Department of Gastroenterology and Diagnostic and Operative Digestive Endoscopy
Director: Dr. Paolo Beretta
Tel.: 02 2393 3055-3045-2252 - Fax: 02 2393 4240
e-mail: paolo.beretta@ic-cittastudi.it

INFORMATIVE NOTE AND INFORMED CONSENT FOR AN OESOPHAGOGASTRODUODENOSCOPY (EGDS)

An oesophago-Gastro-Duodenoscopy (EGDS) is an examination that allows the inside of the upper digestive tract to be explored (precisely the oesophagus, stomach and duodenum) by using a gastroscope, an instrument comprising a flexible tube with diameter smaller than 1 cm fitted with a small camera on the tip that is introduced through the mouth. The examination is brief, painless and does not interfere with normal breathing. The examination is preferably performed on the left side, and a dedicated mouthpiece is used to help the patient keep their mouth open during the procedure and to prevent him or her from biting their tongue and/or the instrument. Any mobile dental prostheses need to be removed before the examination. The stomach will be moderately distended with air to enhance visual accuracy. This might cause a feeling of having a bloated abdomen but this should not alarm you since it is absolutely transient. If deemed necessary by the surgeon, fragments of mucosal tissue (biopsies) might be collected with small forceps during the examination. These will be sent to the laboratory for analysis under the microscope (histological examination), or additional diagnostic or therapeutic procedures might be performed. Depending on the surgeon's opinion, and in agreement with the patient, sedation might be performed with the intravenous administration of a sedative/analgesic, and of pharingolaryngeal anaesthesia with a spray, to desensitise the throat and remove the vomiting reflex. Blood pressure, heart rate, oxygen saturation and, if necessary, electrocardiographic activity will also be monitored. If you wish to undergo the investigation without sedation, you might feel some discomfort in your throat (caused by the transit of the instrument), abdominal bloating and retching during the exploration. These disorders can be partly controlled by breathing normally and by refraining from swallowing. The discomfort might be more intense at times. The biopsy is a painless procedure. At the end of the examination, your throat might still be anaesthetised ("swollen" feeling) for a brief period.

Preparing for the endoscopic examination

To allow an optimal view of the stomach, it's necessary to fast for at least 6 hours. The presence of food or food residue limits the visual field, impairing the diagnostic reliability of the procedure and, in the case of vomiting, it might encourage the transit of food residue into the airways.
Only the intake of water is allowed for up to two hours before the procedure, in the case that you have to take medicines, and if they are essential, but you must not take antacids (e.g., Maalox and the like) or charcoal.
It will not be necessary to suspend your habitual therapies, which might be taken for up to 2 hours before the examination.

Special cases

Proton pump inhibitors: if indications for the examination include the search for a Helicobacter pylori infection, the patient must suspend the intake of antisecretory agents, such as proton pump inhibitors, for at least 2 weeks before the procedure, and the intake of antibiotics for at least one month before.
Oral antidiabetics or insulin: generally these medicines need not be taken considering the fast required to prepare for the examination. In case of doubt, talk to your GP and/or the prescribing specialist.
Double antiaggregant therapy: Aspirin + Plavix/clopidogrel or Brilique/ticagrelor or Duoplavin and similar medicines: contact the prescribing doctor to ascertain the feasibility of temporarily suspending them (generally Plavix-Brilique must be suspended 5 days before the procedure)
Therapies with ticlopidine/Tiklid prasugrel/Efient: contact the prescribing doctor to ascertain the feasibility of temporarily suspending them (generally seven days before the procedure).

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New anticoagulants: Rivaroxaban, Apixaban, Dabigatran (**Pradaxa**, **Xarelto**, **Eliquis, Lixiana**) talk to your GP or to the prescribing doctor (e.g., cardiologist) to evaluate the feasibility of suspending them and the appropriate timing (generally 48 hours before the procedure, except for cases of known renal failure).
Anticoagulants: Coumadin/Sintrom must generally be suspended 3-5 days before the procedure, depending on the INR values, if a surgical examination is envisaged or if biopsies are required. In any case, please talk to your GP or to the reference anticoagulation therapy centre about the feasibility of starting bridge therapy and the dosage of low molecular weight heparin, if required; its administration is allowed except on the morning of the examination.

In view of the particular endoscopic surgical procedures, the feasibility of performing blood tests to evaluate coagulation parameters will be considered.

