

Endoscopic Retrograde Cholangiopancreatography (ERCP)

Information leaflet

Please, read this entire document carefully as this information is very important. Take it home and discuss it with your Physician. If you agree and have no doubts, sign the informed consent.

1 – Clinical situation/Diagnosis

Endoscopic retrograde cholangiopancreatography (ERCP) is an endoscopic procedure that allows the treatment of diseases of the biliary tract (channels that lead the bile from the liver to the intestine) and pancreas. This examination is indicated when a transient/permanent obstruction of the biliary tract is present, being the most frequent culprits gallstones and tumours. This procedure may also allow the treatment of pancreatic diseases when its ducts are obstructed with gallstones or have a stenosis (“narrowing”). The most common symptoms of these diseases are abdominal pain, jaundice (“yellowish skin”), pancreatitis (“inflammation of the pancreas”), cholangitis (“infection of the biliary tract”) and pruritus (“itchiness”).

2 – Description of the procedure

ERCP is performed by a Gastroenterologist or, under her/his supervision, by an advanced Gastroenterology trainee. The procedure is done under deep sedation/general anaesthesia, in a room with fluoroscopy (“X-ray”).

Depending on the techniques and complexity of the particular case, the mean duration of this procedure varies from 30 to 60 minutes. Within this period, you will not feel anything, as you will be deeply sedated/anaesthetised.

In an ERCP, a lateral-view endoscope (duodenoscope) is introduced through the mouth until it reaches the 2nd portion of the duodenum (small intestine) for visualizing the ampulla of Vater. This latter structure is a bulge in the 2nd portion of the duodenum, where the common bile duct and pancreatic duct converge. On this site, through the duodenoscope, the Gastroenterologist cannulates (“introduces a catheter – plastic tube”) the intended duct (common bile duct or pancreatic duct). This will allow the visualization of the duct with the support of fluoroscopy (“X-ray”), after the injection of contrast, enabling multiple therapeutic actions. Cannulation is one of the most challenging steps of ERCP because it is the manoeuvre that grants access to the sites where treatments are to be done.

During the procedure, contrast will be introduced into the biliary and/or pancreatic ducts. Even though some people may be allergic to intravenous contrast, its administration through the biliary and/or pancreatic ducts generally does not cause complications, even in people allergic to intravenous contrast. Nevertheless, you should warn your Gastroenterologist and Anaesthesiologist before the procedure, to minimize risks.

In most patients, ERCP is therapeutic, allowing several treatments, such as gallstone removal (“stones in the biliary ducts or pancreas, but not in the gallbladder”), unblocking of these ducts, stent placement (“small plastic or metal tubes”), biopsies, live visualization of the ducts with a smaller endoscope (cholangioscopy/pancreatocopy) that allow even more complex treatments, such as LASER and shock-wave lithotripsy. To achieve this variety of treatments, a sphincterotomy is generally required (cut in the ampulla of Vater), which allows an easier access to these ducts.

In a minority of patients, ERCP may be exclusively used as a diagnostic tool, when the previous examinations were unable to establish a diagnosis.

The X-ray dose applied to each patient during the procedure is acceptable within the current standards and will be minimized as possible. **Nevertheless, if you are pregnant or if by any chance there is that possibility, this radiation may be extremely harmful, and you should immediately warn the Gastroenterologist that will perform this procedure.**

2.1. – Preparing and performing the ERCP

For this procedure you should fast at least 6 hours for solids and at least 2 hours for liquids (water and tea).

Your current medication may interfere with the ERCP and lead to severe complications. You should notify your Gastroenterologist about all the medication you are currently on. In case you are taking any antiplatelet agents and/or anticoagulants, you should ask your Gastroenterologist if adjustments are required. As a general rule (although this may change from patient to patient) the following medications may require **stopping**:

- You may maintain acetylsalicylic acid (e.g. Aspirin®, AAS®, Cartia®, Tromalyt®) – except if the scheduled intervention is a papillectomy (in case you have a tumour in the papilla of Vater, which will be removed using this technique).
- Other antiplatelet agents:

