

Gastroscopy and Sedation

The following guide to the gastroscopy explains the purpose, flow, and risks of the procedure. After reading it carefully, please sign the attached consent form.

1 Purpose of the examination

A gastroscopy is a procedure in which an endoscope is inserted through the mouth (oral) or nose (transnasal) to observe the esophagus, stomach, and duodenum (Fig. 1). The purpose of the procedure is to evaluate for abnormalities such as inflammation, ulcer, polyp, cancer, and H. pylori infection.

▼ Oral endoscopy versus Transnasal endoscopy

The oral endoscope allows for more precise examination, due to a wider observation range and higher image resolution.

Some people may experience discomfort during the procedure.

The transnasal endoscopy uses a smaller scope, allowing for easier insertion and less discomfort. However the observation range is smaller and image resolution is lower compared to the oral endoscope.

We recommend the oral endoscope for patients who have stomach symptoms, have been diagnosed with chronic gastritis, or have been treated for H. pylori infection in the past.

▼ Helicobacter pylori (H. pylori)

Infection with the bacteria H. pylori typically occurs during childhood and persons infected may develop chronic gastritis. In chronic gastritis, the protective function of gastric mucosa is weakened and the stomach can easily be affected by stress, salty food, and carcinogens, leading to gastric ulcer and cancer. Cancer incidence for those who have the H. pylori infection is reported to be 1 out of 20 persons over a ten-year period.

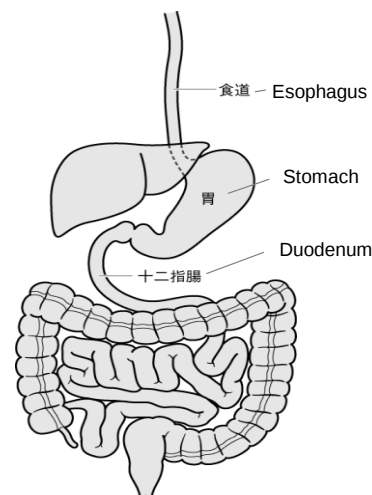


Fig.1 Anatomy of upper gastrointestinal system

2 Overview of the examination

1) Preparation

<A> Oral Endoscopy

① Gastric lavage

You will drink a cup of liquid to clear out the bubbles and mucous inside the digestive tract.

② Anesthesia of throat

A local anesthetic spray called Xylocaine will be given to numb the throat and to prevent to the gag reflex.

 Transnasal Endoscopy

① Gastric lavage

You will drink a cup of liquid to clear out the bubbles and mucous inside the digestive tract.

② Vasoconstrictor nose spray

Both nostrils will be sprayed with vasoconstrictive medication (Privina) to reduce swelling of the nasal mucosa and to lower the risks of nasal bleeding.

③ Anesthesia of nasal mucosa

A jelly type local anesthetic called Xylocaine will be given to numb the nasal mucosa.

In rare cases, medications may cause allergic reactions. If you have experienced any allergic reactions using these medications during endoscopy or dental treatment in the past, please notify the nurse.

2) Intravenous sedation (if applicable)

Sedatives are used to reduce anxiety and discomfort during examinations. However, the use of sedatives comes with certain considerations, such as age restrictions, post-examination activity limitations (* see below), drowsiness, lightheadedness, temporary amnesia (forgetfulness) and risks of complications. While some individuals may fall asleep under sedation, the effects vary from person to person, and on certain days, depending on one's condition, the sedation may leave you feeling "fully conscious" or feel "less effective than before." We kindly ask for your understanding in this matter.

The sedatives used at our clinic are from the benzodiazepine class, which is generally widely used. Please be aware that, although rare, some individuals may find the sedative effects entirely ineffective or insufficient due to their physiology.

3) Insertion of the scope

The scope will be inserted through either your nose or mouth and advanced along the esophagus, stomach, and duodenum.

