Taichung Armed Forces General Hospital
Percutaneous Transhepatic Cholangiodrainage Information

This instruction sheet shall be kept by patient (or patient's family)

經皮穿肝膽道及膽囊攝影引流術說明書

This information sheet provides details about the benefits, risks, and alternative options for the medical procedure you are about to undergo. It can serve as supplementary information for your discussion with your physician. It is important to us that you fully understand what is described in this file, so please read it carefully. If you still have questions after your doctor has explained the examination to you, please discuss your questions sufficiently with your doctor before you sign the form. Your doctor will be happy to answer your questions. Let's work together for your health.

☛ Introduction to percutaneous transhepatic cholangiodrainage

When bile cannot be drained into the intestines through the normal pathway due to various reasons, bile is accumulated, which may lead to jaundice, liver dysfunction, and infections related to the bile ducts, conditions that sometimes are life-threatening. To treat this, multiple methods are available to establish a channel for bile drainage. Percutaneous transhepatic cholangiography and biliary drainage is one such method. This procedure involves inserting a drainage tube through the skin and liver to reach the bile ducts within the liver to drain bile.

☛ Precautions before examination

- This is an invasive procedure, so you must be hospitalized.
- Except for small amounts of water and necessary medications, you must fast for at least four hours. Since a high proportion of patients with obstructed bile have bacterial infections, antibiotics will be administered beforehand to reduce the risk of infection. Any severe ascites or coagulation issues need to be corrected in advance to minimize high risks.
- Please carefully read this information sheet and fill out the Percutaneous Transhepatic Biliary and Gallbladder Imaging and Drainage Consent Form and Contrast Agent Injection Consent Form.

☛ Precautions during examination

- You will need to lie flat on the examination table with your right hand placed above your head. The procedure may last a while and may cause discomfort, but your cooperation is needed.
- The skin on your abdomen will be disinfected and covered with sterile cloths. Pain relief medication will be administered either through muscle or vein, and local anesthetic will be injected subcutaneously. Then, guided by fluoroscopy or ultrasound, a fine needle will be used to puncture the bile duct, followed by the injection of a contrast agent to confirm the needle position.
- To access the bile duct suitable for the drainage tube, this step may need to be repeated several times. Afterward, a guidewire will be inserted via the fine needle. Once the guidewire is successfully inserted along the bile duct, the fine needle will be replaced with a larger needle to expand the path for the drainage tube, while more contrast is injected to clearly visualize the bile duct structure. A thicker guidewire will then be used to replace the previous guidewire, and the drainage tube will be inserted along this guidewire. The drainage tube will be fixed to the skin surface, and the drainage bag will be connected, which completes the procedure. If the placed drainage tube fails to function properly or complications like bleeding occur, it may need to be adjusted or replaced immediately.
- The entire procedure typically takes 40 to 60 minutes. In difficult cases, it may take more than two hours. If the procedure is interrupted halfway, severe complications could arise. Therefore, once you agree to this procedure, full cooperation is required.
- If you already have a drainage tube placed that needs adjustment, some steps above may be omitted.

Precautions after examination

- Always ensure the drainage tube remains unobstructed, and monitor the amount and color of the drainage. If there are any abnormalities, immediately notify the nurse of the ward to contact the responsible doctor for prompt action.
- The drainage bag should be secured to the same side of your upper body clothing, never to pants or the edge of the bed, to prevent the tube from being pulled out during clothing changes or repositioning.

Benefits of the procedure

(The following benefits may be gained through this procedure, but the doctor cannot guarantee that you will gain any of them; the decision between benefits and risks should be made by you.)

The placement of a drainage tube allows bile, which could not otherwise be successfully drained into the intestines, to flow externally or into the intestines. This reduces jaundice and controls infections caused by bile stasis. For some causes of bile stasis, further treatments, such as balloon dilation or stent placement, may be performed through the established drainage route. However, not all causes are suitable for these interventions. The drainage tube will stay in place for a period of time that depends on the underlying cause and available procedures, and sometimes it is even permanent. For those requiring long-term indwelling tube, healthcare professionals will provide instructions on how to care for the tube.

Possible complications (No surgery or procedure is without any risk. Identified risks are listed below, but there are still potential unlisted risks that are not expected by the doctor.)