- Clopidogrel (e.g. Plavix®), Prasugrel (e.g. Efient®) or Ticagrelor (e.g. Brilique®), should be withdrawn 5 to 7 days before the ERCP;
- Ticlopidine (e.g. Tiklyd®, Plaquetal®, Ticlodix®) should be withdrawn 10 days before the ERCP. If necessary, these may be substituted for acetylsalicylic acid;
- If you are on dual antiplatelet therapy (acetylsalicylic acid + clopidogrel/prasugrel/ticagrelor), you should withdraw clopidogrel/prasugrel/ticagrelor 7 days before and maintain acetylsalicylic acid.
- You should be aware that in case of previous “heart attack” with placement of coronary stents or if you had a previous stroke, suspension/substitution can only be done with your Physician’s approval.
- In case you are taking oral anticoagulants (e.g. warfarin - Varfine®, acenocoumarol – Sintron®, fluindione), these should be withdrawn 5 days before the procedure and eventually be substituted for other medication. Do not stop these drugs on your own and discuss the matter with your Physician.
- Regarding the direct-acting oral anticoagulants (e.g. Pradaxa®, Xarelto®, Eliquis®, Lixiana®), these should be withdrawn 3 days before the intervention (in case you have renal insufficiency and you are taking Pradaxa® more time will be required), with clear instructions from your Physician.

In most cases you may resume your medication within 48 hours after the procedure, but you should always confirm this with the Gastroenterologist who performed the ERCP.

If you have had previous heart surgery with valve replacement and your Cardiologist/Cardiothoracic surgeon have clearly stated that you should take antibiotics before particular interventions (dental cleaning/repairs, among others), you should warn the clinical staff about this (it should be noted that only in high-risk situations is prophylactic antibiotic therapy is recommended).

If you have a pacemaker you should warn the clinical staff prior to the ERCP. You should also indicate the type of implanted device, to assess the risks of using electric current during the procedure. In some occasions it may be necessary to inactivate some functions of the pacemaker, especially if it has an incorporated defibrillator.

ERCP is performed under deep sedation/general anaesthesia, with the supervision of an Anaesthesiologist. An Anaesthesiology appointment prior to the procedure may be necessary and you should have with you recent blood tests (hemogram with full platelet count, prothrombin time (PT); activated partial thromboplastin time (aPTT), international normalized ratio (INR), bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, gamma-glutamyl transferase (GGT) and amylase) and electrocardiogram (as well as any other heart-related exams). If you have had previous thyroid surgery and/or are taking any medication for your thyroid, your blood tests should include thyroid function.

2.2. – After the ERCP

In the beginning you will be directed to a recovery room where you will remain until you wake up from the deep sedation/anaesthesia. Occasionally, you may experience abdominal pain, which can be controlled by administering intravenous painkillers. Afterwards, it is expected that you may be discharged within the same day as the procedure or, alternatively, that you may need to remain hospitalised, under surveillance for 24 hours – depending on the procedures that were done during the ERCP. The time of hospitalisation may be extended in case of complications or unexpected events. Exceptionally, under strict protocols, you may be discharged earlier, but it is up to the Gastroenterologist that performs the ERCP to decide on this particular subject.

3 – Benefits

In the majority of cases, ERCP allows the resolution of the clinical problem, in a lesser invasive way than the existing alternatives, avoiding more severe consequences or complications. As will be further clarified, ERCP grants a rapid resolution of the problems, being more preferable than the other treatment alternatives.

4 – Risks and complications

ERCP is an endoscopic procedure with a complication rate that can be as high as 10%. However, >90% of the complications are mild or moderate, only implying a conservative approach and a few more days of hospitalisation. The risk of complications may be increased in patients with anatomical changes, extensive tumoral infiltration, recurrent pancreatitis/previous pancreatitis after ERCP, haemostasis changes (platelets and coagulation), elderly patients, anaemia, dementia, previous pulmonary diseases, obesity, cardiovascular diseases (heart failure, valvular disease) or if it is an emergency procedure.

