

Description for Gastroscopy and sedation

The following is a general guide to the gastroscopy, or upper gastrointestinal (GI) endoscopy, procedure. After reading it carefully, please sign the attached consent form.

1 Purpose of exam (Upper GI Endoscopy)

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) in order to search for abnormalities such as inflammation, ulcer, polyp, cancer and H. pylori infection.

▼ The differences between Oral Endoscopy and Transnasal

The oral endoscope enables the physician to obtain more precise images. There are differences according to each individual, the scope itself is bigger, the test can be very uncomfortable

A thin endoscope is used for the transnasal endoscopic procedure, which is easier for insertion and more comfortable compared to oral endoscopy. However, since the scope of nasal endoscope is smaller, clarity of the image will be inferior.

Oral endoscope is recommended to those patients who have any 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 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.

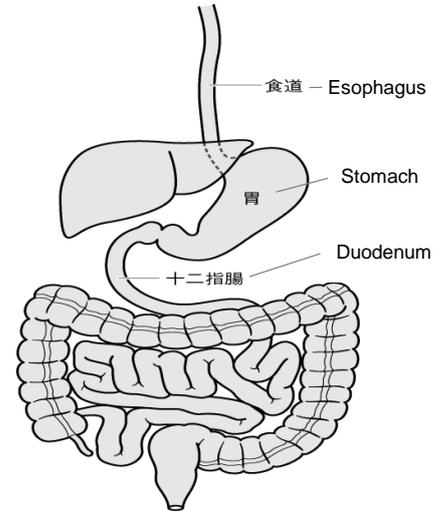


Fig.1 Anatomy of upper gastrointestinal system

2 Overview of Gastroscopy (Upper GI Endoscopy)

1) Preparation

<A> Oral Endoscopy

① Solution to clean the stomach

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

② Local anesthetic spray

A local anesthetic spray called Xylocaine will be given to numb the throat.

 Transnasal Endoscopy

① Solution to clean the stomach

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 Local anesthesia

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

※) it can cause allergic reactions. If you have experienced any allergic reactions to this medicine during endoscopy or dental procedures in the past, please notify the nurse.

2) Intravenous sedation (Those who use sedation)

Conscious sedation reduces discomfort and makes you feel relaxed during the procedure, but there is an age limit and you may experience drowsiness, dizziness and movement restrictions (following below) after the procedure. We kindly ask for your understanding.

3) Insertion of the scope

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

※) 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 scope is smaller and more flexible than the oral scope, discomfort level will be lower than a typical oral endoscopy.

※) Some bleeding or pain in the nose may occur after a transnasal endoscopy, but these are typically transient, and resolve after cooling the nose, applying pressure, and a short amount of rest.

※) Unintentional forceful clenching of the mouthpiece during the test may cause the tooth damage.

If you have artificial dentures, loose teeth, false teeth, implants, etc., please inform the nurse prior to the procedure.

4) Observation of the esophagus, stomach, and duodenum

The esophagus, stomach, and duodenum are observed. Bubbles and mucous attached to the digestive tract will be washed, and air will be introduced through the scope to allow passage of the scope and to improve visibility. You may experience mild discomfort as air is inflated. The procedure generally takes approximately 5 to 10 minutes to be completed.

5) Biopsy

Biopsy (taking tissue sample) will be taken to observe under microscope when suspicious abnormalities were found. Biopsy is essential in the diagnosis of cancer or certain inflammation.

Bleeding can occur from biopsy, but it is usually minimal and stops quickly on its own. Rarely, prolonged bleeding or a large amount of bleeding may occur.

3 Before the procedure

1) Fasting :

Please avoid alcohol on the day before of the procedure and limit your diet according to your reservation time as follows.

We may cancel your procedure if you did not fast properly.

If you take supplements regularly, do not take your supplements on the day of the procedure.

