



Affix Patient Label

Patient Name:

DOB:

Informed Consent: Transjugular Intrahepatic Portosystemic Shunt (TIPS)

This information is given to you so that you can make an informed decision about having a **transjugular intrahepatic portosystemic shunt (TIPS.)**

Reason and Purpose of the Procedure

Liver disease is causing blockage in the veins that go into your liver from your intestine. That increases blood pressure. This is called portal hypertension. Swollen veins have developed in your stomach and esophagus (the passage from the mouth to the stomach). Large amounts of fluid may have built up in your abdomen or chest. Transjugular intrahepatic portosystemic shunt (TIPS) is a procedure that makes a new connection between blood vessels. It may reduce increased pressure and its complications, especially vein bleeding.

TIPS involves placing a plastic tube (catheter) into a vein in your neck. Numbing medicine is injected in the skin over the vein before the catheter is inserted.

After the catheter is placed into the vein, it is moved into the hepatic vein (a liver vein). X-ray contrast (dye) is injected through the catheter and x-ray pictures are taken. You may be asked to hold your breath for several seconds when this happens. During the injection of x-ray contrast, you may experience a warm feeling or a strange taste in your mouth. Both of these feelings will go away soon.

When the catheter is placed into the hepatic vein, a long needle is passed through the tube and used to connect to another vein. This pathway through the liver is enlarged with a balloon catheter. After the enlargement, a stent-graft (metal mesh tube with fabric covering) is inserted. This keeps the path open so blood can flow through more freely. High pressure in the veins is relieved. Bleeding from stomach varicose veins should stop. If the bleeding does not stop, a catheter will be placed into the veins. Medicine to stop the bleeding may be injected.

When the catheter is removed, pressure is applied to the insertion site until bleeding has stopped. To help prevent bleeding, it is very important for you to lie in bed for up to six hours. It is unknown how long the shunt in your liver will remain open. To check the shunt, you may have an ultrasound examination. If the shunt closes, it will need to be reopened.

Benefits of this Procedure

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- Decrease the risk of a varicose vein bursting. A burst vein could result in a large amount of bleeding.
- Treat fluid buildup in the abdomen.
- Treat fluid buildup between the lungs and chest wall.
- Treat vein bleeding that is not controlled by other treatment.
- If you see changes with your skin you should report them to your doctor.

Risks of Procedure

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

General Risks of Procedure

- **Small areas of the lungs may collapse.** This would increase the risk of infection. This may need antibiotics and breathing treatments.
- **Clots may form in the legs, with pain and swelling.** These are called DVTs or deep vein thrombosis. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- **A strain on the heart or a stroke may occur.**
- **Bleeding may occur.** If bleeding is excessive, you may need a transfusion.
- **Reaction to the anesthetic may occur.** The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

Risks of this procedure


- **Pain or discomfort at the catheter insertion site.** This is typically minimal and will pass with time. Treatment may include oral pain medicines.
- **Bleeding at the site.** This is usually controlled by pressing on the site until bleeding stops. Serious bleeding is rare.
- **Injury to a blood vessel.** This may require additional treatment.
- **Infection which may result in an infection of the blood stream.** You may need antibiotics. You will be given instructions for care to decrease the chance of infection.
- **Disturbances in heart rhythm (arrhythmia), or heart failure.** During the procedure your heart rhythm will be monitored. You may need additional treatment.
- **Shock.** Fluids, medications and/or further treatments may be needed.
- **Development of a liver abscess.** This may require further treatment such as antibiotics or an external drain placement.
- **Acute liver failure.** TIPS may be needed again.
- **Excessive drowsiness, sleepiness or difficulties in concentrating (known as encephalopathy) may develop in up to 1 in 3 patients after a shunt is placed.** This is usually manageable with the use of medicines and a low-protein diet. In rare cases, severe encephalopathy or even coma may develop. If this occurs, the shunt may need to be narrowed or blocked to limit the amount of blood flow through the channel.
- **Risks associated with the x-ray contrast material include an allergic reaction and reduced kidney function.** Fluids, medications or further treatments may be needed.
- **Malfunction of the stent, such as narrowing (stenosis) or closing (occlusion). Narrowing of the TIPS stent/malfunction over time is not uncommon.** The shunt may need to be reopened if this occurs. **Approximately 50% of patients require revision of the TIPS within 18 months.**

Potential Radiation Risks

- **Any exposure to radiation may cause a slightly higher risk for cancer later in life.** This risk is low.
- **Skin rashes.** Skin rashes may lead to breakdown of skin and possibly severe sores. This is rare.
- **Hair loss.** This does not happen to everyone. This can be temporary or permanent.
- **It is possible we may have to use higher doses of radiation.** If we do we will tell you.

Risks Associated with Smoking

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

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Risks Associated with Obesity

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Specific to You

Alternative Treatments:

Other choices

- Management with medicines.
- Endoscopic procedure.
- Do nothing. You can decide not to have the procedure.

If you choose not to have this treatment

- Your doctor can discuss other treatments with you depending on the severity of your condition.

General Information

- If you see changes with your skin you should report them to your doctor.
- During this procedure, the doctor may need to perform more or different procedures than I agreed to.
- During the procedure the doctor may need to do more tests or treatment.
- Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.
- Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.
- Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected

Patient Name: _____

DOB: _____

By signing this form I agree

- I have read this form or had it explained to me in words I can understand.
 - I understand its contents.
 - I have had time to speak with the doctor. My questions have been answered.
 - I want to have this procedure: **Transjugular Intrahepatic Portosystemic Shunt (TIPS)**
-
- I understand that my doctor may ask a partner to do the procedure.
 - I understand that other doctors, including medical residents or other staff may help with surgery. The tasks will be based on their skill level. My doctor will supervise them.

Patient Signature _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian**Interpreter's Statement:** I have translated this consent form and the doctor's explanation to the patient, a parent, closest relative or legal guardian.

Interpreter: _____ Date _____ Time _____

Interpreter (if applicable)

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Patient shows understanding by stating in his or her own words:

____ Reason(s) for the treatment/procedure: _____

____ Area(s) of the body that will be affected: _____

____ Benefit(s) of the procedure: _____

____ Risk(s) of the procedure: _____

____ Alternative(s) to the procedure: _____

OR

____ Patient elects not to proceed: _____ Date: _____ Time: _____

(patient signature)

Validated/Witness: _____ Date: _____ Time: _____