What are the alternatives to an ERCP?

An ERCP is primarily a therapeutic procedure. Other kinds of X rays such as an MRCP can be used to obtain information, but cannot perform a therapy. Alternatives to a therapeutic ERCP include a procedure known as a PTC (percutaneous transhepatic cholangiogram), in which the bile ducts are accessed through the abdominal wall, or surgery (either open surgery, or laparascopic 'keyhole' surgery). All of these options also carry significant risks.

There are also risks attached to NOT having an ERCP or alternative procedure such as worsening jaundice, infection, or pancreatitis from stones that remain in the bile duct.

Other important points to note:

As the Mater is a University Teaching hospital, a doctor other than the consultant, such as a registrar (senior trainee), may perform the procedure. That doctor will be under the supervision of a consultant.

During the procedure, video footage and photographs may be taken - these will form part of the medical record and assist the doctor in providing medical treatment. These images may also be used at a later date for audit or research purposes, but will be anonymous.

Giving your consent

I, ...

have read the information provided outlining the procedure itself, the associated risks and complications, the benefits and alternatives to ERCP

I have been given the opportunity to ask questions, and they have been answered to my satisfaction.

I understand that I have the right to withdraw my consent at any time, even after this form has been signed.

I understand that in the event of an emergency, the medical staff will carry out any medically necessary interventions. These may include, but are not limited to surgery, radiologic procedures, anaesthesia, blood transfusion.

Every effort will be made to include me in this decision making process where possible.

I consent to undergo the procedure ERCP.

Signature of patient/guardian: *Date:*

..../../..

Day Month Year

Signature of nurse/doctor:

..../../..

Day Month Year

Signature of Endoscopist:

..../../..

Day Month Year

Interpreter:

I confirm that I have given a sight translation of the consent form in the ..... language and assisted in the translation of verbal and written information given to the patient by the doctor/health care provider.

Full Name: *Block Capitals*

.....

Signature: *Date:*

..../../..

Day Month Year

Mater Misericordiae University Hospital

Consent for an

ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY (ERCP)

PLEASE READ THIS LEAFLET CAREFULLY AND CONTACT US **BEFORE Y**OUR PROCEDURE DATE IF YOU HAVE QUESTIONS OR CONCERNS

GI unit
Phone: (01) 803 2366 Email: giunit@mater.ie
www.mater.ie/services/gastrointestinalunit

What is an ERCP?

An ERCP is a procedure in which the doctor passes a thin, flexible tube through the mouth to the first part of the intestine (duodenum). Then, the doctor can examine the ducts of the liver and pancreas, and carry out treatments such as removal of bile duct stones, insertion of a stent to open a blockage, or other procedures.

During the procedure, biopsies or cytology samples (small pieces of tissue) are often taken. **It is necessary to retain this tissue in order to examine it fully**. Please see the accompanying letter for information on how to prepare for your procedure.

What will happen during the procedure?

You will be checked in by the administrator on arrival at the GI Unit and thereafter, a nurse will call you to complete the medical checks and place an IV line in the arm and administer IV fluids. **Please bring a list of your medications with you.** If you are travelling from another hospital for a day case procedure, the staff will send the relevant information with you. However it is important that you read this **information before leaving your own hospital,** to give you time to ask questions or raise concerns if you have any. It will also give you an opportunity to discuss the procedure with your family.

Tick here to indicate you received the information in your own hospital and have had time to consider it and discuss with relevant parties. ☐

In the endoscopy room, the nurse will go through the safety checks again. A suppository (medication into the back passage) will be given.

You will be given local anaesthetic spray to the throat. You will be asked to lie on your tummy. A mouth guard, which protects the teeth, will be placed in the mouth. Sedation is given at this stage, along with oxygen through the nose. Your pulse, oxygen levels and blood pressure will be recorded throughout the procedure. You will be relaxed and comfortable, which is the desired result of the sedative (you will not be 'knocked out' as you would for an operation).

The ERCP scope will be passed through the mouthguard and down the gullet. It does not interfere with normal breathing. The doctor will put air into the stomach to get good views during the test. Some of this air may be regurgitated (belched) during the procedure. Once the instrument is in the correct position, the doctor will pass instruments through the scope that allow X ray pictures to be taken, and therapeutic procedures to be carried out. Once the procedure is finished, you will be brought to the recovery area and monitored until you are fully recovered from the sedative.

There may be restrictions on eating and drinking after the test, depending on what has been done during the procedure. Once you have recovered from the sedative, an ambulance will bring you back to your own hospital, or you will return to the ward within the hospital.

Specific instructions for your care after the procedure will be sent with you – these depend on the procedures that were carried out.

Risks of an ERCP

ERCP is a therapeutic procedure best considered as 'mini-surgery'. It carries significant risks when compared to a more 'straightforward' diagnostic endoscopy.

Complications can be related to:

1. Pancreatitis:

This is swelling and inflammation of the pancreas, and can occur in **5 of every 100** people undergoing an ERCP. In certain cases, the risk can be considerably higher and will be discussed with you if this is the case. It causes abdominal pain, for which IV fluids, pain relief and a hospital stay will be required. In most cases, it settles down after 24-48 hours. In some cases it can be severe and need further treatment, including surgery or an intensive care unit stay.

2. Medication:

Rarely, a person may suffer from a phlebitis (inflammation of the vein) at the site of the IV line. Additionally, the injected sedatives may cause problems with the heart or lungs, particularly if there is an underlying problem in those areas, or in the elderly, or in an emergency situation. **(between 2 and 5 people per 1,000 procedures** could develop sedation related heart or lung problems). For this reason, we must take care with those medications and avoid 'oversedation'. Rarely, a reaction can occur with the local anaesthetic used to numb the throat. Anaphylaxis, which is a severe life threatening allergic reaction, can occur in response to any medication, but is very rare.

3. Bleeding:

This occurs in **2-3 of every 100** cases. It usually occurs due the 'cut' that is required to remove a stone. Most times, it can be controlled through the endoscope. The risk may be increased by the presence of a bleeding condition, or if a patient is taking blood thinners, so your blood tests will be checked to ensure it is safe to proceed, and blood thinning medication will usually be put 'on hold' to lessen any bleeding risk.

4. Perforation:

This is a tear or hole in the lining of the oesophagus, stomach or duodenum or bile duct. This occurs in less than **1 in 100** cases. Often it will settle with 'conservative measures' – intravenous fluids, pain relief, antibiotics and drainage of the stomach by a nasal tube. However, in other cases, surgery or other techniques may be required.

5. Infection:

This occurs in **2-3 of every 100** patients undergoing an ERCP. The risk of aspiration (overflow of stomach contents into the lungs) is small but is influenced by a number of factors - It is crucial that the 'nil by mouth' pre-procedure instruction is followed for this reason. It is also important to avoid oversedation as this can be associated with aspiration pneumonia. In certain individuals, bacteremia (infection of the blood) can occur as a result of ERCP – this is usually treated with antibiotics.

6. Missed Lesions:

No test is perfect, including ERCP, and in a small number of cases, a significant pathology such as a stone or stricture can be missed, even in experienced hands.

7. Rarely

ERCP or its complications can be life threatening.

8. Failure:

In approximately **5 of every 100** cases, the procedure may be incomplete, which can be influenced by a number of factors. If this is the case, a second attempt at the ERCP or other procedures may also be required.

(see the 'alternatives' section)