American Association for the Study of Liver Diseases Practice Guidelines: The Role of Transjugular Intrahepatic Portosystemic Shunt Creation in the Management of Portal Hypertension

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Abbreviations: BCS = Budd-Chiari syndrome, GAVE = gastric antral vascular ectasia, HVPG = hepatic venous pressure gradient, HRS = hepatorenal syndrome, IVC = inferior vena cava, LVP = large volume paracentesis, MELD = model for end-stage liver disease, PHG = portal hypertensive gastropathy, PTFE = polytetrafluoroethylene, SOS = sinusoidal obstruction syndrome, TIPS = transjugular intrahepatic portosystemic shunt

PREAMBLE

THE recommendations in this article provide a data supported approach. They are based on the following: (i) a formal review and analysis of recently published world literature on the topic (as listed in MEDLINE); (ii) the American College of Physicians' *A Manual for Assessing Health Practices and Designing Practice Guidelines* (1); (iii) policy guidelines, including the American Association for the Study of Liver Diseases' Policy Statement on Development and Use of Practice Guidelines and the American Gastroenterological Association's Policy Statement on the Use of Medical Practice Guidelines (2); and (iv) the authors' years of experience in the care of patients with portal hypertension and use of transjugular intrahepatic portosystemic shunt in the management of these disorders. These recommendations are fully endorsed by the American Association for the Study of Liver Diseases and the Society for Interventional Radiology. Intended for use by physicians, these recommendations suggest preferred approaches to the diagnostic, therapeutic, and preventative aspects of care. They are intended to be flexible, in contrast to standards of care, which are inflexible policies designed to be followed in every case. Specific recommendations are based on relevant published information. In an attempt to characterize the quality of evidence supporting recommendations, the Practice Guidelines Committee of the American Association for the Study of Liver Diseases requires a grade to be assigned and reported with each recommendation (**Table 1**).

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INTRODUCTION

Transjugular intrahepatic portosystemic shunt (TIPS) has been in use for more than 20 years to treat the complications of portal hypertension, and TIPS have been created in thousands of patients with liver disease worldwide (3–6). Despite the extensive use of TIPS to treat the complications of portal hypertension, there initially was a lack of consensus regarding which patients should receive TIPS instead of other forms of therapy. A 1995 conference sponsored by the National Institutes of Health concluded that TIPS was effective in the acute control and prevention of recurrent bleeding from varices, but it was unclear when TIPS should be used instead of medical and surgical therapy for these complications of portal hypertension. In addition, the efficacy of TIPS to control refractory ascites or treat Budd-Chiari syndrome was unclear but promising (7). Since then, more than 1,000 patients have been enrolled in multiple controlled trials comparing TIPS with endoscopic and pharmacological therapy in the prevention of rebleeding from varices and with large-volume paracentesis in the treatment of refractory ascites associated with cirrhosis. Furthermore, approximately 1,000 papers have been published on TIPS in the English literature alone. This body of work allows for more definitive recommendations about in whom and when to use TIPS in the treatment of the complications of portal hypertension. The guidelines are divided into two large categories. The first category is a review of the technical aspects of

Table 1
Quality of Evidence on Which a Recommendation is Based

Grade	Definition
I	Randomized controlled trials
II-1	Controlled trials without randomization
II-2	Cohort or case-control analytical studies
II-3	Multiple time series, dramatic uncontrolled experiments
III	Opinions of respected authorities, descriptive epidemiology

the procedure, its complications, and the data on which patients are most at risk for an adverse outcome following TIPS. The second category is a review of the indications for TIPS. The use of TIPS for primary prevention of variceal bleeding and the control of acute bleeding are discussed first. Next, the two indications for TIPS that have been subjected to controlled trials (prevention of recurrent bleeding from varices and refractory ascites) are discussed, and guidelines are developed. Last, all of the other indications for TIPS that have been described in the literature but have not been subjected to controlled trials are discussed, and guidelines are created.

To prepare these guidelines, a MEDLINE search was performed on papers published between 1966 and 2004. Nine hundred eight papers were found under the subject heading "transjugular intrahepatic portosystemic shunt." Controlled trials and large series were sought. Recently published papers were also used as a source of references missed by the MEDLINE search, as were the personal files of the two authors.