- Risks related to this procedure include pain during and after the procedure, adverse reactions and allergic-like symptoms caused by the contrast agent (including renal function damage, nausea, vomiting, skin rashes, shortness of breath, shock, and even death), bleeding (including internal bleeding and bile duct bleeding) (3-7%), sepsis (3-5%), bile duct rupture or bile leakage along the drainage tube causing peritonitis (15-20%), drainage tube dislodgement (10-20%), pleural puncture causing pleural effusion or pneumothorax (1-5%), and bleeding or rupture of other internal organs due to puncture (<1%).
- Some complications may require additional emergency interventions, including blood transfusion, medication and antibiotic treatment, CPR, chest tube insertion, repositioning of the drainage tube, additional radiation therapy, endoscopic treatment, or surgery. Severe complications can lead to death (0.7-8%).
- Due to varying causes of bile duct obstruction, the complexity of bile duct structures, and the progression of the disease itself, some patients may require multiple adjustments to the drainage tube or the placement of multiple tubes. Even so, some patients may not benefit from drainage to alleviate jaundice symptoms.
- The risk of complications is higher for patients with the following conditions: Older age, chronic medical conditions (such as heart disease, hypertension, diabetes, liver disease, stroke, chronic obstructive pulmonary disease, tuberculosis, etc.), smoking, and alcohol abuse.

Alternative options

Depending on the disease, there may be other procedures available, including endoscopic retrograde biliary drainage and surgery; however, these may not always be feasible. If you have concerns about this procedure, please discuss other possible options and associated risks with your doctor.

Taichung Armed Forces General Hospital
Consent Form for Percutaneous Biliary Drainage (PTC), Percutaneous Transhepatic Cholangiodrainage (PTCD) and Percutaneous Transhepatic Gallbladder Drainage (PTGBD)

* Basic Information

Patient Name_____

Patient Date of Birth____YYYY_____MM_____DD

Patient Medical Record No._____

Name of Attending Physician_____

I. Examination (procedure or treatment) planned (provide brief explanation if not familiar with the medical terms)

1. Disease name:
2. Name of examination (procedure or treatment) recommended:

□ Percutaneous biliary drainage (PTC) □ Percutaneous transhepatic cholangiodrainage (PTCD)

□ Percutaneous transhepatic gallbladder drainage (PTGBD) □Other

3. Reason for recommended examination (procedure or treatment)

II. Physician statement

1. I have explained the examination (procedure or treatment) to the patient in ways as comprehensible as possible to provide the patient with the relevant information, particularly the following:

☐ Reason why the examination (procedure or treatment) must be performed, method and site of the examination (procedure or treatment), and risks of the examination (procedure or treatment).
☐ Examination (procedure or treatment) complications and possible management methods.
☐ I have clearly informed the patient of the potential allergic reactions to the contrast agent.
☐ Patients with any of the following conditions have an increased risk of allergy. Heart, lung, and vascular diseases (impaired cardiac function, hypertension, arteriosclerosis and emphysema). Cirrhosis, liver dysfunction. Kidney dysfunction, uremia. Asthma. Diabetes mellitus for five years or longer. History of allergies (including reactions caused by the injection of iodine-based contrast agents, and allergies to food, other medications, pollen, or other allergens). A senior age with poor physical condition (72 years or above). A young age (infants or small children of two years or younger).
☐ I have given the patient any other information available related to the treatment.

2. I have provided the patient with adequate time to ask the following questions about the examination and I have answered the questions:

(1) ----------

(2) ----------

(3) ----------

Signature of attending physician: Date: YYYY MM DD

Time: hh mm

III. Patient statement

1. The doctor has explained to me and I have understood the information related to the necessity, steps, and risks of the examination (procedure or treatment).
2. The doctor has explained to me and I have understood the possible prognosis of the examination (procedure or treatment) and risks if the examination is not performed.
3. I understand that during the examination (procedure or treatment), if an organ or tissue is removed for the purpose of the examination (procedure or treatment), it will be kept in the hospital for a period of time for tests and reporting, and will then be disposed of carefully according to the law.
4. I understand that this examination (procedure or treatment) may be the best option now.

Based on the above statement, I hereby give my consent to this examination (procedure or treatment).

Statement by woman of childbearing potential: The doctor has clearly informed me of the risks this examination may pose to a pregnant woman and the fetus.

Signature:_____

Consenter Signature: Relationship to patient:

Address: Telephone:

Date: YYYY MM DD Time: hh mm

Witness: Signature:

Date: YYYY MM DD Time: hh mm

Notes:

I. If the consenter is not the patient, the relationship to the patient should be indicated in the "Relationship to patient" field.