It's recommended to:

- bring your primary care physician's prescription, the medical documentation regarding the clinical problem under inspection or regarding relevant diseases, eventual past endoscopic exams, the list of the medication taken;
- come accompanied by a person able to drive or by public transport because, for the type of sedation utilized, it's prohibited to drive for 24 hours;
- tell the doctor that examines you if you posses a pace-maker or an implanted defribillator that could interfere with electromedical tools. Tell the doctor if you suffer from severe heart, lung, liver and kidney diseases or allergies to medicines and other substances;
- the patient must inform us if he/she wears removable dental prostheses so that they can be removed before the endoscope is introduced.

What are biopsies needed for?

During an EGDS, small tissue samples might be collected, if necessary, with specific sterile forceps to identify the type of any lesion observed (inflammatory, infectious, neoplastic), to search for any contamination from Helicobacter pylori, to diagnose coeliachia or other suspected diseases.

What is a chromoendoscopy?

When indicated, staining of mucous tissue might be performed by spraying stains directly on the mucosal tissue through the operative canal of the endoscope to improve the morphological definition of some lesions.

Sedation

An EGDS is usually performed under sedo-analgesia (unless explicitly refused by the patient) in order to considerably reduce discomfort caused by the examination. Besides improving the user's cooperation, sedation guarantees easier and more precise execution of the endoscopic procedure. The main vital parameters will be constantly monitored during the examination, and it will also be possible to administer medicines that are antagonists of sedation/analgesia to obtain adequate recovery. More details on sedation are provided in the dedicated **Informed Consent Form.**
If sedation is performed, it is preferable to leave the Hospital accompanied by an adult. ***You will not be able to perform activities that require complete psychophysical integrity (e.g., driving) until the morning after the examination.***

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Possible risks and complications

A diagnostic EGDS is a safe procedure but since it is an invasive examination, you might experience some complications, such as perforation, bleeding and cardiorespiratory disorders. However, they are very rare complications: perforation is exceedingly rare (0.0004%), it is related to predisposing factors (cervical osteophytes, Zenker's diverticulum, ingestion of caustic agents, oesophageal stenosis, neoplasia, duodenal diverticuli); clinically significant bleeding is rare (< 0.5%), more likely in subjects with thrombocytopenia and/or coagulopathies, and after biopsies of malacic tissues (severe phlogosis/tumours). Cardiorespiratory complications (usually related to premedication and/or to ingestion of reflux materials) is observed in less than 0.9% of cases. In most cases the complications previously reported clear after an observation period in the clinic or a short stay in hospital, but urgent surgery might be required in some cases, and they might only exceptionally be life-threatening.

Integrative procedures for surgical purposes that may be implemented during gastroscopy

Despite being a safe procedure, compared to diagnostic examinations, operative gastroscopy generally presents an increased risk that depends on the type of treatment administered.
Polypectomy. This is an endoscopic technique that allows removal of sessile or pedunculated polipoid lesions from the digestive tract by using diathermic loops connected to an electrosurgical knife, which issues diathermic current. The most frequent complications include perforation and bleeding with an incidence rate in the range of 3.4% to 7.2%. Mortality can reach 0.25%.
Advanced Endoscopic Resection Techniques (EMR and ESD). An EMR or mucosectomy (endoscopic resection of mucosal and submucosal tissue) and an ESD (endoscopic dissection of submucosal tissue) are advanced techniques to remove superficial neoplastic lesions. There are various execution techniques: the most common one is the "lift and cut" method, which entails a submucosal injection using a dedicated needle filled with either a saline or a colloidal solution to elevate the lesion (mucosa and submucosa) from the muscularis propria. The elevated block is then resected with a diathermic loop during the EMR or with the free dissector during the ESD. The most frequent complications of endoscopic mucosectomy are perforation, bleeding and stenosis with an incidence rate in the range of 0.5% to 5%, while for submucosal endoscopic dissection the most frequent complications are perforation (up to 6%) and bleeding (up to 11%). Mortality can reach 0.25%.
Haemostasis. The aim is to stop bleeding. Haemostatic therapies include thermal techniques, injections and mechanical procedures. Two or more techniques might be combined. Even endoscopic haemostasis techniques can be aggravated by complications.
The efficacy of treatment improves if the digestive tract has been cleaned in advance.
The rate of complications varies depending on whether it is haemostasis for varicose bleeding (35-78%, with 1-5% mortality) or non-varicose bleeding (≤ 5%, with mortality ≥ 4.5%). Elastic ligature of varicose veins can be performed even as primary prophylaxis, precisely in patients who never experienced bleeding. In this case the percentage of complications is in the range of 5% to 15%. In the case of varicose bleeding, as for prophylactic ligature, complications include: late postprocedural bleeding, inhalation of blood into the airways, perforation, ulceration or intramural haematoma at the injection site of the haemostatic substance and stenosis. In the case of non-varicose bleeding, complications include: perforation and exacerbation of the bleeding.
Removal of foreign bodies. Many accessories allow removal of foreign bodies that have been either accidentally or intentionally introduced into the upper digestive tract. In particular cases, such as the presence of sharp objects, a protective cuff can be placed on the distal end of the endoscope to avoid lesions during removal. The complications of this procedure are mucosal laceration (≤ 2%), bleeding (≤ 1%) and perforation (≤ 0.8%). The mortality rate, however small, is strictly related to the complications of the procedure. Special care is required when managing foreign bodies that contain drugs (ovuli, condoms) since

