Complete Summary

GUIDELINE TITLE

The role of transjugular intrahepatic portosystemic shunt in the management of portal hypertension.

BIBLIOGRAPHIC SOURCE(S)

Boyer TD, Haskal ZJ. The role of transjugular intrahepatic portosystemic shunt in the management of portal hypertension. Hepatology 2005 Feb;41(2):386-400. [117 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Complications of portal hypertension including:

- Development of esophago-gastric varices
- Esophageal variceal rebleeding
- Bleeding from gastric varices
- Portal hypertensive gastropathy
- Ascites
- Refractory hepatic hydrothorax
- Hepatorenal syndrome
- Hepatic encephalopathy
- Porto-pulmonary hypertension

- Hepatopulmonary syndrome

GUIDELINE CATEGORY

Evaluation
Management
Prevention

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Radiology

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide a data-supported approach to the use of transjugular intrahepatic portosystemic shunt (TIPS) in the management of the complications of portal hypertension

TARGET POPULATION

Patient with complications of portal hypertension

INTERVENTIONS AND PRACTICES CONSIDERED

1. Pre-transjugular intrahepatic portasystemic shunt (TIPS) evaluation, including routine tests of liver and kidney function, as well as Doppler ultrasound of the portal venous system, contrast-enhanced abdominal computed tomography, or magnetic resonance imaging of the liver
2. Creation and placement of TIPS
3. Post-TIPS monitoring by Doppler ultrasound and clinic visits to look for the development of TIPS dysfunction

MAJOR OUTCOMES CONSIDERED

- Rate of success, major procedural complications, and the risk of rebleeding following transjugular intrahepatic portosystemic shunt (TIPS)
- Mortality following TIPS
- Optimal hepatic venous pressure gradient (HVPG) for the prevention of rebleeding from varices and for control of refractory ascites associated with cirrhosis
- Complications of TIPS
- Sensitivity, specificity, and predictive value of Doppler ultrasound

- The rates of primary patency in polytetrafluoroethylene (PTFE)-covered and bare stent groups of patients

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

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.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Grade I: Randomized controlled trials

Grade II-1: Controlled trials without randomization

Grade II-2: Cohort or case-control analytic studies

Grade II-3: Multiple time series, dramatic uncontrolled experiments

Grade III: Opinions of respected authorities, descriptive epidemiology

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The literature was critically reviewed by the authors and the members of the practice guidelines committee who then provided a consensus opinion.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The guideline developers reviewed a published cost-analysis.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline was commissioned and approved by the American Association for the Study of Liver Diseases (AASLD) and the Society of Interventional Radiology.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations are followed by quality of evidence ratings (Grades I, II-1, II-2, II-3, III) which are defined at the end of the "Major Recommendations" field.

The Procedure; Pre-TIPS Evaluation and Contraindications; Mortality

1. Transjugular intrahepatic portosystemic shunt (TIPS) should only be performed by experienced interventional radiologists (or specially trained physicians). Success and complication rates should be monitored; if they fail to meet expected rates, review of the program should be considered **(Grade III)**.
2. 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 **(Grade III)**.
3. Preceding creation of a TIPS, tests of liver and kidney function should be performed in addition to cross-sectional imaging of the liver to assess portal system patency and exclude liver masses **(Grade III)**.
4. Reduction in hepatic venous pressure gradient (HVPG) to less than 12 mm Hg should be achieved when the indication is bleeding esophageal varices.

Embolization of gastric varices may be required despite adequate decompression of the portal venous system **(Grade II-2)**.

5. The degree of reduction in HVPG to control ascites is unclear, but at present a gradient of 8 mm Hg or less has been suggested to be a reasonable goal **(Grade II-2)**.
6. Patients with high predicted 30-day mortalities should be informed of their prognosis, and TIPS should be performed only in the absence of other options **(Grade II-2)**.
7. In high-risk patients, the need for liver transplantation should be discussed before the performance of an elective TIPS **(Grade III)**.

Complications; TIPS in the Transplant Candidate

8. Physicians who perform TIPS need to be aware of both the procedural complications and the complications due to portal diversion and must be experienced in their management **(Grade II-3)**.
9. Each center performing TIPS should have an established program of TIPS surveillance, and although there are no established guidelines, Doppler ultrasound should be performed before the patient is discharged from the hospital and at specified intervals following the procedure and the yearly anniversary of the TIPS thereafter **(Grade II-1)**.
10. Ultrasonographic findings suggesting TIPS dysfunction or recurrence of the complication of portal hypertension that lead to the initial TIPS should lead to repeat shunt venography and intervention, as indicated. The recurrence of symptoms in the face of a "normal" ultrasound does not eliminate the need for TIPS venography **(Grade II-2)**.
11. TIPS stenosis is common, especially in the first year, and Doppler ultrasound lacks the sensitivity and specificity needed to identify many of these patients. Therefore, repeat catheterization of the TIPS or upper endoscopy should be performed at the 1-year anniversary of placement, especially in those patients who bled from varices **(Grade II-3)**.