(※) With transnasal endoscopy, if one nostril is narrow and insertion of the scope is difficult, we will confirm passage of the other nostril. If both nostrils are narrow, we may insert the scope orally. Since the nasal scope is smaller and more flexible than the oral scope, discomfort level will be lower than a typical oral endoscopy.

(※) In rare cases, unintentional forceful clenching of the mouthpiece during the test may cause tooth damage. If you have artificial dentures, loose teeth, false teeth, implants, etc., please let the nurse know prior to the examination. Risk of tooth damage is especially high for front teeth and for those who are not seeing a dentist regularly.

4) Observation of the esophagus, stomach, and duodenum

The esophagus, stomach, and duodenum are observed carefully while bubbles and mucous are washed away and air is introduced through the scope. You may experience discomfort as air is introduced to inflate the stomach. The procedure generally takes 5 to 10 minutes to be completed.

5) Iodine staining

We may apply Lugol iodine solution to the mucous membrane to aid in the diagnosis of head and neck cancer and esophageal cancer. You may experience chest pain or a stinging sensation, which will resolve over a few days.

6) Biopsy

If an abnormality is found or suspected, a biopsy may be performed, in which a small fragment of tissue is obtained and evaluated under a microscope. This enables us to diagnose the type of lesion, such as a tumor or inflammation. After biopsy, minor bleeding may occur, but typically it resolves on its own. However, in rare cases persistent bleeding or profuse bleeding may occur after biopsy.

3 Restrictions before the examination

1) Fasting

Please avoid alcohol on the day before the examination and fast according to your reservation time as below. We may cancel your examination if you do not fast properly. If you take supplements regularly, please do not take your supplements on the day of the procedure.

【Procedure time】

8:00~14:00	PLEASE DO NOT EAT ANYTHING AFTER 9 PM. Please finish a light meal by 9 pm the day before the examination. Do not eat breakfast.
14:00~	PLEASE DO NOT EAT ANYTHING FOR 8 HOURS *) prior to your reservation time. You can eat a small amount of easily digested food up to 8 hours before your reservation time.

(※) You can drink a small glass of water* on the day of the procedure.

(*Do not drink beverages containing sugars and artificial sweeteners, and carbonated drinks)

For individuals undergoing health checkups or comprehensive medical exams, please scan the QR code to check dietary and drink restrictions.



Midtown Clinic Medical Corporation

2) Regular medication

Please bring your prescription records if you are on medications.

① Medications for hypertension, epilepsy, psychiatric conditions, or arrhythmias

Please take your regular medications on the morning of the procedure.

(※) If you take other medications, please contact us in advance to determine which medications to take.

Oral medications

Do not take your morning and lunch time medications on the day of the colonoscopy.

Injections

Be sure to check with your diabetes doctor regarding dosing and timing of injections before and after the procedure. Please be sure to bring your injection kits (with needles) in case an injection is required prior to the procedure.

③ Warfarin Potassium (Warfarin, Warfarin K)

The risk of thrombosis and embolism when you stop taking warfarin is variable, but they can have serious consequences if they do occur. Therefore, you should continue taking warfarin before the endoscopy. However, since it may be difficult to stop bleeding, in our clinic we do not perform any biopsies and we will perform observation only. If you do need a biopsy we will refer you to another medical institution.

3) Intravenous sedation

If you undergo intravenous sedation, you may feel drowsy or lightheaded for a while, so you cannot drive a car or motorcycle or ride a bicycle until 6 am the morning after the procedure. In addition, drowsiness may cause impaired judgment, so we recommend that somebody accompany you home as much as possible. Please do not make important decisions that require serious judgment on the day of the procedure.

There are several restrictions regarding the use of sedation, as below.