PROCEDURE

A TIPS is created by an interventional radiologist or, in Europe, by a specially trained physician. The technique is reviewed in several publications and will not be discussed here (3,4,7). The procedure may be performed under conscious sedation (most common) or general anesthesia. If the procedure is going to be prolonged or the patient is hemodynamically unstable, then general anesthesia is preferred because it allows for careful monitoring by the anesthesiologist. The success rate with TIPS for the decompression of the portal vein is high—more than 90% of cases in most series (8–14). The Society of Interventional Radiology developed guidelines for creation of a TIPS in 2001, and the consensus was that a technically successful outcome (including both creation of the shunt and a decrease in portal pressure to 12 mm Hg) should be achieved in 95% of patients, and clinical success (resolution of the complication of portal hypertension) should be achieved in 90% of cases. Failure to achieve this threshold should lead to a review of departmental policy and procedures (15,16).

Early mortality following TIPS placement was originally reported to be quite high as a result of poor patient selection, but subsequent analysis demonstrated that preprocedure clinical features (such as high model for endstage liver disease [MELD] or APACHE II scores, high total bilirubin levels, emergent vs. elective setting, or presence of pneumonia; see Mortality) accounted for this high death rate. In most situations, death is due to progressive liver disease, perhaps as a result of portal diversion, and is not due to complications of the procedure itself, such as intraperitoneal bleeding (see Mortality) (14,17–19). In a retrospective series of 1,750 patients, the incidence of fatal complications (intraabdominal hemorrhage, laceration of the hepatic artery or portal vein, and right heart failure) was 1.7% (range, 0.6%–4.3%). Interestingly, the risk of fatal complications was 3%in institutions that had performed fewer than 150 TIPS total compared with 1.4% in those that had performed a greater number (14). These data suggest that there is a learning curve associated with the safe creation of a TIPS. Major procedural complications are expected in no more than 3% of cases; if rates exceed these levels, internal quality assessment should be considered (16). Authors of manuscripts on TIPS have been asked by the Society of Interventional Radiology to report the approximate number of TIPS performed in their centers before instituting the reported study to obtain a better understanding of the amount of training required to perform TIPS with an acceptable morbidity and mortality, and it is hoped these data are forthcoming (16).

The purpose of a TIPS is to decompress the portal venous system and therefore prevent rebleeding from varices or stop or reduce the formation of ascites. Regarding varices, it is well established that if the hepatic venous pressure gradient (HVPG) can be reduced to less than 12 mm Hg, the risk of bleeding will fall significantly. More recent data suggest that achieving a HVPG of less than 12 mm Hg may not be required to prevent rebleeding. In one series, the risk of rebleeding following TIPS revision was 18%, 7%, and 1% in patients whose HVPG had been reduced by 0%, 25% to 50%, and more than 50%, respectively (20). In a second series, a 50% reduction in the initial HVPG was associated with a rebleeding rate at 1 year of 11%, whereas patients with a lesser reduction had a 31% probability of rebleeding during the first year (21). In the latter study, the only absolute value for prevention of rebleeding was an HVPG of less than 12 mm Hg, but at the cost of an increased incidence of encephalopathy. Although the gold standard for prevention of rebleeding remains an HVPG of less than 12 mm Hg, further studies are needed to determine if lesser reductions have acceptable efficacy with a lower incidence of encephalopathy. The optimal HVPG that needs to be obtained for the control of refractory ascites associated with cirrhosis is even less clear. In one series, the degree of portal decompression did not correlate with successful treatment of refractory ascites associated with cirrhosis, and the authors suggested that a HVPG of less than 8 mm Hg should be the hemodynamic goal (22). The selection of a value of 8 mm Hg is based on limited data, and because the development of ascites associated with cirrhosis reflects changes in both hepatic and renal function, it may be difficult to establish an absolute value of decompression that needs to be achieved in most patients with refractory ascites. In patients with significant pre-existing encephalopathy in whom a TIPS may still be necessary for ascites control, a higher gradient may be appropriate (to limit worsening encephalopathy); this affords the opportunity to further enlarge the TIPS at a later date if diuresis is inadequate and encepha-