Indications

Primary Prevention of Variceal Bleeding; Acutely Bleeding Esophageal Varices Refractory to Medical Treatment; Esophageal Variceal Rebleeding; Bleeding from Gastric Varices; Prevention of Bleeding From Portal Hypertensive Gastropathy and Gastric Antral Vascular Ectasia

12. The use of TIPS to prevent bleeding from varices that have never bled is contraindicated because of the risk of increasing morbidity and mortality **(Grade III)**.
13. TIPS is effective in controlling acute bleeding from varices that is refractory to medical therapy and is preferred to surgery in this situation **(Grade II-3)**.
14. TIPS should not be used for the prevention of rebleeding in patients who have bled only once from esophageal varices, and its use should be limited to those who fail pharmacological and endoscopic therapy **(Grade I)**.
15. TIPS is effective in the prevention of rebleeding from gastric and ectopic varices (including intestinal, stomal, and anorectal varices) and is the preferred approach for the prevention of rebleeding in this group of patients **(Grade II-3)**.

16. Pending further studies, in patients with good liver function, either a TIPS or a surgical shunt are appropriate choices for the prevention of rebleeding in patients who have failed medical therapy **(Grade II-2)**.
17. In patients with poor liver function, TIPS is preferred to surgical therapy in the prevention of rebleeding in patients who have failed medical therapy **(Grade III)**.
18. The use of TIPS in the management of portal hypertensive gastropathy (PHG) should be limited to those who have recurrent bleeding despite the use of beta-blockers **(Grade II-3)**.
19. TIPS is ineffective in controlling bleeding from gastric antral vascular ectasia (GAVE) in patients with cirrhosis and should not be used in this situation **(Grade II-3)**.

Ascites Associated With Cirrhosis; Refractory Hepatic Hydrothorax; Hepatorenal Syndrome (HRS)

20. Although TIPS will decrease the need for repeated large-volume paracentesis in patients with refractory ascites associated with cirrhosis, it should be used only in those patients who are intolerant of repeated large-volume paracentesis **(Grade I)**.
21. TIPS is effective in the control of hepatic hydrothorax, but it should be used only in patients whose effusion cannot be controlled by diuretics and sodium restriction **(Grade II-3)**.
22. TIPS is not recommended for the treatment of HRS, especially type 1 HRS, pending the publication of controlled trials **(Grade II-3)**.

Budd-Chiari Syndrome (BCS); Veno-occlusive Disease or Sinusoidal Obstruction Syndrome; Hepatopulmonary Syndrome

23. The decision to create a TIPS in a patient with BCS should be based on the severity of disease, and only patients with moderate disease appear to be reasonable candidates for a TIPS **(Grade II-3)**.
24. Patients with BCS and mild disease can be managed medically, whereas those with more severe disease or acute hepatic failure are best managed by liver transplantation. **(Grade II-3)**.
25. The use of TIPS to treat sinusoidal obstruction syndrome cannot be recommended **(GradeII-3)**.
26. The use of TIPS to treat hepatopulmonary syndrome cannot be recommended **(Grade II-3)**.

Conclusions

TIPS is an important part of the current armamentarium used to treat the complications of portal hypertension. Most fellowship-trained interventional radiologists are capable of creating a TIPS in a patient with patent hepatic and portal veins. Creation of a TIPS ranks among the more complex procedures performed by interventional radiologists, and it is important that each physician monitor their success and complication rates. As with any complex intervention, the decision to create a TIPS should be reached by a gastroenterologist or hepatologist who is experienced in the management of these patients in concert with an interventional radiologist. Pre-TIPS evaluation includes routine tests of liver and kidney function as well as Doppler ultrasound, contrast-enhanced

abdominal computed tomography, or magnetic resonance imaging of the liver. Once a TIPS is created, it cannot be forgotten--the patient requires frequent monitoring by Doppler ultrasound and clinic visits to look for the development of TIPS dysfunction. The use of polytetrafluoroethylene (PTFE)-covered stents may reduce the risk of TIPS dysfunction, but this will not eliminate the need for continued surveillance.