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rupture, if any, of the shell during removal can cause absorption of the drugs with a subsequent overdose syndrome and high risk of death.

• **Dilation of stenosis.** Dilation is performed by inserting, along the guide wire previously positioned in the stenotic segment, a dilator that can be either hydropneumatic (balloon for progressive dilation by filling with water or air) or mechanical (rigid probe with progressive calibre). Multiple sessions might be required to resolve the disease because, to be safe and effective, dilation must be slow and gradual. Complications associated with dilation of the stenosis include perforation and bleeding with a total incidence rate in the range of 0.1% to 0.4%. These percentages increase in the event of pneumatic dilation for acalasia, reaching values in the range of 1.6% to 8%. Mortality varies from 0.1% to 0.5%.

Positioning an endoprosthesis. An endoprosthesis is a medical device that allows the patency of the intestinal lumen to be restored and maintained. Endoprostheses are either plastic or metal “tubes”. The positioning manoeuvre is performed under radiological and/or endoscopic guidance, and consists of inserting the endoprosthesis on a guide wire through the stenotic segment or with a fistula. Diseases that might require treatment with an endoprosthesis are stenosis or benign fistulae, and palliation of inoperable malignant stenoses. Early (2-12%) and late complications are distinguished when positioning endoproshteses. The former include inhalation of gastroenteric material into the airways, breathing difficulty due to tracheal compression, bleeding and perforation. The latter are obstruction (14-27%), fistulisation (up to 6%) and dislocation of the prosthesis (3-20%). Mortality is 1%.

Positioning an intragastric balloon. This is an endoscopic treatment method for pathological obesity and comprises the insertion into the gastric cavity of a therapeutic device in the form of a balloon filled with a physiological solution and either methylene blue or air. The balloon partly fills the stomach causing a sensation of early and lasting satiety in the patient. Positioning takes about twenty-thirty minutes. The balloon is kept in the gastric site for six months and, in selected cases, may be replaced with a second balloon, or an adjustable type can be positioned to remain in place for up to 12 months. The main immediate complications are inhalation of gastric content into the lungs and lesions or perforation of the digestive system. Late complications include oesophageal or gastric or intestinal occlusion in the case of migration of the deflated balloon, persistent nausea and vomiting, gastroesophageal reflux, ulcers, haemorrhage, gastric or intestinal perforation. Overall the percentage of complications can vary from 0.21% to 2%, with a 0.07% risk of mortality.

Removal of an intragastric balloon. This is an endoscopic method to remove the previously positioned balloon at the end of treatment. Overall complication and mortality rates are the same as indicated for positioning.

After the examination

At the end of the examination, after a brief period of rest, you may return to your domicile.

If sedoanadgesic drugs were administered, or if during the exam terapeutic procedures had been performed, under a doctor's judgement, a prolonged clinical observation could be indicated. If the exam is conducted under sedation, at the end of it somnolence, dizziness, blurred or double vision could be experienced. It could rarely happen that a sensation of discomfort at the throat could remain but will revert in a couple of hours. The food resumption could happen once the throat sensitivity returns, normally after 30 minutes. Different specific indications will be explained and described on the endoscopic report.

If, in the hours or days after the exam, abdominal pain, fever, difficulties in breathing, bowels not opened or fecies with abundand blood or black are noticed, contact immediatly your primary care physician or with our Digestive Endoscopic Centre (at the number 02.2393.3055/2252), or go to the emergency room with the endoscopic exam's report.

