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

References

1. Sarfeh IJ. Comparative study of portacaval and mesocaval interposition shunt. Am J Surg 1981; 142:511–513.
2. Adam R, Diamond T, Bismuth H. Partial portacaval shunt: renaissance of an old concept. Surgery 1995; 111:610–616.
3. Darling CR, Shah DM, Chang BB, et al. Long-term follow-up of poor risk patients undergoing small diameter portacaval shunt. Am J Surg 1992; 164:225–228.
4. Rosemurgy AS, McAllister EW, Kearney RE. Prospective study of a prosthetic H-graft portacaval shunt. Am J Surg 1991; 161:159–164.
5. Rypins EB, Sarfeh IJ. Small diameter portacaval H-graft for variceal hemorrhage. Surg Clin North Am 1990; 70:395–404.
6. Zemel G, Katzen BT, Becker GJ, et al. Percutaneous transjugular intrahepatic portosystemic shunt. JAMA 1991; 266:390–393.
7. Martin M, Zajko AB, Wright H, et al. Transjugular intrahepatic portosystemic shunt in the manage of variceal bleeding: indications and clinical results. Surgery 1993; 114:719–726.
8. Jalan R, Redhead DN, Hayes PC. Transjugular intrahepatic portasystemic stent—shunt in the treatment of variceal hemorrhage. Br J Surg 1995; 82:1158–1164.
9. LaBerge JM, Sonberg KA, Lake JR, et al. Two year outcome following transjugular intrahepatic portosystemic shunt for variceal bleeding: results in 90 patients. Gastroenterology 1995; 108:1143–1151.
10. Crecelius SA, Soulen MC. Transjugular intrahepatic portosystemic shunts for portal hypertension. Gastroenterology 1995; 24: 201–219.
11. Rosemurgy AS. Small diameter interposition shunt. In: Nyhus L, Baker R, Fischer J, eds. Mastery of Surgery. Boston, MA: Little Brown and Co; 1996 (in press).
12. Coldwell DN, Ring EJ, Rees CR, et al. Multicenter investigation of the role of transjugular intrahepatic portosystemic shunt in the management of portal hypertension. Radiology 1995; 196:335–340.
13. Miller-Catchpole R. Diagnostic and therapeutic assessment: transjugular intrahepatic portosystemic shunt (TIPS). JAMA 1995; 273: 1824–1830.
14. Rosemurgy AS, McAllister EW. Small diameter H-graft portacaval shunt. In: Nyhus LH, ed. Surgery Annual. Norwalk, CT: Appleton & Lange; 1994:101–113.
15. Rubin RA, Haskal ZJ, O'Brien CB, et al. Tranjugular intrahepatic portasystemic shunting: decreased survival for patients with high Apache II scores. Am J Gastroenterol 1995; 90:556–563.

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

analysis, because I suspect that is where most of your morbidity and mortality really lies.

I think it is a very important study. I commend you for getting on the bandwagon early. There are further studies planned looking at TIPS against surgical shunts with some larger numbers: this is important.

DR. I. JAMES SARFEH (Orange, California): I congratulate you on an important study that needed to be done at a time when transjugular intrahepatic portasystemic stent shunts (TIPS) are being used almost indiscriminately without mind to long-range efficacy compared with other established modalities.

We have to understand that use of TIPS in their current state of development is a treatment that requires continuous monitoring, repeated revisions, dilatations, or thrombectomies. Clearly then, its attractiveness as a minimally invasive procedure has to be counterbalanced by its tendency to stenose or to occlude.

So I am drawn to the inescapable conclusion made by Dr. Rikkers a number of years ago that for patients who have limited access for repeated visits to the highly technical world of interventional radiology, one definitive treatment should remain our major goal for treating variceal hemorrhage.

To address this issue then, I urge you to expand your study, add more patients to it, and give us more long-term follow-up carried on to at least approximately 5 years, because that is when I think you are going to see major differences between the two procedures.

My question to you is, how many of your patients with TIPS needed manipulations or replacements of their shunts to make them functional?

The concern is that when TIPS are used for long-term control of variceal bleeding rather than as a bridge to transplant, repeated intrahepatic procedures may ultimately hasten the need for transplantation.

