inferior vena cava pressures were measured intraoperatively before and after shunting. Intraoperative assessment of portal and cava flow was undertaken before and after shunting using color-flow Doppler ultrasound. Extensive efforts to ligate collaterals from the portal vein were not undertaken. Shunt patency was assessed venographically near the fifth postoperative day via transfemoral cannulation of the shunt. Large collateral varices were embolized if present and easily accessible.

Patients undergoing TIPS placement had color-flow Doppler assessment of the shunt 6 to 12 weeks after shunting. Again, midstent flow velocities of 100 cm/sec or more were sought. Slower flow velocities led to transjugular shunt cannulation and, if necessary, shunt thrombectomy/dilatation.

All patients were followed, at a minimum, through semiannual clinic visits, which included color-flow Doppler assessment of shunt patency. One year after placement, all shunts were studied using transvenous cannulation, venography, and pressure measurement.

Failure of shunting was defined as an inability to accomplish shunting despite repeated attempts and appropriate anatomy, unexpected liver failure leading to trans-

Table 1. COMPARISON OF PATIENTS UNDERGOING TRANSJUGULAR INTRAHEPATIC PORTASYSTEMIC STENT SHUNTS (TIPS) OR 8-MM PROSTHETIC H-GRAFT SHUNTS

	TIPS	H-Graft Shunt
Patients	35	35
Age (yr) (mean ± SD)	53 ± 12.9	53 ± 13.5
Gender	8F, 27M	16F, 19M
Ascites (%)	74	69
Encephalopathy (%)	37	23
Child's class	8A, 14B, 13C	8A, 19B, 8C

plantation, major variceal rehemorrhage, irreversible shunt occlusion, or death. Ascites was defined as none, mild (well palliated with high-dose diuretic therapy and volume restriction), or severe (persistent and troublesome despite treatment). Encephalopathy was defined on a clinical basis: none, mild (clears with lactulose and dietary protein restriction), or severe (persistent and requiring hospitalization despite lactulose and dietary restriction).

Emergency shunts were undertaken as quickly as possible in patients with unremitting and uncontrolled variceal bleeding. Urgent shunting was defined as shunting undertaken within 24 hours, generally in accordance with response to aggressive nonsurgical management. Occasionally, the urgency in which shunting was undertaken was partially determined by surgeon/radiologist convenience. Shunting was elective when it was undertaken solely at surgeon/radiologist convenience.

All patients are being followed prospectively. None are lost to follow-up. Data pertinent to this trial were entered into a file-based registry (dBase IV, Borland International, Inc., Borland, TX) on an computer. Data are presented as mean ± standard deviation when appropriate. Statistical analysis was undertaken using TRUE EPISTAT (EPISTAT, Richardson, TX). Statistical significance was assigned with 95% probability.

RESULTS

Seventy patients were randomized in pairs to undergo either TIPS or 8-mm prosthetic H-graft shunt placement. There was no difference in age, gender, Child's class, incidence of ascites, or incidence of encephalopathy, which was always mild, between those undergoing TIPS *versus* H-graft shunt placement (Table 1). In patients undergoing TIPS placement, cirrhosis was due to alcohol abuse (83%), viral hepatitis (9%), alpha-1 antitrypsin deficiency (3%), or idiopathic causes (6%). For patients undergoing H-graft shunt placement, cirrhosis was due to alcohol abuse (75%), viral hepatitis (11%), methotrexate toxicity (3%), autoimmune hepatitis (3%), or unknown causes (11%). Shunting was undertaken as an emergency, urgently, or electively similarly in both groups (Table 2). In two patients (6%), TIPS could not be placed despite repeated attempts and acceptable anatomy. In each case, the liver was too hard to be penetrated for access to the portal vein.

Table 2. TIMING OF SHUNTING IN PATIENTS UNDERGOING TRANSJUGULAR INTRAHEPATIC PORTASYSTEMIC STENT SHUNTS (TIPS) OR H-GRAFT SHUNTING

	TIPS (%)	H-Graft Shunt (%)
Elective	63	80
Urgent	31	9
Emergency	6	11

Transjugular intrahepatic portasystemic stent shunts and H-graft shunts significantly reduced portal pressures and reduced portal vein–inferior vena cava pressure gradients in all patients (Table 3). Early occlusion of TIPS occurred in less than 30 days in six patients (17%) and was corrected by transvenous thrombectomy/stent dilatation in each. Despite close follow-up, late occlusion occurred in four patients and could only be corrected in one. Occlusion of H-graft shunts occurred in three patients (9%) within 30 days of shunting. In two, reoperation achieved shunt patency without major morbidity, although one required conversion to a mesocaval shunt. Late H-graft shunt occlusion occurred in one patient (3%). This was detected during routine follow-up and was corrected nonoperatively by transvenous shunt