If sedoanalgesic drugs were administered, cars or motor-vehicles cannot be driven or perform risky or psycho-fisical demanding activities in the 24 hours after the procedure. It is therefore preferred to come accompanied.

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The exam's report will be handed over immediatly, whereas for the histologic report (the outcome of eventual biopsies or polypectomies) it'll be necessary to wait a couple of days.

Diagnostic alternatives to an EGDS

A gastroscopy is the examination of choice when diagnosing organ lesions, such as ulcers and tumours; alternatives include X-rays with contrast medium and CT scans. These alternatives present lower diagnostic accuracy, do not allow for biopsies or operative procedures and, in any case, must often be integrated with a subsequent endoscopy. The alternative to an intervention procedures is generally surgery that entails higher risks.

Predictable consequences of not performing the examination

Failure to perform the examination prevents the definition of a diagnosis. It might cause aggravation of the basic disease with possible consequences, such as haemorrhage, obstruction of the intestinal canal, any malignant evolution.

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INFORMED CONSENT

In a doctor-patient relationship it is deemed necessary and ethically correct for the patient to play an informed and active role in invasive diagnostic examinations and treatments to which he or she submits voluntarily.

Hence, this document provides the information, and the doctor who presents and explains it to you will provide the extensive and clear information required to understand it, ensuring that you have clearly understood the contents submitted to your attention below, which require your final signature.

It is important for you to deem the information provided as exhaustive and clear and, particularly, for you to have clearly understood the procedure proposed for an appropriate therapeutic treatment. The benefits of the procedure that will be performed, the possible risks and any alternatives will be explained to you, so that you can make a voluntary and, therefore, an informed decision in this regard. Hence you are also given written information that is as detailed and as complete as possible, to ensure that the explanation is both comprehensible and exhaustive. If you deem it necessary, do not hesitate to request further information which you might consider useful to clear any doubts or to clarify any parts of the explanation that you did not fully understand. Hence, we invite you, before you give your written consent by signing this form, to clarify with the doctor who explains it to you, every aspect you have not fully understood.

I, the undersigned, _____ confirm that today I had an informative interview with Dr.

_____

who explained that due to my disease,

DIAGNOSIS

_____

it is necessary/appropriate to perform the following invasive procedure:

OESOPHAGOGASTROSCOPY + BIOPSY, IF ANY, AND THERAPEUTIC TREATMENTS

In this regard I have been exhaustively and comprehensibly informed about:

- my diagnosis resulting from the visit and/or examination;
- the most appropriate treatment, schedule and implementation methods;
- the potential benefits of the treatment;
- the possible complications, risks and related additional medical procedures;
- the possibility of failure;
- the particular risks related to my case;
- the discomfort that might arise after the treatment;
- the timeline and methods of recovery;
- the alternative therapeutic options to the diagnostic/therapeutic treatment proposed to me;
- including refusal to accept treatment and the related risks;
- the instruments required.

I also confirm:

- that I have had the opportunity to ask questions about the treatment proposed, and that the doctor was willing to provide any further clarifications I might require;
- that I am aware of the possibility of having to sign a new form, if the treatment is divided into various appointments, depending on which hazards might arise for my health;
- that I have been informed about the option of withdrawing my consent, if I do not want to continue the treatment;

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- that I am aware of the fact that when changes are required to the already agreed procedures, I will have to express my consent once again;
- that I have understood that, if required, a change in the surgical strategy that cannot be foreseen at this moment might be necessary during surgery.

Hence, I freely provide my informed consent to submit to the recommended treatment, having received the information required to evaluate its feasibility.

ACT OF CONSENT

With this statement, which shall be effective as the full, free and unconditional expression of my will, I, the undersigned, declare that I have received and understood the information briefly described above and presented in the enclosed technical document, and:

☐ I give my consent	☐ I do not give my consent/I withdraw my consent
Patient's signature, guardian/parent _____ Referring doctor's signature _____ *Examining doctor's signature* _____	Patient's signature, guardian/parent _____ Referring doctor's signature _____ *Examining doctor's signature* _____
Date: _____	

Details of the declaring party:

- ❑ patient
- ❑ guardian of the incapacitated patient
- ❑ parents of the minor patient exercising parental authority

use upper case to enter the first and last name and date of birth of the declaring party, if different to the patient:
_____

Signature of the other parent _____

Specify the name of the mediator / interpreter, if any _____

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INFORMATIVE NOTE AND INFORMED CONSENT TO PERFORM SEDO-ANALGESIA FOR THE ENDOSCOPIC EXAMINATION

What is sedation/analgesia?