【Courses starting at 】

8:00~14:00	<u>PLEASE DO NOT EAT ANYTHING AFTER 9PM.</u> Please finish a light meal by 9 pm the day before the procedure. Do not eat breakfast.
14:00~	<u>PLEASE DO NOT EAT ANYTHING FOR 8 HOURS prior to your checkup.</u> Appropriate small portion that you can take up to 8 hours before your checkup.

※ You can drink a small glass of water* before check-in.

(*Excluding beverages containing sugars and artificial sweeteners, and carbonated beverages)

2) Regular medication

Please bring your prescription records if you are on medications.

① Medications for hypertension, epilepsy, psychiatric conditions, or arrhythmia.

Please take your regular medications in the morning.

※) Depending on the content of the medication, the exam may be affected.

If you need to take anything other than the above, please contact our clinic in advance.

② Medications • injection for diabetes (blood sugar lowering agents)

PLEASE SKIP the usual morning dose.

③ Warfarin Potassium (Warfarin, Warfarin K)

Although the risk of thrombosis when you stop taking warfarin is variable, if thrombosis does occur, it can have serious consequences. Thus, you should continue taking warfarin before endoscopy.

We perform observation only since it could be difficult to stop bleeding after biopsy. In case you need a biopsy we will refer you back to your doctor or refer you to other medical institutions.

3) Intravenous sedation ***Only patients 18 to 75 years old are eligible for sedation.**

If you opt for sedation, you may experience drowsiness and dizziness after the procedure. Please refrain from coming to our clinic by driving cars and motorcycles or riding bicycles on the day of the procedure.

Sedation can also interfere with your judgment ability and therefore, we recommend an escort to take you home after the procedure if possible.

In addition, you should avoid making important decisions on the day of the procedure.

Please note the various restrictions mentioned below.

- ① Only patients 18 to 75 years old are eligible for sedation.
- ② If you have myasthenia gravis, you can only observe and not use sedatives because it may worsen your symptoms.
- ③ If you are breast feeding and receive sedation, please refrain from breast feeding for 12 hours after the procedure.
You can pump (and freeze) breast milk before the procedure if necessary.
- ④ If you have liver, kidney, or respiratory diseases, or if you are currently taking anti-epileptic medication, the doctor may decide that safe use of sedation is difficult and discuss with you about the cancellation of sedation or its dosage.

- ⑤ If you are diagnosed or suspected with [glaucoma (with increased intraocular pressure)]or [enlarged optic disc depression]you should consult with an ophthalmologist in advance , and receive confirmation that you may use sedatives with documents (medical certificate etc.)or confirm by consulting or phoning an ophthalmologist.

After confirming with the ophthalmologist, please check the suitable box of the consent form.

- ※ 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 sedation medication we use, midazolam, may increase eye pressure abruptly, which could cause headache, eye pain, eye redness, nausea, and in some cases blindness. Therefore, we may not be able to use sedation for these 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 who have recovered by laser treatment for acute closed angle glaucoma.
- ※ Enlarged optic disc depression is a finding seen in glaucoma. If you have been diagnosed with this, 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.

After the procedure

1) Drinking / Eating restrictions

Please do not eat or drink for an hour after the procedure 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.

2) Restriction of behavior when using sedation

If you receive sedation, you may experience drowsiness and dizziness after the procedure, therefore you will be observed in the recovery room for about an hour after the procedure to ensure your recovery. Even after you recover, if possible we recommend you to have someone escort you home after the procedure to ensure your safety.
If sedation is used, you may not consume any alcoholic beverages or drive any vehicles after the procedure until 6 AM the following day.

3) Prevention of bleeding after biopsy

If you get a biopsy, please avoid eating high fiber food, oily food, and spicy food to prevent bleeding.
You may not drink any alcohol on the day of the procedure. Hemorrhage can occur after you leave the clinic.
If you become unwell, vomit blood, or notice black stool, please contact our clinic immediately.