The main complications are:

- **Pancreatitis** – occurs in 4-10% of patients. In 90% of cases is mild to moderate, only requiring conservative treatment and hospitalisation for a few days. However, in 10% of cases it can be severe and treatment may require multiple interventions and a prolonged hospital stay, and in some cases it may be lethal (see below). The risk of

pancreatitis depends on several factors, such as the person and his/her clinical history, the endoscopic technique and the course of the intervention. This risk is aggravated in patients who: 1) have a suspicion of sphincter of Oddi dysfunction; 2) are female; 3) are <30 years-old; 4) had previous recurrent pancreatitis; 5) had previous post-ERCP pancreatitis. Besides these, there are other factors directly related to the procedure itself that rise the risk of pancreatitis, such as multiple pancreatic injections and/or cannulations, pancreatic sphincterotomy and dilation of an intact papilla with a large calibre balloon. Nowadays, some measures that reduce the risk of pancreatitis are routinely used, such as intravenous fluid therapy during and after the procedure, NSAIDs suppositories and/or pancreatic stents, which are used according to the risk and clinical status of the patient.

- **Haemorrhage** – occurs in 0.3-2% of patients. It is usually a consequence of the sphincterotomy, which is essential to perform therapeutic acts. It may occur during the procedure or hours to days after the ERCP. The risk is higher in patients with coagulation disorders, in those who did not adequately stop the anti-platelet therapy or anticoagulants and in cases of resuming anticoagulants within 3 days after the procedure. When a major haemorrhage, though controlled, arises during the ERCP, there is an increased risk of haemorrhage within hours/days following the exam. This haemorrhage may lead to other endoscopic procedures, transfusions or, in more severe cases, the need for imaging exams or even surgery.
- **Perforation** – occurs in 0.08-0.6% of patients (oesophagus, stomach, duodenum or biliary tract). The risk is higher in patients with anatomical changes (previous stomach surgery, *situs inversus*), elderly people, extensive tumoral infiltration or those submitted to prolonged/complex therapeutic manoeuvres. Perforation may lead to the need for surgical treatment.
- **Cardiovascular and respiratory complications** – cardiac arrhythmia, severe allergic reactions called anaphylaxis, “heart-attack”, pulmonary embolism, stroke, and aspiration of food/fluids into the lungs leading to pneumonia. These events are more common in elderly people with other conditions (anaemia, dementia, pulmonary disease, obesity, cardiac insufficiency, valvular heart disease) or in emergency exams.

Less often, **other complications** may arise:

- **Cholangitis** (infection of the bile within the biliary tract) – increased risk in patients that during the procedure have an incomplete biliary drainage, previously transplanted patients and those submitted to cholangioscopy.
- **Acute cholecystitis** (inflammation of the gallbladder), **liver haematomas** (blood accumulation in the liver), **air embolism** to the systemic circulation leading to circulatory collapse and/or serious stroke, **spleen rupture**, **pneumothorax**, **contrast allergy**, **hepatic abscess** (accumulation of purulent debris in the liver) are extremely rare complications, but they may occur.

These complications may be solved with non-invasive medical therapy, but, under certain circumstances, radiologic interventions (percutaneous drainage), new endoscopic interventions, blood transfusions and even surgery may be required.

As in every other medical intervention, ERCP is associated with a risk of mortality, though very low (0.2-0.4%).

The goal of the Gastroenterologist is to always perform this technique with success and without any complications, but this is not always feasible for the multiple reasons. There are situations where important lesions cannot be identified and cases where the preconized treatments cannot be executed, or the anticipated improvement does not occur. In some cases, the clinical status of the patient may even worsen.

5 – Alternatives to the ERCP

It is important to emphasize that, even though there are alternatives to ERCP, such as digestive endoscopic ultrasound or echoendoscopy, interventional radiology or surgery, these are usually more invasive, with a lower success rate and bear with them frequently similar or even higher risks compared to ERCP. Additionally, these alternative treatments are not always feasible or applicable in many cases. In case you have any questions, discuss these alternatives with your Physician.

6 – Risks of not being treated

In most cases, not treating the underlying cause either by ERCP or by an alternative chosen technique the patient, if feasible, may lead to an irreversible worsening of the clinical status. In some cases, it may even lead to death.

DO NOT HESITATE TO ASK FOR ADDITIONAL INFORMATION, AND TO QUESTION THE CLINICAL TEAM WHO PROPOSED YOU THE ERCP OR IS GOING TO PERFORMING IT – THAT IS A RIGHT THAT YOU POSSESS!

Please read this entire document carefully. The performing Gastroenterologist will confirm that you are appropriately informed for the procedure to be carried out. If you agree with all the information and are fully clarified, please sign the informed consent.