Dear User, the examination you have been requested to submit to might be uncomfortable and, in particular cases, painful.
To reduce the discomfort and to make your examination more comfortable, we suggest that you submit to the intravenous administration of certain medicines, opiates and benzodiazepines, to reduce the pain and sedate you. They might, at times, cause retrograde amnesia. During sedo-analgesia, you will preserve the capacity to breathe independently, to respond to tactile stimuli and to respond to verbal commands.
The choice of medicines is made by the endoscopist based on the evaluation of your general clinical conditions and on the type and estimated duration of the procedure. Sedo-analgesia is performed while constantly monitoring the patient's cardiorespiratory functions.

Why is it performed?

The aim of sedation during endoscopy is to considerably reduce discomfort for the user and to make the examination less uncomfortable. Besides improving patient cooperation, sedation guarantees easier and more precise execution of the endoscopic procedure.

What are the complications?

- nausea and vomiting - relatively more frequent (5-7% of cases);
- respiratory depression, apnoea and, in very rare cases, cardiorespiratory arrest (severe complications 1-3 out of one thousand, with overall mortality < 0.3/1000);
- muscular contraction;
- altered blood pressure and cardiac rhythm;
- allergic reaction with rare cases of bronchospasm/hives;
- euphoria;
- possible failure of the sedation, which is quite rare, related to individual resistance.

The onset of such complications can be controlled and treated by continuously monitoring vital functions, and by having access to mechanical medical aids and antidotes.
They can have a fatal outcome in very rare cases. Finally, rare cases might manifest local complications at the injection site used for medicines, such as pain, bleeding or thrombophlebitis and adverse reactions to plaster patches.
The user must abstain from driving and using potentially dangerous machinery, from performing strenuous work and from making legal decisions during the 24 hours after the endoscopic examination.

What is the alternative? To perform the endoscopic examination without sedation; conversely this entails the need for greater cooperation on your part to face the procedure, and can contribute to further limiting the diagnostic reliability of the examination.

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INFORMED CONSENT TO SEDATION/ANALGESIA

I, the Undersigned, declare that I have been clearly and comprehensibly informed by the doctor, who has signed this document below, of the possibility of performing the endoscopic examination proposed under pharmacological sedation.
I declare that I have carefully read and received explanations regarding the information about sedation, that I have, therefore, clearly understood the indications and methods of execution, and that I am fully aware of the objectives, benefits, failures and any risks and complications related to the administration of the medicines used.
I have also been informed about any alternative to being submitted to the examination without sedation.

ACT OF CONSENT

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- possible failure of the sedation, which is quite rare, related to individual resistance.

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The user must abstain from driving and using potentially dangerous machinery, from performing strenuous work and from making legal decisions during the 24 hours after the endoscopic examination.

What is the alternative? To perform the endoscopic examination without sedation; conversely this entails the need for greater cooperation on your part to face the procedure, and can contribute to further limiting the diagnostic reliability of the examination.

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I have also been informed about any alternative to being submitted to the examination without sedation.

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Signature of the other parent _____

Specify the name of the mediator / interpreter, if any _____

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DECLARATION OF PERSONAL PROPERTY MANAGEMENT

I, the undersigned_____

DECLARE

I have been informed by the designated staff that:

- Hospitals are exposed to the deplorable and distressing phenomenon of frequent thefts targeting patients.

- The Management has implemented various measures to prevent such occurrences (e.g., monitoring clinic access with surveillance cameras, etc.), but these measures are not always sufficient to completely eliminate the issue.

- The Management strongly advises all patients not to leave wallets, money, debit cards, credit cards, mobile phones, dentures, and other valuable items unattended. Furthermore, it recommends that all patients who have the opportunity to do so, entrust any unnecessary items (debit cards, credit cards, mobile phones, watches, cash, or other valuable belongings) to their family members or companions.

I ALSO DECLARE

that I do not have any valuable belongings with me and/or that I will personally manage any possessions I have, including any personal aids (such as eyeglasses, prostheses, canes, etc.).

I therefore release the facility and all its personnel from any liability in the event of loss.

Milan, _____ *Patient Signature* _____