TIPS will effectively prevent rebleeding from varices and decrease the need for repeat thoracentesis in patients with hepatic hydrothorax or for large-volume paracentesis in patients with refractory ascites. However, TIPS will increase the incidence of hepatic encephalopathy and will not improve survival in any of these patients. Hence, TIPS should not be considered as primary therapy for any complication of portal hypertension with the exception of bleeding gastric or ectopic varices. In all other situations, TIPS should only be created when the patient has failed or is intolerant of other forms of medical therapy (i.e., pharmacological or endoscopic therapy, diuretics, or repeated large-volume paracentesis or thoracentesis). In patients with good liver function and recurrent bleeding from varices despite medical treatment, it is unclear whether a surgical shunt or TIPS is the better form of therapy pending the publication of additional controlled trials. Which patients with BCS are best managed by TIPS remains undefined, although creation of a TIPS in select patients may be of benefit. Creation of a TIPS for the treatment of HRS or hepatopulmonary syndrome is of unproven benefit and should be considered investigatory.

Definitions:

Quality of Evidence

Grade I: Randomized controlled trials

Grade II-1: Controlled trials without randomization

Grade II-2: Cohort or case-control analytic studies

Grade II-3: Multiple time series, dramatic uncontrolled experiments

Grade III: Opinions of respected authorities, descriptive epidemiology

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate selection of patients for and use of the transjugular intrahepatic portosystemic shunt (TIPS) in the treatment of complications of portal hypertension
- Control of acute bleeding from varices that is refractory to medical therapy
- Prevention of rebleeding from gastric and ectopic varices
- Decrease in the need for repeat thoracentesis in patients with hepatic hydrothorax or for large-volume paracentesis in patients with refractory ascites

POTENTIAL HARMS

Complications of Transjugular Intrahepatic Portosystemic Shunt (TIPS)

- TIPS dysfunction (thrombosis, occlusion/stenosis)
- Transcapsular puncture
- Intraperitoneal bleed
- Hepatic infarction
- Fistulae
- Hemobilia
- Sepsis
- Infection of TIPS
- Hemolysis
- Encephalopathy
- Stent migration or placement into inferior vena cava or too far into portal vein

CONTRAINDICATIONS

CONTRAINDICATIONS

Absolute Contraindications to Placement of a Transjugular Intrahepatic Portosystemic Shunt (TIPS)

- Primary prevention of variceal bleeding
- Congestive heart failure
- Multiple hepatic cysts
- Uncontrolled systemic infection or sepsis
- Unrelieved biliary obstruction
- Severe pulmonary hypertension

Relative Contraindications to Placement of a TIPS

- Hepatoma, especially if central
- Obstruction of all hepatic veins
- Portal vein thrombosis
- Severe coagulopathy (international normalized ratio [INR] >5)
- Thrombocytopenia of less than 20,000/cm^3

- Moderate pulmonary hypertension

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These recommendations suggest preferred approaches to the diagnostic, therapeutic, and preventive aspects of care. They are intended to be flexible, in contrast to standards of care, which are inflexible policies to be followed in every case.
- In patients with good liver function and recurrent bleeding from varices despite medical treatment, it is unclear whether a surgical shunt or transjugular intrahepatic portosystemic shunt (TIPS) is the better form of therapy pending the publication of additional controlled trials.
- Which patients with Budd-Chiari syndrome (BCS) are best managed by TIPS remains undefined, although creation of a TIPS in select patients may be of benefit.
- Creation of a TIPS for the treatment of hepatorenal syndrome (HRS) or hepatopulmonary syndrome is of unproven benefit and should be considered investigatory.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Boyer TD, Haskal ZJ. The role of transjugular intrahepatic portosystemic shunt in the management of portal hypertension. Hepatology 2005 Feb;41(2):386-400. [117 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Feb

GUIDELINE DEVELOPER(S)

American Association for the Study of Liver Diseases - Private Nonprofit Research Organization

SOURCE(S) OF FUNDING

American Association for the Study of Liver Diseases

GUIDELINE COMMITTEE

Practice Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Drs. Boyer and Haskal are paid consultants for W. L. Gore and Associates, Inc., the manufacturer of a polytetrafluoroethylene-covered stent used for transjugular intrahepatic portosystemic shunt (TIPS).

ENDORSER(S)

Society of Interventional Radiology - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Association for the Study of Liver Diseases Web site.

Print copies: Available from the American Association for the Study of Liver Diseases, 1729 King Street, Suite 200; Alexandria, VA 22314; Phone: 703-299-9766; Web site: www.aasld.org; e-mail: aasld@aasld.org.

AVAILABILITY OF COMPANION DOCUMENTS

This guideline is available as a Personal Digital Assistant (PDA) download via the APPRISOR™ Document Viewer from www.apprisor.com.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 17, 2005. The information was verified by the guideline developer on June 13, 2005.

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