- ① Only patients 18 to 75 years old are eligible for sedation.
 - ② If you have myasthenia gravis, sedation cannot be used because it may worsen your symptoms.
 - ③ Patients taking HIV protease inhibitors (ritonavir, saquinavir, etc.), HIV reverse transcriptase inhibitors (efavirenz, etc.) cannot undergo sedation.
 - ④ If you are breast feeding and opt for using sedation, please refrain from breast feeding for 12 hours after the examination. For your child's safety, we recommend you pump (and freeze) breast milk before the examination, if necessary.
 - ⑤ If you have liver, kidney, or respiratory diseases, or if you are currently taking anti-epileptic medication, the doctor may decide that sedation is unsafe and discuss with you about cancelling sedation or adjusting its dosage.
 - ⑥ If you use a wheelchair or cane, or if your gait is unstable due to injury or illness, please note that you are at increased risk of falling after using sedation.
 - ⑦ If you have glaucoma, suspected glaucoma, or have increased cupping of the optic disc, please consult with your ophthalmologist before the procedure and confirm whether or not you can undergo sedation. Please obtain a medical document from your ophthalmologist stating you may undergo sedation, or obtain permission in person or by phone.
- (※) Glaucoma is a disease in which your eye (intraocular) pressure increases and your visual fields become narrow. In general, the fluid inside your eyeball increases, leading to increased eye pressure, which in turn increases pressure on the optic nerve. The sedative medication we use may increase eye pressure abruptly, which could cause headache, eye pain, eye redness, nausea, and in some cases blindness. Therefore, we may be unable to use sedation for those patients.
- (※) Glaucoma is classified into acute closed angle glaucoma and open angle glaucoma. Sedation may be used for patients with open angle glaucoma and those with acute closed angle glaucoma who have undergone laser treatment.
- (※) Increased cupping of the optic disc is a common finding seen in glaucoma. If you have this finding, please consult an ophthalmologist and confirm whether or not you have glaucoma. If you have already seen an ophthalmologist and have been told you do not have glaucoma, sedation can be used.

4 Restrictions after the procedure

1) Drinking and eating

Please do not eat or drink for an hour after the examination as your throat may still be numb. Before you start eating or drinking, please have a sip of water first to check if you can swallow normally.

After using a sedative, drowsiness and lightheadedness will remain, so you will be asked to rest for about an hour in the clinic's recovery room. However, the effects of the sedative may still linger after discharge, so we recommend having an accompanying person to assist you in returning home whenever possible.

Additionally, please refrain from drinking alcohol, driving vehicles (cars, motorcycles, bicycles, etc.), engaging in physical activity, or using saunas until 6 a.m. the next morning.

3) Biopsy

If you undergo biopsy, please take only a light easily-digestible meal to prevent bleeding. You may not drink any alcohol on the day of the procedure, as alcohol may increase risk of bleeding by stimulating the mucosa and increasing blood flow.

Rebleeding can occur after you leave the clinic. If you feel unwell, vomit blood, or notice black stool, please contact us immediately or go to the nearest emergency department.

5 Possible complications and risks

(Incidence rates are based on the 7th National Survey Report 2019–2021 by the Japan Gastroenterological Endoscopy Society.)

Our endoscopic instruments are cleaned, sterilized, and disinfected following the guidelines set by the Japan Gastroenterological Endoscopy Society. Individually disinfected instruments are used for each patient, so there is no risk of infection from the equipment.

1) Preparation before the procedure

There are allergic reactions caused by xylocaine® used for pharyngeal anesthesia and drugs that suppress stomach movements (anticholinergic drugs), and blood pressure lowering and respiratory depression due to sedatives. The incidence rate of these effects is 0.072%, with a fatality rate of 0.002%.

2) Endoscopy procedure

Procedural accidents caused by endoscopy or biopsy include lacerations (e.g., Mallory-Weiss syndrome), respiratory suppression, bleeding (including nasal bleeding), aspiration, tooth damage, perforation or temporomandibular dislocation. The incidence rate is 0.076% with no reported fatalities. When classified by equipment type, accidental cases were 0.044% for oral upper gastrointestinal endoscopy and 0.291% for nasal upper gastrointestinal endoscopy.

