

# 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.

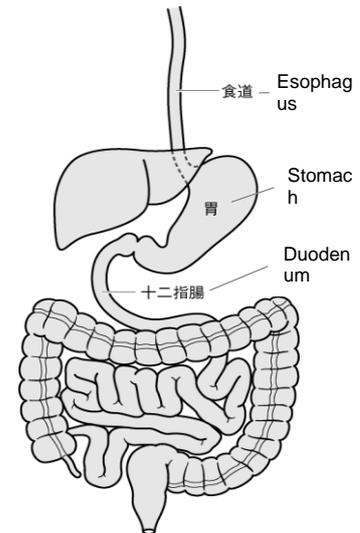


Fig.1 Anatomy of upper gastrointestinal system

## 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.

#### <B> 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)

We may use sedation to reduce anxiety and discomfort during the procedure. However, please be aware that there are age limitations, restrictions after the procedure (\*detailed below), and risks to sedation, and that you may experience drowsiness and dizziness after its use.

### 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)

#### 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.

##### ② Medication for diabetes (blood sugar lowering agents, including injections)

PLEASE SKIP the morning dose of both oral medications and injections on the day of 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 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.), and chronic hepatitis C medication (ombitasvir, paritaprevir, 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.

### 2) Sedation

If you receive sedation, you may experience drowsiness and dizziness after the procedure, therefore you need to rest in the recovery room for about an hour. Even after resting, there may be residual effects from sedation, so we recommend you have someone accompany you home. You may not consume any alcoholic beverages or drive any vehicles including motorcycles and bicycles until 6 am the following day.

### 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

The statistics are from national study report conducted by the Japanese Gastroenterological Endoscopy Society (from 2008 to 2012).

The endoscopic equipment used at our clinic is cleaned and sterilized after each patient according to the Japan Gastroenterological Endoscopy Society guidelines so there is no need for concern for contamination from the equipment.

## 1) Preparation before the procedure

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

## 2) Endoscopy procedure

The endoscopy 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.

Some bleeding or pain in the nose may occur after a transnasal endoscopy, however these are typically transient, and resolve after cooling the nose, applying pressure, and resting for a short amount of time.

In rare cases, aspiration pneumonia, temporomandibular joint dislocation due to clenching the mouthpiece, and tooth damage may occur.

You may experience a sore throat after the examination however it will usually resolve in a couple of days.

## 3) Sedation

Sedation may cause respiratory depression, a drop in blood pressure, shock from an allergic reaction, drowsiness and dizziness, temporary memory loss, or inflammation at the injection site. Some patients may experience side effects such as involuntary movements, which may increase the risk of falling from the examination table or bowel perforation. In such cases, the doctor may decide to discontinue the procedure to ensure your safety.

# 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) Brain aneurysm

**If the size of your aneurysm is 4 mm or larger, please consult with your neurosurgeon and obtain permission for undergoing the endoscopy before the procedure. If you do not have permission from a neurosurgeon, you cannot undergo endoscopy at our clinic.**

## 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) Patients with cancer

Please confirm with your physician whether you can undergo endoscopy and biopsy, if you are undergoing chemotherapy (injection or oral) for cancer, or if you have cancer that is not yet cured. The final decision on whether to proceed with the endoscopy will be made by the doctor performing the procedure. Depending on the situation, we may refer you to your primary physician or to another medical facility.

**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**

Our clinic does not perform endoscopy for patients who have undergone abdominal surgery in the past 6 months.

**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) Weight limit**

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.

**12) Cancelling or rescheduling the procedure**

**※If the physician determines that the endoscopy cannot be safely performed, the test may be canceled or postponed. Example: Significant hypertension (180/110 mmHg) or high intraocular pressure on the day of examination (intraocular pressure over 25) and symptoms such as eye ache.**

\* 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.