Endoscopic Retrograde Cholangiopancreatography (ERCP)

Free and informed consent

Please, read this entire document carefully as this information is very important. Together with this consent, you will receive a second document with additional information on this procedure. If you agree and have no doubts, please sign this document.

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.

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/anesthetised.
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. Use of contrast and fluoroscopy ("X-ray"), allows for various 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.
In your case, ERCP is a therapeutic procedure – ☐
In your case, ERCP will be performed to diagnose biliary tract and/or pancreatic diseases, when previous exams did not allow to establish a diagnosis – ☐
The X-ray dose that is 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 notify the Gastroenterologist that will perform this procedure.**

2.1. – Preparing and performing the ERCP
Are you fasting for at least 6 hours for solids and at least 2 hours for liquids (water and tea)? _____
Are you taking any medication? _____ (talk to your Physician)
Do you have any known cardiac disease or have had any previous stroke? _____ (talk to your Physician)

- 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 limited abdominal pain. Afterwards, it is expected that you may be discharged within the same day of 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.

3 – 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 it is mild to moderate, only requiring conservative treatment and hospitalisation for a few days.

- **Haemorrhage** – occurs in 0.3-2% of patients. It is usually a consequence of the sphincterotomy, which is essential to access biliary "channels" and perform therapeutic acts.
- **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 require 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.
  - It is important to mention that the administration of contrast may trigger an allergic reaction, occasionally very severe. If you have a past history of allergic reactions to iodine and/or contrast products (e.g. the one used in CT scans) you should immediately warn your Physician and the one who will be performing the procedure. However, this risk is extremely low, because the contrast used in the ERCP is directly administered in the biliary or pancreatic ducts and not in the bloodstream. Additionally, during the procedure, the medical team will take the necessary measures to lower this potential risk.

Less often, **other complications** may arise, such as **cholangitis** (infection of the bile within the biliary tract), **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).
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.**

DO NOT HESITATE TO ACQUIRE FURTHER ADDITIONAL INFORMATION BY ASKING THE CLINICAL STAFF THAT HAS PROPOSED YOU THE ERCP OR THAT WILL BE PERFORMING IT – THAT IS A RIGHT THAT YOU POSSESS!
Please read this entire document carefully, as well as the information leaflet. Make sure you understand all the information given. The performing Gastroenterologist will assure that you are fully clarified before the procedure, for this to be conducted. If you agree with all the information and are fully clarified, please sign the statement below.

Health-care professional
Here in, I confirm that the patient indicated below received the essential information to be adequately informed regarding the intervention that is referred in this document. Additionally, I was available to answer all the questions raised before the procedure and ensured a period of reflection for the decision-making. I have also guaranteed that, in case of refusal, the best care will be provided within the context, respecting the patient's rights.
Physician's full name (legible): _____ Professional number: _____
Signature of the performing physician: _____ Date: ___/___/___

Patient or guardian
Please read this entire document carefully, as well as the additional detailed information document that was handed to you. Do not hesitate to ask for further information if you are not fully clarified. Check that all the information you provided is correct. If you have no further concerns, please sign the statement below:
I declare that I have fully understood the goals of what was proposed and explained by the health-care professional that signs this document. I was given the opportunity to ask and obtained clarifying answers to all the questions regarding the procedure. I was guaranteed no forfeiture to my rights if I refuse this procedure. I was given enough time to reflect on this proposal.
☐ **I authorize** the indicated act, as well as any other potentially necessary related procedures, on my own self-interest (or the represented person's interest) and justified with clinically based reasons.
☐ **I do not authorize** the indicated act, as well as any other potentially necessary related procedures, on my own self-interest (or the represented person's interest) and justified with clinically based reasons.
(check the intended box)
Full name: _____
Signature: _____ Date: ___/___/___

I declare that I was given an information leaflet about ERCP (Endoscopic retrograde Cholangiopancreatography), that I have read it and was clarified on any potential questions or issues regarding this procedure.

Signature: _____ Date: ___/___/___