GERD and Your Treatment Options

EndoGastric Solutions®

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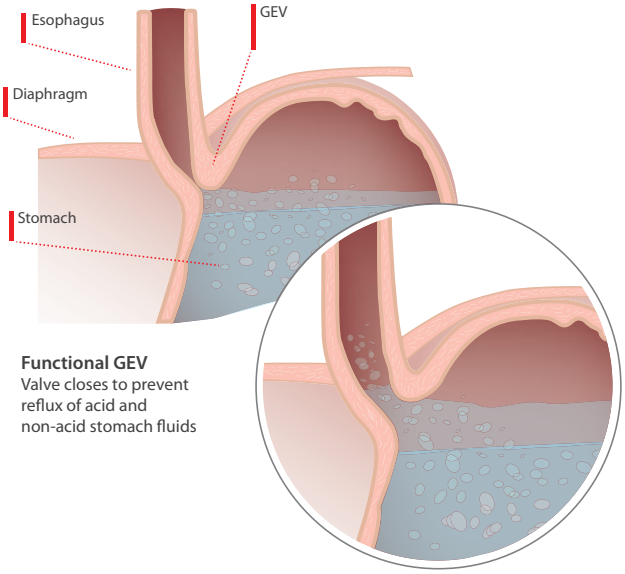
What is GERD?

Gastroesophageal Reflux Disease

- Chronic symptoms or mucosal damage produced by abnormal reflux of gastric contents into the esophagus
- Very common problem: more than 60 million people in the U.S. are affected by GERD
- More than 25% of the adult population experience symptoms each week and nearly 10% experience symptoms daily[1]



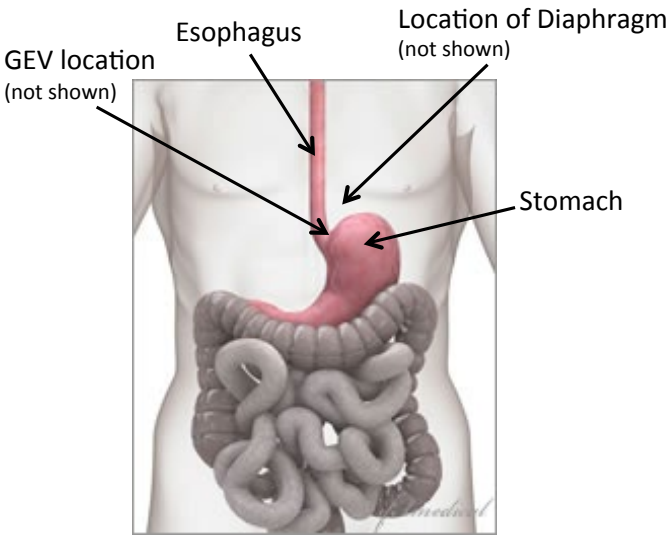
Functional GEV
Valve closes to prevent reflux of acid and non-acid stomach fluids

Dysfunctional GEV
Valve is unable to close, allowing stomach fluids to reflux into esophagus

Anatomy

Digestive Tract

- Esophagus passes food from the mouth to the stomach
- Diaphragm separates chest from abdomen and has a small opening (the hiatus) that allows the esophagus to pass through on its way to connect to the stomach
- The gastroesophageal valve (GEV), located below the diaphragm at the junction of the esophagus and stomach, prevents stomach contents from backwashing into the esophagus



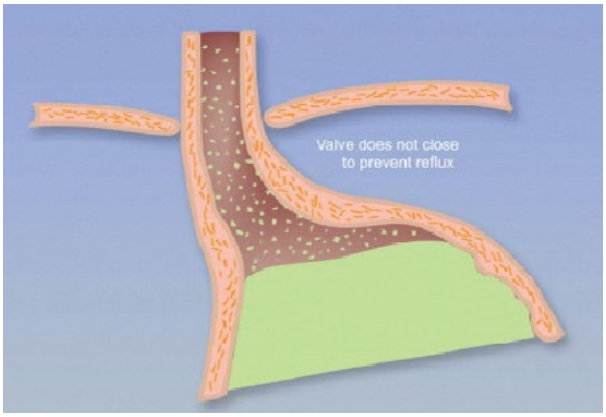
What Causes GERD?