Table 3. PORTAL PRESSURES AND PORTAL VEIN–INFERIOR VENA CAVA PRESSURE GRADIENTS BEFORE AND AFTER SHUNTING

	TIPS (mmHg)	H-Graft Shunt (mmHg)
Preshunt portal pressure	32 ± 7.5	30 ± 4.6
Postshunt portal pressure	25 ± 7.5*	19 ± 5.3*†
Preshunt pressure gradient	18 ± 5.8	17 ± 3.8
Postshunt pressure gradient	10 ± 3.9	6 ± 3.8‡

TIPS = transjugular intrahepatic portasystemic stent shunts.
* Less than preshunt pressure ($p < 0.01$, paired Student's t test).
† Less than portal pressure after TIPS ($p < 0.01$, Student's t test).
‡ Less than pressure gradient after TIPS ($p < 0.01$, Student's t test).

Table 4. CAUSES OF DEATH WITHIN 30 DAYS OF TRANSJUGULAR INTRAHEPATIC PORTASYSTEMIC STENT SHUNTS (TIPS) OR SMALL DIAMETER PROSTHETIC H-GRAFT PORTACAVAL SHUNT

	TIPS	H-Graft Shunt
Liver failure	4	4
Variceal hemorrhage	2	0
Adult respiratory distress syndrome	0	1
Total	6	5

thrombectomy. Late follow-up documented continued shunt patency.

Major variceal rehemorrhage occurred in four patients (11%) after TIPS placement, fatally in one (3%). In three of four patients, rehemorrhage occurred more than 30 days after TIPS. In each with rehemorrhage, the TIPS were patent, although in two, mild stenosis was noted and the stent was dilated. No patients rehemorrhaged after H-graft shunts. Within 30 days after TIPS placement, encephalopathy occurred in 10 patients (29%) and ascites was present in 65 (92%). Within 30 days after H-graft shunt placement, encephalopathy occurred in 9 (26%) and ascites was present in 48 (68%). Within 30 days of shunting, six patients (17%) died after TIPS placement and five (14%) died after H-graft shunt (Table 4). After TIPS placement, six died more than 30 days postprocedure; after H-graft shunt, three died late (Table 5). All late deaths occurred by 1 year after shunting. In all, 12 patients (34%) died after TIPS placement and 8 (20%) died after H-graft shunts. One patient required liver transplantation, *i.e.*, after TIPS placement. Failure of shunting occurred in 20 patients (57%) after TIPS placement and in 9 (26%) after H-graft shunts (Table 6). Major morbidity and mortality after shunting are summarized in Table 7.

Table 5. CAUSES OF DEATH MORE THAN 30 DAYS AFTER TRANSJUGULAR INTRAHEPATIC PORTASYSTEMIC STENT SHUNTS (TIPS) OR SMALL DIAMETER H-GRAFT SHUNT

	TIPS	H-Graft Shunt
Liver failure	4	2
Car accident	1	0
Variceal hemorrhage	1	0
Colon cancer	0	1
Total	6	3

Table 6. CAUSES AND OCCURRENCES OF SHUNT FAILURE AFTER TRANSJUGULAR INTRAHEPATIC PORTASYSTEMIC STENT SHUNTS (TIPS) AND SMALL DIAMETER PROSTHETIC H-GRAFT SHUNTS

	TIPS	H-Graft Shunt
Could not place shunt	2	0
Irreversible occlusion	3	1
Major variceal hemorrhage	4	0
Liver transplantation	1	0
Death within 30 days	6	5
Death after 30 days	6	3
Total failures	20*	9†

* There were 22 occurrences of shunt failure in 20 patients.
† Less than after TIPS ($p < 0.02$, chi square test).

DISCUSSION

The concept that partial portal decompression can be obtained nonoperatively and without surgeon intervention is attractive to many, particularly to "nonsurgeons." Large series of TIPS placement have been generated, with results thought to promote further application of TIPS.[12,13] Placement of TIPS has become, to many, the treatment of choice for bleeding gastroesophageal varices due to cirrhosis and portal hypertension, especially as a bridge to liver transplantation. The role of TIPS, however, has remained ill defined to others because TIPS placement has not been compared to other forms of shunting. This trial has, for the first time, prospectively compared TIPS with an operatively constructed shunt. In this trial, TIPS are inferior to 8-mm prosthetic H-graft portacaval shunts in achieving partial portal decompression and adequate clinical outcome.

