

Dear Lady, Dear Sir,

An EGD is a procedure in which your doctor will examine the lining of your upper gastrointestinal tract and identify and potentially treat any abnormalities that are found. As you lie on your left side, a small mouthpiece will be placed between your teeth. The exam is done with a thin flexible tube (scope) with a small camera and light attached: the doctor will pass gently the scope through your mouth into your stomach and within the first part of your small intestine. Your doctor will watch the exam on a TV screen. Tissue samples (biopsies) may be taken by passing small instruments through the scope: taking biopsies will be not painful for you. You may experience some cramping and bloating due to the gas (carbonic dioxide) your doctor is putting in during the procedure. The procedure itself usually takes anywhere from 5 to 10 minutes, but you should plan on one to two hours for waiting, preparation and recovery.

EGD is generally not painful, but rather unpleasant and somewhat distressing. You may prefer to undergo EGD without any medication, with topical pharyngeal anesthesia, or with intravenous sedation. If you decide to have pharyngeal anesthesia, the doctor will spray your throat with a numbing medicine (lidocaine) to relax your gag reflex. If intravenous sedation is planned, the nurse will put a drip into a vein in your forearm, or hand. This is where the sedation is injected. Sedation is the use of drugs that have an analgesic-effect and give you a 'sleep-like' feeling: a benzodiazepine and/or an opioid (a synthetic derivative of opium) are usually used. Your blood pressure, respirations, pulse, and oxygen level will be monitored by a nurse throughout the procedure. **Sedation will affect your judgment for about 24 hours. For your own safety and in some cases legally:** do not drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person; do not operate machinery; do not make important decisions or sign a legal document; do not drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.

Therapies/treatments may be performed during an EGD: they include, but are not limited to: dilatation (stretching narrowed areas by passing special instruments); hemostasis (stopping bleeding by injection of drugs, heat, or placing of small clips); removal of polyps and foreign objects (passing special instruments to retrieve them). Therapeutic EGDs are performed with sedation.

An EGD requires at least 6/8 hours of fasting. If your examination is performed in the morning, you should not eat anything after a light meal the evening beforehand, while if your examination is scheduled after 2:00 pm, you may have a light breakfast in the morning before 8:00; milk is not allowed. If you are diabetic, you should not eat anything for at least 12 hours. In any case, you may drink small quantities of tea, water or sweetened water up to two hours before your examination. We suggest you, to bring all your prescribed drugs, those drugs you buy over the counter and show the gastroenterologist what you are taking. Tell the doctor about any allergies or side effects, you may have; pharyngeal anesthesia may be contraindicated if you are asthmatic, affected by chronic obstructive pulmonary disease, or allergic to local anesthetics. If you take drugs for diabetes, get some advice from your General Practitioner about any modification of dosage and time schedule. If you take Warfarin (Coumadin), you can assume it, as usual, but you will be requested to show the gastroenterologist a recent determination of International Normalized Ratio (I.N.R.). If you take Eliquis, Lixiana, Pradaxa, or Xarelto, skip the morning dose.

EGD is generally safe, but there are risks with the procedure. The personnel are trained to recognize and immediately treat any adverse event. Common adverse events include the following: after the sedation, you may feel drowsy and may sleep for a short time; you may feel bloated from the gas inserted during the procedure (you will be encouraged to expel the gas); you may experience pain, redness or bruising at the sedation injection site, or muscle aches; you may have allergy to medications given at time of the procedure. Uncommon risks include:

- Tear or perforation (a hole) of esophagus, stomach or duodenum. Surgery may be needed to repair this injury.
- Rarely, bleeding may happen in consequence of biopsies, removal of polyps, or tear of the mucosal lining. Further EGD, a blood transfusion or an operation may be necessary.
- Heart and lung problems such as heart attack, or vomit in the lungs, causing pneumonia. Infection occasionally may happen.
- The gastroenterologist will be very meticulous in performing your examination; nevertheless, lesions may be occasionally missed.
- An existing medical condition that you may already have getting worse.
- Severe allergy to medications given, at the time of the procedure.
- Damage to teeth and dental works.

Your doctor suggested EGD, because he thinks this examination is useful to give you the correct diagnosis and treatment; furthermore, EGD allows to take biopsies and to perform treatments, as discussed above. If you don't have the procedure, your symptoms may become worse and the doctor will not be able to give you the correct treatment without knowing the cause of your problems. A possible alternative to an EGD is a CT scan, or an upper GI series, which is an upper GI X-ray where pictures are taken to check for abnormalities. A contrast (for instance barium) is swallowed and X-ray pictures are taken. The benefit of CT scan or an upper GI series is that they require no sedation.

Radiologic examinations do not give the in-depth information and direct visibility that an EGD provides; they can't detect thin mucosal lesions, and do not allow to obtain biopsies and to perform various the treatments outlined above.

After EGD, notify the hospital Emergency Department straight away if you have; severe ongoing abdominal pain; black tarry motions or bleeding from the back passage (more than ½ cup of blood); a fever; sharp chest or throat pain; have redness, tenderness or swelling for more than 48 hours where you had the injection for sedation.

DECLARATION OF CONSENT (in accordance with the Law 219/2017)

I hereby,

or I, delegate

Signature of the patients, who delegates

Date

or I, legal representative

In the case of a subject without decision-making autonomy, the documentation will be enclosed showing the source of the decision-making authority.

I acknowledge that the doctor has fully explained:

- my medical condition and its prognosis
- what is the EGD, its benefits and risks, including the risks of sedation.
- the other diagnostic options and their benefit and risks.
- The risks of not having the procedure.

I acknowledge also that:

- I was able to ask questions and raise concerns with the doctor. My questions and concerns have been discussed and answered to my satisfaction.
- I have fully understood the information the doctor gave to me.
- I had time enough to mature the decision to consent.
- if immediate life-threatening events, or other unpredictable events happen during the procedure, the proposed procedure may be changed and the necessary treatments may be immediately implemented.
- I understand I have the right to change my mind at any time.

Place.....Date.....

I CONSENT (Signature).....

I DO NOT CONSENT (Signature).....

I consent to EGD, but I do not consent to sedation
(Signature).....

The doctor, who informed the Patient
(Signature)..... (Date).....

The doctor, who performed the procedure
(Signature).....(Date).....