Chemical Causes

Inability of esophagus to tolerate refluxed material due to low acid tolerance, medication use, or ingested substances such as alcohol and tobacco

Anatomical Dysfunction

GEV does not close appropriately, allowing abnormal amounts of acidic and non-acidic contents to backwash into esophagus. For the majority of sufferers, GERD stems from anatomical changes



A disruption of the GEV allows stomach contents to reflux into the esophagus, causing irritation

What Causes GERD?

There are many anatomical changes that can cause GERD and any one or combination of these can result in abnormal exposure to acid reflux.

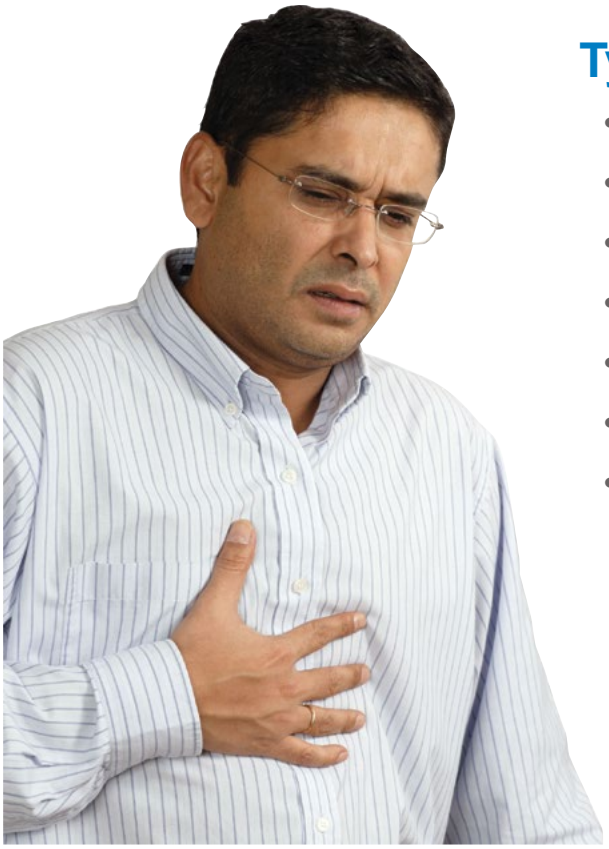
Genetic: Anatomy varies from person to person; some people naturally have less competent valves than others

Injury to Upper Chest: Often the result of a sports-related injury or a traumatic accident, these incidents can cause the valve to lose its shape

Obesity/Diet: Excess weight can cause distortion of normal anatomy

Age: As people age, musculature can lose its integrity and affect gastroesophageal anatomy

Symptoms of GERD



Typical symptoms:

- Heartburn
- Excessive salivation
- Regurgitation
- Gas and bloating
- Pain or discomfort in the chest
- Trouble sleeping
- Intolerance of certain foods and liquids

