

DIGESTIVE ENDOSCOPIC ULTRASONOGRAPHY WITH OR WITHOUT SEDATION – FREE AND INFORMED CONSENT¹

1. Diagnosis and/or description of the clinical situation

2. Description and aim of the procedure

Digestive endoscopic ultrasonography is a procedure intended to assess the wall of the digestive tract and surrounding structures. To this end, a long and flexible tube (echoendoscope), equipped with a small camera and an ultrasound probe on its tip, transmits video and ultrasonography images to a monitor within the room. In the **upper digestive endoscopic ultrasonography**, the echoendoscope is inserted into the mouth and goes through the oesophagus, stomach and initial portion of the small intestine (duodenum), assessing its wall and surrounding structures, namely the pancreas, biliary tract, liver, left adrenal gland and lymph nodes. In the **lower digestive endoscopic ultrasonography**, the echoendoscope is inserted in the rectum through the anus allowing the assessment of its wall and surrounding structures, namely lymph nodes. As the echoendoscope advances in the digestive tract, air and/or carbon dioxide will be inflated through the scope. As this exam is performed under sedation, your vital signs will be monitored and intravenous sedative medication will be administered to you. Throughout the intervention, it may be necessary to perform additional procedures such as **biopsies** (obtaining small tissue samples with the use of forceps, for further analysis), **punctures** (obtaining small tissue samples with the use of a needle, for further analysis), **neurolysis/neurolytic blockage** (drug injection for neural desensitization), **fiducial injection** (small markers, which are introduced within tumours to guide future radiotherapy), **stent placement** (placement of plastic and/or metal tubes in the biliary tract, pancreas or collections to allow their drainage) and/or **tattoos**. **The decision to perform these procedures or not is taken by the Physician during the procedure, according to the indication and/or to the findings throughout the digestive endoscopic ultrasonography. It should be noted that some of these procedures may have an added cost (depending on your health-care system or insurance) and the corresponding payment charge may be requested after the endoscopic procedure is finished.**

Usually, digestive endoscopic ultrasonography takes between 30 and 60 minutes to be completed. However, and according to the digestive endoscopic ultrasonography's indication and need to perform additional procedures, a greater or shorter length of time may be required. Once the procedure is finished, you will be transferred to a recovery room, where you will remain under surveillance for 1-2 hours.

3. Benefits

The main benefits of the digestive endoscopic ultrasonography are:

- Ability to detect and assess abnormalities within the digestive tract wall and surrounding structures, namely bile duct stones, pancreatitis and tumours;
- Ability to perform biopsies, punctures, and therapeutic procedures.

4. Severe and common risks

Digestive endoscopic ultrasonography is an invasive procedure. Therefore, it has associated risks, which increase if additional procedures/interventions are required. Although this is a procedure with a complication rate under 1%, **these might occur both in diagnostic and therapeutic digestive endoscopic ultrasonography**. On the other hand, there are **specific risks associated to the sedation**, namely cardiorespiratory and cerebrovascular complications and allergic reactions to the administered drugs.

The most common adverse events include:

- Pain or mild discomfort at the neck, thorax or abdomen, intestinal cramps and flatulence;
- Nausea, vomiting and/or swallowing difficulty;
- Dizziness or fainting sensation after standing at the end of the procedure;
- Headache;
- Pain, redness, and swelling at the puncture site where sedation or medication was administered;
- Muscle pain;
- Allergic reaction to drugs that were administered during the procedure.

Severe complications associated to this procedure are rare, and include:

- **Cardiovascular and respiratory complications** (1 in every 100 procedures), such as severe allergic reactions called anaphylaxis, "heart-attack", pulmonary embolism, cardiac arrhythmia, stroke, and aspiration of food/fluids into the lungs leading to pneumonia. Though rare, these events are more common during exams where sedation is administered, emergency exams, and for elderly people with other conditions (anaemia, dementia, pulmonary disease, obesity, cardiac insufficiency, valvular heart disease);
- **Infection** (1 in every 200 procedures), particularly if additional procedures are performed, namely punctures, amongst other;
- **Acute pancreatitis** (1 in every 200 procedures), which is an inflammation of the pancreas. The risk of this event increases if additional procedures are performed, namely pancreatic punctures, amongst other;

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- **Haemorrhage** (1 in every 1000 procedures), particularly if additional procedures are performed (biopsies, punctures,...), and if the patient is taking anticoagulant/antiplatelet medication or has blood clotting disturbances;
- **Perforation** (1 in every 1500 procedures), particularly if additional procedures are performed (biopsies, punctures,...). This event is more common for elderly people, and if there is a history of previous surgery or radiotherapy (thoracic, abdominal or pelvic), adhesions, stenosis (“narrowing”), diverticula or digestive tumours.

Should haemorrhage or perforation occur, in most cases they are managed and solved during the procedure. However, in certain cases, adequate and definitive complication treatment may require blood transfusion, radiological or surgical intervention and hospitalization.

As in other invasive health-related interventions, there is a risk of mortality for both therapeutic and diagnostic procedures, though this risk is extremely low.

Digestive endoscopic ultrasonography is not a foolproof examination and there is a possibility that some false negatives (negative diagnosis in the presence of disease) and some false positives (positive diagnosis in the absence of disease) may occur. There is also the possibility that the desired treatment may not be accomplished during the procedure.

5. Alternative reliable and scientifically recognized procedures

Digestive endoscopic ultrasonography is an excellent examination to assess the multiple layers of the digestive tract and surrounding structures. Particularly, it is considered the best procedure to perform punctures of abnormalities within these structures, specially tumours. According to the indication, there are alternative procedures, such as endoscopic examinations, ultrasound, CT scan and MRI. Nevertheless, these may not be as reliable in the diagnosis of abnormalities of the multiple layers of the digestive tract and surrounding structures.

6. Risks of not performing the procedure

The decision of not performing the digestive endoscopic ultrasonography may impair or delay the diagnosis and treatment of relevant diseases, including cancers.

In case you have questions regarding the procedure, further clarification should be obtained with the Physician that requested it and/or Gastroenterologist that will perform the examination. In case sedation is needed, further clarification should be obtained with the Anaesthesiologist who will be sedating you, before the beginning of the procedure.

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: _____ **Professional number:** _____

Date: ___/___/___ **Signature of the performing physician:** _____

Patient or guardian: Please read this entire document carefully. Do not hesitate to ask for further information if you do not fully understand the contents of this document. 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 read the 2 pages of this document, 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 obtain 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 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 and justified with clinically based reasons

Patient’s full name: _____

Date: ___/___/___ **Signature:** _____

If the patient is unable to sign due to minority status or incapacity:

Guardian’s full name: _____ **Degree of relationship:** _____

Identification number _____ Date/Expiration date: _____

Guardian’s signature: _____

¹ According to normative nº015/2013 of Direção-Geral da Saúde
This document has 2 copies – one for the clinical file and another to stay in possession of who consents