

ADVANCED GASTROENTEROLOGY

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INFORMED CONSENT FOR ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATICTOGRAPHY (ERCP)

Explanation of Procedure

ERCP is a specialized technique used to examine the ducts (drainage routes) of the gall bladder, pancreas, and liver. Areas are visualized through an endoscope with the aid of dye and x-ray. A sphincterotomy (widening of narrow areas) may be done or a stent (tube for drainage) may be inserted. Biopsies of abnormal tissue can be obtained if necessary. _____ (initials)

Principal Risks and Complications

Serious risks and possible complications may include, but are not limited to the below. Your physician will discuss their frequency with you, if you desire, with particular reference to your own indications for an ERCP. YOU MUST ASK YOUR PHYSICIAN IF YOU HAVE ANY UNANSWERED QUESTIONS ABOUT YOUR TEST. All of the complications are potentially life threatening and can rarely lead to loss of life. _____ (initials)

1. **PANCREATITIS:** Inflammation of the pancreas. Occurs in 5-10%. This usually results in 3-5 days of hospitalization, but rarely could result in prolonged hospitalization and need for surgery or other procedures. At least 1% of patients can have chronic sequelae. _____ (initials)
2. **PERFORATION:** The risk is about 1 in 500. Passage of the instrument may result in an injury to the gastrointestinal wall with possible leakage of gastrointestinal contents into the body cavity. If this occurs, surgery to close the leak and/or drain the region could be required. Perforations are usually small requiring 4-5 days hospitalization, but could be severe requiring prolonged hospitalization or additional procedures, including surgery. _____ (initials)
3. **BLEEDING:** Bleeding or the management of this complication may consist of careful observation and may require transfusions or possibly a repeat ERCP and even surgery. _____ (initials)
4. **INFECTION:** This would usually be a consequence of perforation or pancreatitis. Rarely passage of the endoscope and manipulations may cause infection elsewhere in the body. _____ (initials)
5. **PHLEBITIS:** Infection or irritation resulting in inflammation (phlebitis) may occur at the intravenous site and may require treatment. _____ (initials)
6. **SEDATION:** Sedation and analgesia, which are usually administered by an anesthesiologist, are given to produce sedation, a state that helps you relax and minimizes unpleasant sensations while maintaining adequate heart and lung function. Potential complications of sedation include: breathing problems (decreased respiration, aspiration, and airway blockage), heart problems (low blood pressure, or irregular rhythm) for which you will be monitored and treated if necessary. The medication may also cause an allergic reaction which will be treated but may rarely lead to loss of life. _____ (initials)
7. **OTHER RISKS:** Include drug reactions and complications from other diseases you may already have. Instrument failure is extremely rare, but remains a possibility and could require a repeat procedure. There is

a possibility of a heart attack or stroke. A serious complication could result in death or permanent disability. You must inform your physician of all of your allergic tendencies and medical problems. _____ (initials)

Alternatives to an ERCP

Although an ERCP is a safe and effective means of examining the bile ducts, it is not 100 percent accurate in diagnosis. In a small percentage of cases, a failure of diagnosis or misdiagnosis may result. Other diagnostic or therapeutic procedures, such as medical treatment, x-ray, and surgery are available. Another option is to choose no diagnostic studies and/or treatment. Your physician will be happy to discuss these options with you. _____ (initials)

The presence of any known **medical allergies:** ___ Not Present ___ Present

If present, please list:

My pregnancy status: ___ I am pregnant ___ I am not pregnant ___ Does not apply

I certify that I understand the information regarding an ERCP. I have been fully informed of the risks and possible complications of my procedure. I hereby authorize and permit Ghanshyam Gupta, M.D. and whomever he may designate as his assistant to perform this procedure on me. _____ (initials)

If any unforeseen condition arises during this procedure calling for (in the physician's judgment) additional procedures, treatments, or operations, I authorize him to do whatever he deems advisable. I am aware that the practice of medicine and surgery is not an exact science and I acknowledge that no guarantees have been made to me concerning the result of this procedure. I am aware that in the event of a life threatening emergency, the physician will perform any necessary medical procedures if that is necessary.

Print Patient's Name

Today's Date

Signature

If Legal Representative, provide relationship to Patient

Patient Date of Birth

Witness Signature (for office use only)