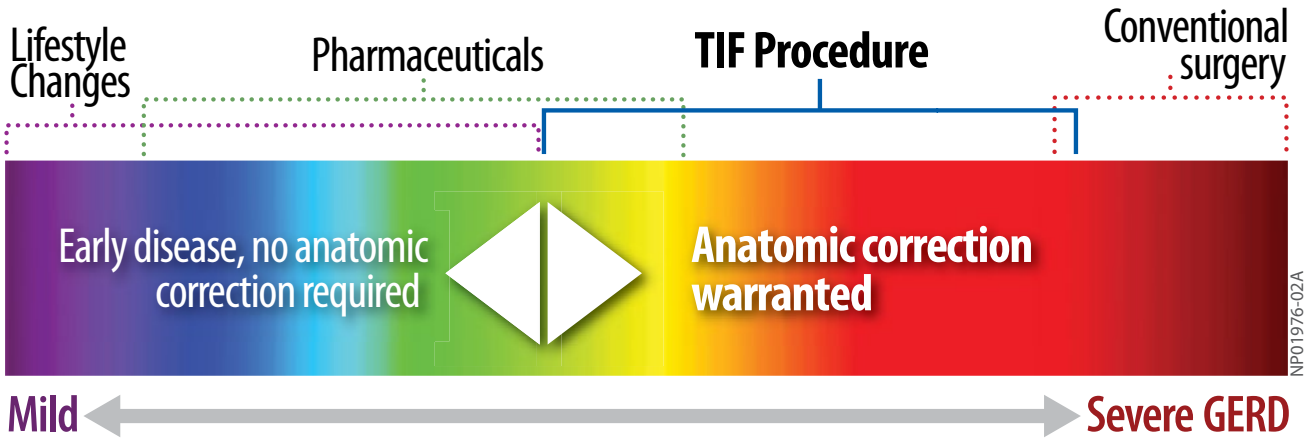
Symptoms of GERD

Other symptoms:

- Dysphagia (difficulty swallowing)
- Bad breath or a sour taste in the mouth
- Hoarseness or laryngitis
- Frequent swallowing
- Asthma or asthma-like symptoms
- Excessive clearing of the throat
- Chronic irritated or sore throat
- Persistent cough
- Burning in the mouth or throat
- Dental erosions or therapy-resistant gum disease or inflammation
- Discomfort in the ears and nose

Treatment Options

The most common treatment options are lifestyle changes and pharmaceuticals. For moderate to severe GERD, a surgical option may be recommended.



Treatment Options

Lifestyle Changes

Avoid foods that can trigger symptoms

- Coffee, tea, or carbonated beverages
- Fatty, fried, or spicy foods
- Citrus fruits, tomatoes, garlic, onions, peppermint, or chocolate

Don’t drink alcohol or smoke tobacco

Raise the head of your bed

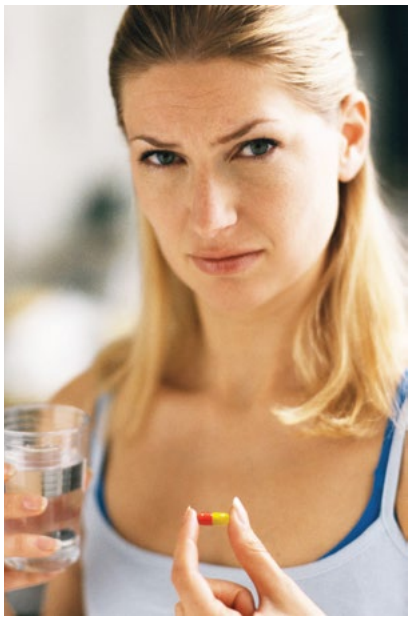
Reduce pressure on the stomach

- Maintain a healthy weight
- Avoiding tight belts and clothing

Treatment Options

Medical Therapy

Medications that buffer or neutralize the acid in the stomach provide temporary relief from intermittent GERD symptoms.



- Proton pump inhibitors (PPIs) prevent the production of acid in the stomach
- With little or no acid, many patients don't feel the symptoms and discomfort from their reflux
- Long-term use of PPIs is associated with side effects such as vitamin B12 deficiency, pneumonia, reduced gallbladder motility, increased risk of osteoporosis fractures, and an increased risk of bacterial gastroenteritis [2-10]
- FDA approved for 8 weeks of use

Treatment Options

Surgery

For many patients, lifestyle changes and/or pharmaceuticals can alleviate GERD symptoms. However, they don't solve the underlying anatomical problem and generally don't stop disease progression.

