PREPARING FOR YOUR HALO 360 UPPER ENDOSCOPY PROCEDURE



PREPARATION FOR HALO 360 UPPER ENDOSCOPY - For your safety, **STOP** consuming all liquids and nothing by mouth 6 hours prior to your procedure or your procedure will be cancelled and rescheduled. Please follow detailed instructions below.

Cancel or reschedule your appointment:

If you must cancel or reschedule your appointment, please call 612-871-1145 as soon as possible.

Transportation:

You must arrange for a responsible person to escort you to your procedure and stay at our facility for the duration of your procedure. A taxi ride is not an option unless you are accompanied by a responsible person. If you fail to arrange transportation with a responsible person that can stay for the duration of your procedure, your procedure will be cancelled and rescheduled.

The night before your exam:

- Stop eating solid foods and begin clear liquid diet at 11:45pm. Clear liquids include things you can see through. Examples of a clear liquid diet include: water, tea (no milk or non-dairy creamer), clear broth or bouillon, Gatorade, Pedialyte or Powerade, carbonated and non-carbonated soft drinks (Sprite, 7-Up, Gingerale), strained fruit juices without pulp (apple, white grape, white cranberry), Jell-O and popsicles.
- The following are not allowed on a clear liquid diet: red liquids, alcoholic beverages, dairy products, protein shakes, cream broths, juice with pulp and chewing tobacco.

Day of your procedure:

Morning Medications: You may take all of your morning medications including blood pressure medications, blood thinners (if you have not been instructed to stop these by our office), methadone, and anti-seizure medications with sips of water 3 hours prior to your procedure or earlier. If you have diabetes, contact your monitoring provider for further direction on insulin and/or blood sugar management.

Continue the Clear Liquid Diet up to 6 hours prior to your procedure, then stop drinking. Avoid red liquids, dairy products, protein shakes, alcoholic beverages, chewing tobacco and illicit drugs. Use of these will result in your procedure being cancelled.

6 hours prior:

- STOP consuming all liquids.
- Do not take anything by mouth during this time.

Bring the following to your procedure:

- Bring the completed Health History form included in this packet with you the day of your appointment.
- Insurance Card / Photo ID
- List of Current Medications including over-the-counter medications and supplements
- Bring your rescue inhaler if you currently use one to control asthma
- Bring contact lens supplies as you will be asked to remove contact lenses prior to the start of your procedure

Advance Directives: If you have an Advance Directive, please bring a copy of your Advance Directive with
you to your endoscopy appointment. Advance Directives are not honored at MNGI facilities, and in the
event of a life-threatening situation, life support measures will be instituted in every instance and our
patients will be transported to a higher level of care facility (i.e., hospital). In the unlikely event that you
require an emergency transfer to a higher level of care facility, your Advance Directive should accompany
you to that facility.

DESCRIPTION OF HALO 360

is a Halo procedure?

Halo is a procedure that uses radio frequency (RF) energy delivered to a specific area in the esophagus where Barrett's esophagus exists. Barrett's Esophagus is a condition in which the esophagus changes so that some of the esophageal lining is replaced by a type of tissue similar to that normally found in the intestine. This change can sometimes lead to cancer of the esophagus.

During the Halo procedure, RF energy will destroy the Barrett's cells without destroying the normal tissue in the deeper layers of the esophagus. The esophagus is expanded by a balloon and the RF energy heats the Barrett's cells and destroys them allowing healthy new tissue to grow in place.

What should I expect during the Halo procedure?

Plan to spend up to 2 hours at the endoscopy center. The procedure itself takes about 30 to 60 minutes to complete.

Before the procedure:

Your medical history will be reviewed with you by your health care team including a nurse, your gastroenterology physician and an anesthesia provider. An IV line will be placed.