Table 7. MAJOR MORBIDITY AND MORTALITY OCCURRING AFTER TRANSJUGULAR INTRAHEPATIC PORTASYSTEMIC STENT SHUNTS (TIPS) AND H-GRAFT SHUNTS

	TIPS (%)	H-Graft Shunt (%)
Occlusion within 30 days	17	9
Deaths within 30 days	17 (6/35)	14 (5/35)
Occlusion after 30 days	14 (4/29)	3 (1/30)
Deaths after 30 days	21 (6/29)	10 (3/30)
Variceal rehemorrhage	11	0
Shunt failure	57*	26

* Greater than after H-graft shunts ($p < 0.02$, chi square test).

Patients in this trial generally were older alcoholic men with ascites. Encephalopathy preshunt was not common, but was mild when it did occur. Patients undergoing TIPS placement and those undergoing H-graft shunt placement were very similar. Age, gender, or presence of ascites or encephalopathy were not different between the groups undergoing placement of each of the shunts. Patients in both groups were predominantly of Child's class B and C. Less than one quarter of each group belonged to Child's class A. Furthermore, etiologies of cirrhosis were similar between those undergoing TIPS placement and those undergoing H-graft shunt placement.

Both shunts decreased portal pressures and reduced portal vein–inferior vena cava pressure gradients. Procedural difficulties were not common with TIPS placement. Transjugular intrahepatic portasystemic stent shunts could not be placed in a small number, consistent with many other reports. Thrombosis, both early and late, was more common with TIPS despite close follow-up and surveillance monitoring. This tendency has been noted by others.[7–10] Late occlusion often was irreversible. The patency rates of TIPS are best thought of in terms of "assisted" patency because surveillance color-flow Doppler scanning and prompt intervention are required to maintain TIPS patency in a substantial number.

Late occlusion of small-diameter prosthetic H-graft portacaval shunts have been unusual in our overall experience,[14] as well as in this trial. Routine surveillance studies have shown us that less than 3% of the more than 100 8-mm prosthetic H-graft shunts we have placed have occluded, with follow-up currently reaching 9 years.

Rehemorrhage seems more frequent after TIPS than H-graft shunt placement, in part, presumably because TIPS are more likely to narrow and occlude. Nonetheless, variceal rebleeding unfortunately is common after TIPS placement, even when patency is maintained, as in this trial. Rehemorrhage did not occur after 8-mm prosthetic H-graft shunt placement in this trial, and in our larger experience, it is very uncommon.[14] When rebleeding does occur after H-graft shunt, it is nearly uniformly due to gastric variceal bleeding or bleeding from hypertensive gastropathy with a patent shunt. Splenic artery embolization has proven useful in this unusual event.

Neither shunt in this trial seems particularly prone to causing encephalopathy. Although difficult to quantitate in quality, clinically apparent encephalopathy was equally frequent in each shunt group preshunt and postshunt. Qualitative differences in encephalopathy between groups were not studied thoughtfully, and any comments would be speculative and merely conversational.

Neither shunt is ascitogenic; TIPS does not relieve ascites as well as H-graft shunts do, presumably because the latter produces lower postshunt portal pressures and portal vein–inferior vena cava pressure gradients.

Early mortality after either shunt occurs in nearly one in six. This relatively high mortality rate is a reflection of our lack of selection in patient entry. The patients operated on in this trial were "all comers" and thus, generally older alcoholic men with ascites. The high number of "elective" shunts is misleading because a great number of these patients had survived variceal hemorrhage, trials of sclerotherapy, variceal balloon compression, and aggressive pharmacotherapy before randomization. Because their shunts were undertaken at surgeon/radiologist convenience during hospitalization, the shunts were classified as elective. Nonetheless, intervention was necessary in a timely fashion, reflecting the inadequacy of our classification system more than the "elective" nature of their problem. The mortality rate of this trial undoubtedly was affected by the high number of Child's class B and C patients. The small number of Child's class A patients reflects the profile of patients available to us.

Late mortality occurs somewhat more frequently after TIPS placement. This seems to be a result of progressive hepatic deterioration, as has been noted elsewhere,[7,15] but objective corroborative data generally are lacking. All deaths occurred by 1 year after shunting. Undoubtedly and unfortunately, we can expect further patient fall-out as our follow-up continues. We expect late deaths to primarily occur with TIPS. Our large overall experience with small-diameter prosthetic H-graft shunts shows us that death more than 1 year after shunting is relatively uncommon.[14] We expect that continued follow-up will favor H-graft shunts over TIPS.