II. The fields for the witness may be left blank if no witness is available.

III. If the patient is a minor, a legal representative should sign the consent form.

IV. Possible complications

1. Risks related to this procedure include pain during and after the procedure, adverse reactions and allergic-like symptoms caused by the contrast agent (including renal function damage, nausea, vomiting, skin rashes, shortness of breath, shock, and even death), bleeding (including internal bleeding and bile duct bleeding) (3-7%), sepsis (3-5%), bile duct rupture or bile leakage along the drainage tube causing peritonitis (15-20%), drainage tube dislodgement (10-20%), pleural puncture causing pleural effusion or pneumothorax (1-5%), and bleeding or rupture of other internal organs due to puncture (<1%).
2. Some complications may require additional emergency interventions, including blood transfusion, medication and antibiotic treatment, CPR, chest tube insertion, repositioning of the drainage tube, additional radiation therapy, endoscopic treatment, or surgery. Severe complications can lead to death (0.7-8%).
3. Due to varying causes of bile duct obstruction, the complexity of bile duct structures, and the progression of the disease itself, some patients may require multiple adjustments to the drainage tube or the placement of multiple tubes. Even so, some patients may not benefit from drainage to alleviate jaundice symptoms.
4. The risk of complications is higher for patients with the following conditions: Older age, chronic medical conditions (such as heart disease, hypertension, diabetes, liver disease, stroke, chronic obstructive pulmonary disease, tuberculosis, etc.), smoking, and alcohol abuse.

V. Alternative options: Depending on the disease, there may be other procedures available, including open abdominal surgery; however, these may not always be feasible. If you have concerns about this procedure, please discuss other possible options and associated risks with your doctor.

Radiology Department of Taichung Armed Forces General Hospital Contrast Agent Injection Consent Form

Examinations involving the intravenous injection of a contrast agent utilize the contrast's effect on the area to be examined to enhance and improve the visibility of the organs or lesions under examination to reach a diagnosis. Conventional ionic iodine-based contrast agents may cause allergic reactions in a small number of patients (the incidence of allergic reactions is 10%). Symptoms include nausea, vomiting, skin rashes, itching, and in a few severe cases, shock or even sudden death (the reported mortality rate is approximately 1 in 100,000, according to international statistics). However, if you have any of the following conditions, you have a significantly increased risk of allergy.

□ 1. Heart, lung, and vascular diseases (impaired cardiac function, hypertension, arteriosclerosis and emphysema).

□ 2. Cirrhosis, poor liver function.

□ 3. Kidney dysfunction, uremia.

□ 4. Asthma.

□ 5. Diabetes mellitus for five years or longer.

□ 6. History of allergies (including reactions caused by the injection of iodine-based contrast agents, and allergies to food, other medications, pollen, or other allergens).

□ 7. A senior age with poor physical condition (72 years or above).

□ 8. A young age (infants or small children of 2 years or younger).

□ 9. Critical illness.

If you have any of the above conditions, please indicate a ˇ in the corresponding □

Signature of patient or family:_____

If the patient is a minor, a legal representative should sign the consent form.

※Please read these instructions before deciding to sign the examination consent form※

Date: YYYY MM DD Time: hh mm

Name:_____

ID No.:_____

Date of birth: __YYYY__MM__DD

Radiology Department of Taichung Armed Forces General Hospital

Pre-Contrast Injection Risk Assessment Form

※ **Please read the following questions first and complete the known ones. The remaining questions will be completed by the physician in the examination room.**

Have you ever had a history of allergies in the past? Allergy

☐ None

☐ Previous allergy to a contrast agent injected, and the type of allergy is:_____

☐ Allergy to food, drug or others, and the type is:_____

☐ Unknown

Contraindication

☐ None

☐ Severe hyperthyroidism

☐ Severe de-compensated heart failure

☐ Severe hepato-renal dysfunction

☐ Oliguria or anuria

Assessment of high risk conditions

☐ None

☐ Asthma, allergy constitution

☐ Renal dysfunction

☐ Cardiovascular disease

☐ Pulmonary hypertension

☐ Cerebral disease

☐ Thyroid disease

☐ Pheochromocytoma

☐ On metformin for diabetes mellitus

Cre values in last three months:_____(mg/dL)__

Evaluation physician:_____ Date: YYYY MM hh mm