DR. LOUIS R. DEL GUERCIO (Valhalla, New York): I, too, am amazed at Dr. Rosemurgy's ability to perform controlled trials in these very difficult patients. I simply rise to point out that there are better ways of doing transjugular intrahepatic portasystemic stent shunts (TIPS) that keep the surgeons involved.

To do the transfemoral transmesenteric approach to TIPS gives you complete control and allows you to identify the closest branch of the portal vein to the right hepatic vein. There can be considerable differences in the anatomy of these patients and when you are stabbing blindly from above through the jugular approach, you release thromboplastins from the liver parenchyma every time you stab that needle, and you also get into the bile ducts. This does not happen with the transmesenteric approach.

It has been clearly shown that the incidence of TIPS thrombosis is primarily related to bile staining during that blind stabbing to find your portal branch. If you know exactly which branches come closest to each other, by rotating the C arm it is then very simple to do a very short TIPS, which is less likely to thrombose.

Our manipulation and thrombosis rate and need to readjust the shunts is 16% at 17 months when using this approach. And as I pointed out, it also allows the surgeon to be involved. We feel this approach has given us a much better long-term shunt survival rates. And this also can be done generally under local anesthesia. (Del Guercio LRM, Rozenblit G, Savino SA. Minimally invasive approaches to patients with bleeding esophageal varices. Surgical Rounds 1996; 19:185–196.)

DR. MARSHALL J. ORLOFF (San Diego, California): For 12 years, radiologists failed in repeated attempts to produce a viable intrahepatic portal-systemic shunt. Then, intravascular expansile stents were developed and the percutaneously placed shunt, at last, succeeded. In the 5 years since transjugular intrahepatic portasystemic stent shunts (TIPS) were developed, they have been used widely throughout the world to treat portal hypertension, based entirely on unscientific, anecdotal reports. Therefore, I applaud Dr. Rosemurgy and his colleagues for undertaking a prospective randomized comparison of TIPS and another form of portal decompression—the small diameter surgical portacaval shunt (PCS) using a synthetic H-graft. I must point out, however, that their report must be considered preliminary because 1) the number of patients, 35 in each group, was small, and 2) the period of follow-up was very short. Because patient entry started in 1993 and continued through 1995, undoubtedly some patients were followed up for less than 6 months. The results might prove to be very different with more patients and at least 5 years of follow-up.

To meet the tests of scientific validity, I will appreciate Dr. Rosemurgy's answers to the following questions:

First, exactly how were the patients selected for the study? Dr. Rosemurgy said that failure of medical therapy was a criterion for study entry, but he did not tell us what kind of medical therapy and how much medical therapy they had failed.

Second, he said that patients were excluded who, in his opinion, could not tolerate a general anesthetic, a factor that introduced patient selection and perhaps bias. How did you determine, Dr. Rosemurgy, who could not tolerate a general anesthetic? Since we have been doing emergency shunts in "all comers" during the past 35 years, I can tell you that we have come across almost no patients who could not tolerate a general anesthetic.

Third, how did you define the urgency of shunting? How did you define emergency shunt and elective shunt? I got the distinct impressions that most, if not all, of your patients were treated electively after they had recovered from a bleeding episode and medical treatment.

Fourth, the portal pressure reduction in both groups was surprisingly small, and patients were left with substantial portal hypertension—25 mmHg after TIPS and 19 mmHg after H-graft portacaval shunts (HGPCS). Would you comment on this? We would consider this degree of pressure reduction to be unacceptable. Moreover, the portal-systemic gradient postshunt was 10 mmHg after TIPS and 6 mmHg after HGPCS, a distinct and troublesome difference that makes the two groups different.

Finally, outcome was analyzed in two periods, before 30 days and after 30 days. Would you define "after 30 days" more precisely? Ordinarily, it is unacceptable to report results in this chronic disease in terms of "after 30 days."