Failure of shunting is more common after TIPS placement, occurring in more than half of the patients undergoing TIPS placement and just one quarter undergoing H-graft shunt placement. Failure of shunting, as we defined it, is an all encompassing term that includes occurrences beyond death, major variceal rehemorrhage, and occlusion. When focusing just on these events, TIPS failed nearly two-and-a-half times as often as H-graft shunts.

After this trial, it seems difficult to support TIPS in the treatment of bleeding esophagogastric varices due to cirrhosis and portal hypertension, except as an immediate bridge to transplantation and in patients whose cardiorespiratory ill health precludes surgical intervention. The use of TIPS as a bridge to transplantation warrants further consideration. As this trial documents, the application of TIPS to cirrhotic patients with bleeding varices may not be a "bridge" to hepatic transplantation, but instead hasten the need for transplantation. In cirrhotic patients with bleeding varices, TIPS should only be used for those with documented marginal hepatic reserve in

whom survival would be limited even if the variceal bleeding had not occurred.

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Discussion

DR. HARRY H. LEVEEN (Charleston, South Carolina): I rise to congratulate the authors and to welcome back into surgical thinking the idea of lowering the portal vein pressure. The rise in the portal vein pressure is progressive and unrelenting. Portal pressures, as found by the authors, are really not venous pressures but arteriolar pressures. The dilatation of the portal vein extends through the venules and capillaries into the arterioles. This progressive arterialization of the portal circulation must be interrupted by lowering the portal vein pressure with a portocaval shunt. Persistently high venous pressure inevitably causes A-V communications. However, I should like to discuss the disabling encephalopathy that often follows portocaval shunts.

Thirty percent of all the urea in the body is converted to ammonia every day in the colon by bacterial urease. Through a grant from a pharmaceutical company, a small research group has developed a nonenzymatic urease antigen. Immunization with this urease antigen halts the normal turnover of urea to ammonia in the colon, thereby alleviating the encephalopathy. This development may possibly eliminate the major drawback to portocaval shunts. Anyone interested in utilizing this immunization, please communicate with me. We will donate the antigen and information.

DR. J. MICHAEL HENDERSON (Cleveland, Ohio): Transjugular intrahepatic portasystemic shunt (TIPS) are topical. This is clearly one of the hottest topics in portal hypertension in the 1990s. I commend Dr. Rosemurgy and his group for being the first to present to us a prospective randomized controlled trial comparing TIPS to surgical shunts.

To date, there have been four prospective randomized trials comparing TIPS to sclerotherapy, most being presented in abstract form or at meetings with less than a year follow-up. The data are compatible with your TIPS data, with rebleeding rates in most studies running at 18% for TIPS compared with 25% in the sclerotherapy groups. The mortalities in those studies have been equivalent in TIPS with sclerotherapy. The encephalopathy rate in TIPS in those studies is 29%, again parallel with your rate of encephalopathy, compared with 6% in the sclerotherapy groups. I have several questions related to your presentation.

First, did you include all patients who needed variceal decompression since 1993, or was this population selected from a larger pool of patients? I may have missed it, but I am not sure what your median follow-up is to date for the data you presented. Perhaps you could reemphasize this?

My next question relates to the experience of your radiologists with TIPS before the initiation of this study. I am a little surprised to see you doing them under general anesthesia. I think most centers do them under sedation. In our hands, the majority of these are very easily accomplished by a radiologist within 30 to 40 minutes nowadays. Are you still doing these under general anesthesia? I sensed a little hesitancy with your radiologist leaving catheters in for 2 to 4 days and recatheterizing all of your shunts before discharge. Our routine is a 24-hour Doppler flow study and if patency is good at that point, they then get into a protocol with 6 weeks and 3 months follow-up. I would like further comment on your radiologists' experience. Were they beyond the learning curve?

You did not present any data on ascites. In your manuscript, the incidence of ascites was very high. You quoted a 90% incidence of ascites following TIPS. Transjugular intrahepatic portasystemic stent shunts have been widely used to treat ascites, and I was concerned that you had such a high rate in the TIPS group. Again, at later follow-up, what is happening to ascites in this group of patients? Maybe you could elucidate that for us.

Finally, although the numbers are small, it is not clear to me if there is a difference by the subgroups. You have a 30% Child's class C population. I wonder if you have looked at that subset