Complications and Risks

The statistics are from national study report conducted by the Japanese Gastroenterological Endoscopy Society.(from 2008 to 2012)
The endoscopy used at Tokyo Midtown Clinic is cleaned and sterilized per patient usage according to the Japan Gastroenterological Endoscopy Society so there is no risk of contamination with the inspection equipment.

1) Pre-procedure preparation

There have been rare reports of hypersensitivity reactions to the local anesthetic (Xylocaine) and anticholinergic medication, and drop in blood pressure and respiratory depression due to the sedation medication. The incidence is reported to be 0.0028%.

2) Endoscopy procedure

The endoscope or biopsy may cause bleeding and perforation (a tear or hole) which are rare events with the incidence reported to be 0.014%.
There were 782 complications (0.014%) and 13 deaths (0.00013%) out of 11.26 million procedures of diagnostic upper gastrointestinal endoscopy examination (including biopsy).

In case of severe bleeding, treatment by endoscopic methods or blood transfusions may become necessary.
If bleeding cannot be controlled or if perforation occurs, emergency surgery may be required.
Such cases will be managed promptly and appropriately.

In rare cases, aspiration pneumonia, dislocation of the jaw joint, of the teeth or tooth damage due biting on the mouthpiece

You may experience a sore throat after the procedure but this will usually disappear in a couple of days.

Complications will be managed accordingly.

3) Sedation

Complications of sedation may include respiratory depression, a drop in blood pressure, inflammation at the injection site, or allergic reaction. Some patients may experience side effects of the sedation medication such as involuntary movements, which may lead to incomplete examination, insufficient observation, or increased risk of perforation. The physician may decide to discontinue the procedure to ensure patient safety.

Other considerations

1) Under 20 years old

- ① Patients 17 years of age and under are not eligible for endoscopy examination at our clinic.
- ② Patients 18 to 19 years old are required to obtain parental consent and must be accompanied by the parent or legal guardian to undergo the procedure.

2) Pregnancy or Pregnancy possibility

Our clinic does not perform any endoscopic procedure.

In endoscopies performed in patients without symptoms as part of the medical checkup, the benefit of the procedure may not significantly outweigh the possible risks, including risks to the fetus.

If you have particular symptoms (such as persistent upper abdominal pain), please consult your physician.

3) Brain aneurysm

If the size of your aneurysm is 4.0 mm or more:

You will need to discuss the risks with your neurosurgeon and obtain permission for undergoing the gastroscopy.

You may not undergo the procedure at our facility without written permission from your neurosurgeon.

4) Glaucoma, Enlarged Prostate, Cardiac disease, Arrhythmia, Hyperthyroidism

We usually do not use medication that suppresses movement of the digestive tract (anticholinergic medication).

However, we may use these medications if necessary.

Please notify the nurse if you have any of the above conditions.

5) Patients undergoing hemodialysis

At our facility, we do not perform sedation or biopsy to patients undergoing dialysis.

- ※) In the case of patients receiving dialysis, there is a risk that the bleeding will not stop and may have hemorrhage after the procedure, so there will be no biopsy and only observation. If biopsy is necessary we will make a referral to a specialized medical institution.

6) Weight limit

The endoscopy examination table's load limit is 135kg (297lb). Please understand that we are not able to conduct the endoscopy to patients with a weight over 135 kg on the examination day for safety perspective.

7) Cancellation or rescheduling of procedure

If the procedure cannot be performed safely (e.g., if a patient has severe untreated hypertension, high intraocular pressure on the examination day), the physician may decide to cancel or reschedule the procedure.

- ※) Please understand that all medical procedures carry risks and uncertainties and that the results may not be conclusive in all cases. However, we strive to provide you with the most accurate results and information in a clear and concise manner.

7 Alternatives

Please feel free to ask our staff regarding alternative tests, such as barium inspection, pepsinogen test, and H. pylori antibody test. Please note that biopsy is possible only with an endoscopy.

8 Your right to withdraw the consent prior to the procedure

You have the right to change your mind and withdraw the consent before starting the procedure, even after you have signed the consent form. In that case, please inform us as soon as possible.