If the bleeding is severe, endoscopic treatment or blood transfusion may be required. If it is difficult to stop the bleeding or if a perforation occurs, emergency surgery may be required, but we will respond appropriately and promptly.

If you experience nasal bleeding or nasal pain after a nasal endoscopy, please be assured that in general it is transient and will be relieved in most cases by cooling the nose, compression, and short rest.

A sore throat may occur after the examination, but in most cases it will disappear within a few days.

If aspiration, tooth damage or temporomandibular dislocation occurs, appropriate measures will be taken.

3) Sedation

Procedural accidents of sedative use include respiratory depression, lowering blood pressure, shock due to allergies, drowsiness and lightheadedness, temporary amnesia symptoms (forgetfulness), inflammation at the injection site and falls. Rarely, nausea or vomiting may occur.

Sedatives may also cause disinhibited behavior, such as significant body movements and attempting to remove the endoscope during examinations. In such situations, there is an increased risk of falling from the examination table or causing perforation. For safety reasons, the examination may be discontinued at the discretion of the physician.

6 Other considerations

1) Patients under 18 years of age

We do not perform endoscopy in patients who are under 18 years of age.

2) Pregnancy or possible pregnancy

Our clinic does not perform endoscopy in women who are pregnant or may be pregnant.

We do not perform procedures when the risks of the procedure (including possible effects on the fetus) may outweigh the benefits.

3) Patients with brain aneurysm 3 mm or larger

Brain aneurysms, including very small ones, are found in about 4% of people. Most of them are smaller than 3mm and have an extremely low risk of bursting. However, aneurysms that are 3mm or larger have a possibility of bursting (for 3 to 4mm sizes, the risk is reported to be about 0.36% per year). However, it is very difficult to accurately predict whether an individual aneurysm will burst in the future. For this reason, it is important to manage your blood pressure, quit smoking, and avoid drinking too much alcohol. Additionally, depending on the size and shape of the aneurysm, a specialist doctor may consider treatment options. Even if you have a brain aneurysm, exercises like golf and surgeries using local or general anesthesia are generally safe to perform. Upper and lower endoscopies (camera tests) are also widely performed. According to a Japanese report, brain bleeding related to endoscopy is extremely rare, occurring in only about 1 to 2 cases out of 10 million procedures. If you have been told in the past that you have a brain aneurysm of 3mm or larger, and you have never consulted a brain specialist (such as a neurosurgeon or neurologist), we recommend that you consult a specialist in advance if you have concerns.

4) Patients with glaucoma, enlarged prostate, heart disease, arrhythmia, or hyperthyroidism

We may use medication that suppresses movement of the digestive tract (anticholinergic medication). Please notify us if you have any of the above conditions, as we may avoid use of the medication or use alternate medications.

*If we use anticholinergic medication, you must refrain from driving vehicles or riding motorcycles or bicycles until 6 am the following morning.

5) Patients on dialysis

Our clinic does not perform endoscopy with sedation or biopsy for patients receiving dialysis.

(※) Patients undergoing dialysis are at increased risk of bleeding or rebleeding at a later date, therefore treatments such as biopsy is not performed and only observation is performed. If you need a biopsy, we will refer you to your primary physician or to another medical facility.

6) Those currently undergoing cancer treatment or currently suffering from cancer

If you are currently undergoing cancer treatment or currently suffering from cancer, please check with your doctor in advance about whether or not you can have an endoscopic examination and biopsy.

The final decision on whether or not to have an endoscopy will be made by our endoscopist. Therefore, please understand that we may refer you to your primary care physician or another medical institution.

7) Patients with neuromuscular disease (ALS, myopathy, myositis, myasthenia gravis, etc.)

Our clinic does not perform endoscopy for patients with amyotrophic lateral sclerosis (ALS). For patients with other progressive or irreversible neuromuscular disease, please bring a medical note from your neurologist regarding whether you can undergo the endoscopy and sedation. The final decision on whether to proceed with the endoscopy and sedation will be made by the doctor performing the procedure.