During the procedure:

During your procedure, the anesthesia provider will administer medications and monitor vital signs which is a process known as Monitored Anesthesia Care (MAC). While most patients sleep through the procedure, some remain awake and aware. The anesthesiologist and/or certified registered nurse anesthetist (CRNA) will help determine the appropriate type of drug to be used during the procedure to keep you safe and comfortable. The doctor will carefully advance a flexible, hollow tube, called an endoscope, through your esophagus to the area of the abnormal Barrett's cells. You may have a feeling of pressure or fullness. The Halo device will be passed through the endoscope to treat the Barrett's cells. Once abnormal cells are eliminated, healthy new tissue will grow in its place.



What should I expect after the procedure?

The physician will talk with you about the initial results of your procedure and will prepare a full report for the healthcare provider who referred you for your upper endoscopy. You may have some bloating after the procedure which is normal. Your throat may feel sore for a short time. You may also experience mild chest pain or nausea for two to three days. This is normal. Any tissue samples or polyps removed during the procedure will be sent to a lab for evaluation. It may take 5-7 working days for you to be notified of the results by mail or through the Patient Portal.

You may resume most of your regular activities the day after the procedure. However, medication given during the procedure will prohibit you from driving for the rest of the day. Diet instruction will be discussed with you before you leave the endoscopy center. A liquid diet may be recommended for one to two days following the procedure. You should avoid sharp-edged food (such as chips, nuts, popcorn, croutons, etc.) during this time.

Are there possible complications from a Halo procedure?

Although serious complications are rare, any medical procedure has the potential for risks. Risks from an upper endoscopy include perforation, or a tear, of the lining of the stomach or esophagus, bleeding from a biopsy site, reactions to medications, heart and lung problems, and dental or eye injuries.

How many treatment sessions will I need an over what time frame?

Most people need two or three Halo treatment sessions to achieve a cure over a four to twelve-month time period until there is no more visible Barrett's esophagus. Some people will need more, some less. Your doctor will then take biopsy samples of your esophagus, similar to previous surveillance endoscopies you may have had to monitor your Barrett's esophagus. This is to confirm that your Barrett's esophagus is gone.

What are the cure rates?

In the peer-reviewed medical literature, published cure rates of Barrett's esophagus are 77%-100% with radiofrequency ablation (Halo).

How often does Barrett's esophagus come back after Halo treatment?

In a recent study evaluating durability of cure in Barrett's esophagus patients who had undergone Halo treatment, 92% of patients remained cured at 5 years. Barrett's esophagus recurred in 8% of the patients. In the patients with recurrent Barrett's esophagus, the recurrent disease was the same grade as the original (baseline) disease. In other words, there was no disease progression in these patients. It is extremely important to maintain good acid control after Halo treatment. This may be achieved by medications (such as PPIs) or by surgical or endoscopic repair, or a combination of the two. The patients described in the study above continued acid-suppression medication (mostly PPIs) after Halo to prevent Barrett's esophagus recurrence.

Will I still need to undergo endoscopy (EGD) with biopsy surveillance after undergoing Halo therapy?

Currently, most doctors continue to perform endoscopic biopsy surveillance in patients who have undergone Halo. You should discuss the specific terms of your post-Halo endoscopic biopsy surveillance schedule with your doctor.

Will I still need to take my acid reflux (PPI) medication after undergoing Halo treatment?

Halo treats Barrett's esophagus, not acid reflux. Therefore, your acid reflux will need to be managed after Halo. You and your doctor will decide on the best management strategy based on your individual needs.

Will I still have reflux after undergoing Halo?

Yes. The Halo procedure does not treat acid reflux. Halo treats Barrett's esophagus, which is a change in the cells that line the esophagus that occurs as a result of chronic acid reflux. So, Halo treats Barrett's esophagus, but not its cause. You and your doctor will determine the best management for your reflux after undergoing Halo treatment.

For more information:

- 1. http://www.curebarretts.com/
- 2. <u>http://www.asge.org/PatientInfoIndex.aspx?id=8954</u> -American Society for Gastrointestinal Endoscopy (ASGE)
- 3. <u>http://www.acg.gi.org/patients/gihealth/barretts.asp</u> -The American College of Gastroenterology (ACG)