

Consent for Creation of Transjugular Intrahepatic Portosystemic Shunt (TIPS)

INTRODUCTION:

Your liver disease is causing blockage and increased blood pressure in the veins that drain into your liver from your intestine. As a result, distended varicose veins have developed in your stomach and esophagus (the food passage from the mouth to the stomach) or you have developed large amounts of fluid in your abdomen or chest. If you have experienced distended varicose veins in your stomach and esophagus, some of them have burst and caused severe bleeding. The bleeding can no longer be adequately controlled with medication or endoscopic (a flexible tube inserted through your mouth and into your esophagus and stomach) treatment methods. This bleeding can be very dangerous, or even fatal, if no further treatment is provided. If you have experienced the development of large amounts of fluid in your abdomen or chest, diuretic medications (water pills) have not been effective at relieving the fluid buildup. To relieve the blockage and decrease the blood pressure in the veins that drain your liver, it is recommended that you undergo creation of a transjugular intrahepatic portosystemic shunt (TIPS) with a metal and fabric stent-graft. During this procedure, a new channel (shunt) will be created through your liver to decrease the high blood pressure in your stomach veins. This will result in a decrease in distended varicose veins or reduce the amount of fluid being formed in your abdomen. We are asking you to read and sign this form so that we can be sure you understand the procedure and potential benefits, along with the associated potential risks, complications, alternatives, the likelihood of achieving the goals, and the recuperative process. Please ask questions about anything on this form that you do not understand.

PROCEDURE:

A TIPS procedure involves the placement of a plastic tube (catheter) into a vein in your neck. Some numbing medicine will be injected in the skin over the vein that will be used before the catheter is inserted. Intravenous medications may also be given to you to make you more comfortable and relaxed. This is known as moderate sedation.

Once the catheter has been placed into the vein, it will be advanced through the blood vessels and into the hepatic vein (a liver vein). During this time, x-ray contrast material (x-ray dye) will be injected through the catheter and x-ray pictures taken. You may be asked to hold your breath for several seconds as these pictures are taken. During the injection of x-ray contrast material, you may experience a warm feeling or a strange taste in your mouth. Both of these sensations are temporary and will go away soon. Once the catheter is placed into the hepatic vein, a long needle will be passed through the tube and used to connect to the portal vein branch (a liver feeding vein). This shunt through the liver will then be enlarged with a special balloon catheter. Following this enlargement, a stent-graft (metal mesh tube with fabric covering) is inserted to prevent closing of the shunt. Once this is done, the high pressure in the veins will be relieved as blood now flows through the liver shunt. Any bleeding from stomach varicose veins should stop at that time. If the bleeding does not stop, a catheter will be directed into the veins and material injected to stop the bleeding. At the completion of the TIPS procedure, the catheter will be removed and pressure will be applied to the insertion site until the bleeding has stopped. To help prevent bleeding, it will be 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 assess the status of the shunt, you may be monitored with periodic ultrasound (sound wave) examinations. If the shunt is found to be closed, it will need to be reopened.

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RISKS:

Risks associated with the procedure include, but are not limited to, pain or discomfort at the catheter insertion site, bleeding at the site, injury to a blood vessel, infection which may result in an infection of the blood stream, disturbances in heart rhythm (arrhythmia), heart failure, shock, the development of a liver abscess, and acute liver failure. 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 encephalopathy is usually manageable with the use of medications 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. The medications used for the moderate sedation are associated with the risks of aspiration (inhaling food or liquid into your lungs) or respiratory depression. In addition to these potential risks associated with the procedure, the x-ray contrast material, and the moderate sedation medications, there may be other unpredictable risks including death.

(Complete this paragraph if applicable or document "NA") Due to your additional medical history of _____ added risks for you include but are not limited to:

ALTERNATIVES:

There may be other methods, including surgery, to treat your liver disease. If you are unsure about undergoing a TIPS procedure, please discuss these other alternatives with your physician.

AGREEMENT:

The information on this form was explained to me by _____. I understand the information and I have had the opportunity to ask any other questions I might have about the procedure, the reasons it is being performed, the associated risks, and the alternatives to the procedure. I agree to undergo the procedure to be performed by an authorized member of the Division of Vascular and Interventional Radiology and his/her associates, assistants, and appropriate hospital personnel, and accept the risks. I also agree that fellows, residents and surgical assistants may participate in significant tasks that are part of the procedure. In addition, I agree to have any other appropriate personnel present for the procedure.

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AGREEMENT (cont'd):

I assign to the University of Pennsylvania Health System (“Health System”) all rights to any tissues, organs, cells, body parts, and/or body fluids that may be removed during this procedure and I authorize the Health System to use or dispose of such specimens according to its standard practices.

The University of Pennsylvania Health System routinely suspends all resuscitative aspects of living wills and Do Not Attempt Resuscitation orders during the pre-procedure, procedural and post-procedural period, unless you specifically tell us otherwise. This applies to all invasive and operative procedures.

Signature: _____ Date: _____ Time _____
Patient

Signature: _____ Date: _____ Time _____
Authorized Healthcare Professional obtaining
and witnessing patient’s signature

Signature: _____ Date: _____ Time _____
Attending physician (if applicable)

To be used if the patient is a minor, unconscious, or otherwise lacking decision making capacity.

I, _____, the _____
Relationship to patient
of _____ hereby give consent.

Signature: _____ Date: _____ Time _____
Legally Authorized Representative

Signature: _____ Date: _____ Time _____
Authorized Healthcare Professional obtaining
and witnessing representative’s signature

Signature: _____ Date: _____ Time _____
Attending physician (if applicable)

Signature: _____ Date: _____ Time _____
Witness to telephone consent