In addition, please bring an updated medical note each time you undergo a procedure, as your condition may have changed.

8) Patients who recently underwent surgery

If you have had abdominal surgery, you will not be able to undergo upper gastrointestinal endoscopy for one month after the surgery.

9) Patients taking an MAO inhibitor (Parkinson disease medication)

Privina, which is a medication used in the transnasal endoscopy, cannot be used in combination with MAO inhibitors. Therefore, you cannot undergo transnasal endoscopy.

10) Patients taking GLP-1 or GIP/GLP-1 Receptor Agonists for diabetes or obesity treatments or weight loss purposes

For patients taking GLP-1 or GIP/GLP-1 Receptor Agonists, even if you have abided by the fasting period, significantly more likely to have retained gastric contents at EGD. Please consult your doctor in advance. Please understand that retained gastric contents interfere with visualization of the stomach thereby often requiring the doctor to terminate the procedure due to the heightened risk for aspiration.

11) Patients with diabetes receiving insulin treatment

If you do not have a regular blood test on the day of your endoscopy, we will perform a simple blood sugar measurement before the test. Depending on the measurement results, we may take action to treat low blood sugar or high blood sugar. Please note that if your blood sugar level stays at 69 mg/dL or below, or 251 mg/dL or above, we may cancel the test for your safety.

The endoscopy table's load limit is 130 kg (286lb.). For safety reasons, we cannot conduct the endoscopy for patients who weigh over 130 kg on the procedure day.

13) Cancelling or rescheduling the procedure

※If the physician determines that the colonoscopy cannot be safely performed, the test may be canceled or postponed.

Example: Severe hypertension (180/110 mmHg or above), fasting blood sugar less than 70 mg/dL or greater than 250 mg/dL, or high intraocular pressure on the day of examination (intraocular pressure over 25) with symptoms such as eye pain.

- * Please understand that there is always uncertainty in medical care and the test results are not completely guaranteed. We strive every day to obtain the best results and share any relevant information with you.

7**Alternative examinations**

Please let us know if you would like any information or have question regarding alternative tests such as barium study, pepsinogen test, and H. pylori antibody test. Of note, biopsy is possible only with an endoscopy.

8**Your right to withdraw consent**

Even after submitting the consent form, you can withdraw your consent until the procedure begins. If you wish to cancel the procedure, please inform our staff.

Thank you for your understanding.

To Patients with 【Glaucoma】 ※1 【Suspected Glaucoma(High Intraocular Pressure, etc.)】 【Optic Disc Cup Enlargement】 ※2

Glaucoma is an eye disease characterized by elevated intraocular pressure and progressive loss of the visual field. Generally, this condition develops when increased aqueous humor within the eye raises intraocular pressure, compressing the optic nerve. However, the sedative (Dormicum) used at our clinic can cause a sudden rise in intraocular pressure.

As a result, it may cause headaches, eye pain, redness, or nausea, and in the worst cases, there is a risk of blindness. Therefore, we may decline to administer sedatives to individuals who fall into this category.

～ WARNING ～

If you fall under, 【glaucoma】 【 suspected glaucoma (high intraocular pressure, etc.)】 【optic disc cup enlargement】 please contact your ophthalmologist in advance to confirm whether sedatives can be used via a medical certificate, examination, phone call, or other means.

After confirmation, please check the relevant box in the “Explanation and Consent Form for Sedative Use” regarding this matter.

※1 Glaucoma is classified into angle-closure glaucoma and open-angle glaucoma. Sedatives may be used for patients with open-angle glaucoma and those with angle-closure glaucoma who have undergone laser treatment

※2 Enlargement of the optic disc cup is a finding observed in glaucoma. Individuals who have been informed of this should visit an ophthalmologist to be examined for glaucoma. If you have already been examined and your ophthalmologist has determined there is no issue, sedatives may be used.