This slide compares our early experience with TIPS with our large experience in 824 patients with elective PCS. This comparison did not result from a randomized clinical trial, but the differences are striking: the 30-day mortality rate was 16% in TIPS *versus* 1.6% in elective PCS; the 2-year mortality rate was 41% in TIPS *versus* 14% in elective PCS; shunt occlusion with variceal rebleeding was 67% in TIPS *versus* 0 in elective PCS; and recurrent encephalopathy was 63% in TIPS *versus* 7% after elective PCS. There is a profound difference in outcome between TIPS and elective PCS. I might add that our results of emergency PCS in 320 unselected patients during the past 18 years are very similar to our results of elective PCS. Moreover, our results of elective PCS in every aspect are much better than the results of HGPCS reported today by Dr. Rosemurgy, in which the failure rate was 26%.

I cannot emphasize too strongly that the only way we will find out if TIPS a legitimate role in treatment of portal hypertension is by long-term randomized clinical trials comparing TIPS with established modes of therapy. Dr. Rosemurgy and his colleagues are in the preliminary phase of one such trial, and I hope that they will continue to add patients and obtain long-term follow-up so that 5 years from now they can report meaningful results. Moreover, I hope that they will develop precise objective criteria for selecting patients for their trial so that they compare apples with apples.

DR. ALEXANDER S. ROSEMURGY (Closing Discussion): Dr. Leveen, that is an intriguing concept and I will be contacting you about it.

Dr. Henderson, the patients that were included in the study were "all comers." Patients were only excluded if they had complete portal vein thrombosis and if their ill health was so profound that they were not candidates for general anesthesia. I felt in randomizing these patients, they had to be candidates for both procedures to be considered for this protocol. So if I did not think that they were healthy enough to undergo an operation, then they were not considered to be candidates for this protocol.

For example, a Child's class C patient who was intubated and had a major variceal hemorrhage with Blakemore tube in place with massive ascites and encephalopathy was a candidate for this procedure.

This study began in 1993, so at most there was a 3-year follow-up, but the majority of the patients now have been followed for more than 1 year.

The experience of our radiologists does not seem to be an issue in our data. The radiologists had placed transjugular intrahepatic portasystemic stent shunts (TIPS) before beginning this study. One of the radiologists had considerable experience before coming to Tampa.

The first patients that got TIPS in our hospital are not included into this prospective study. The patients who had problems in this study did not have procedurally related difficulties and the problems seemed to be related to the TIPS themselves. So from a technical standpoint, our radiologists did very well.

All the patients have been studied after TIPS placement with color-flow Doppler ultrasound study. It works very well. It is very sensitive, as you know, and it can direct the intervention at the time of venography if venography is necessary.

With time, TIPS do decrease the significance of the ascites, but TIPS do not clear up ascites overnight. Also, if the patients remain noncompliant in terms of volume consumption, TIPS do not seem to be very good at treating ascites.

We currently have in place a prospective randomized trial comparing TIPS to peritoneovenous shunts. To date, it involves a small number of patients. But the peritoneovenous shunt, with its many limitations, seems to be better at treating ascites than TIPS. We have not stratified our data by Child's class at this point, but as has been pointed out, the numbers are still quite small. However, it would be a surprise to no one that our mortality data support that the Child's class C patients do worse.

Dr. Sarfeh asked about the number of patients that need to have manipulation of the TIPS. In this study, six patients had early occlusion of their TIPS and four had late occlusion of their TIPS for 10 of 35 patients. There were additional patients, probably five or six more, that had to have venography done with stent dilatation because the color-flow Doppler study noted slow or no flow in their stent. Generally, we try to have 100 cm a second of flow in the stent. I am willing to accept less if less has been previously seen and venography at that time showed a good stent without thrombosis or kinking and if the stent is appropriately placed in the hepatic vein and into the portal vein. So if the patient, for example, had 65 cm per second of flow in the midstent, I would not restudy that patient with venography if that flow remained constant from previous examinations.

Dr. Orloff asked a host of questions. I agree with him that longer follow-up is necessary. I think longer follow-up will support the use of the surgical shunt. The gradient with the shunt is different between the surgical shunts and TIPS. I believe that is because of the length of the TIPS. Although both of them are generally 8 mm in diameter, the TIPS are longer and that limits flow through the shunt.