Surgery may be an appropriate option for patients who are[11]:

- Unable to achieve symptomatic relief with lifestyle changes and medical therapy
- Concerned about the long-term effects or costs associated with medical therapies
- Dissatisfied with lifestyle changes required to control their GERD

Treatment Options

Surgery

Laparoscopic Surgery

- Performed through 3-5 ports (small 5-12 mm incisions) in the abdomen
- Can be performed on patients with any size hiatal hernia
- Patients typically return to work in 1-2 weeks

Incisionless Surgery

- Performed through the mouth with no abdominal incisions
- Option for patients who do not have large hiatal hernias
- Patients typically return to work in less than a week

Treatment Options

Transoral Incisionless Fundoplication (TIF)

The TIF procedure is an incisionless natural orifice surgery (NOS) procedure, based on long-established surgical principles of gold-standard conventional reflux surgery.

Lower-risk solution for patients who:

- No longer adequately respond to or are dissatisfied with pharmaceutical therapies
- Are experiencing heartburn or non-heartburn symptoms of GERD
- Are concerned about long-term effects of a lifetime of taking pills

What is TIF?

The TIF procedure treats the underlying cause of GERD by reconstructing the antireflux valve without incisions.

- The device and an endoscope are gently inserted through the mouth
- The device forms and fastens tissue folds to reconstruct the valve at the junction of the esophagus and stomach

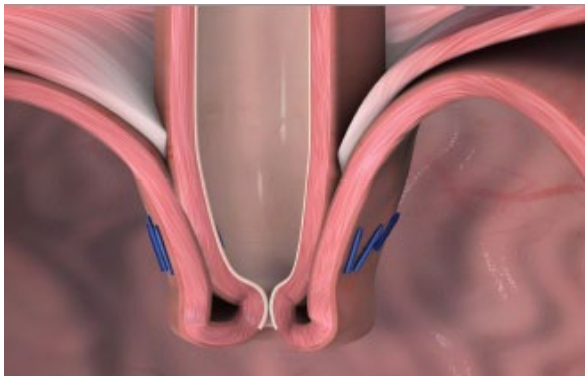


Illustration of a reconstructed esophageal valve after the TIF procedure

TIF Procedure

Similar to conventional fundoplication, the stomach is wrapped around the esophagus to repair anatomical defect

Fasteners are used to secure the reconstructed valve

Reconstructed valve is designed to mimic natural anatomy and minimize side effects such as gas bloat and dysphagia commonly associated with conventional surgery

Results comparable to conventional antireflux surgery with a significantly lower rate of adverse events (2.8% vs. 28.6%)*,[12]

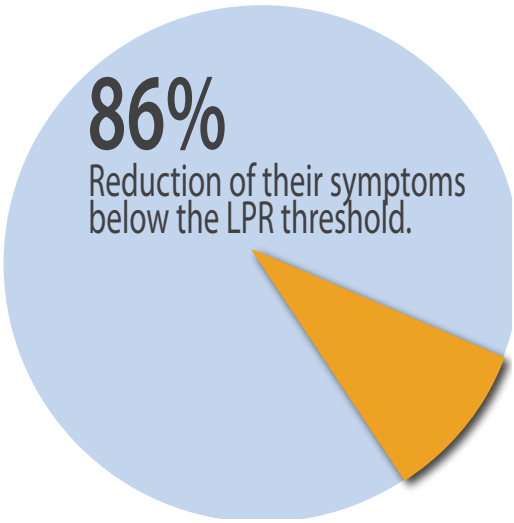
Temporary side effects include sore throat, left shoulder pain, abdominal pain, difficulty swallowing or nausea. Symptoms generally resolve 3-7 days post-procedure.

*Compilation of all applicable peer-reviewed articles published on TIF procedure in which adverse events were assessed and reported. Data on file at EndoGastric Solutions.

Effectiveness of TIF

In recent studies,[13-19] TIF has demonstrated the following results:

- 74% noted a significant improvement in quality of life
- More than 80% of patients were able to discontinue daily medical therapy
- After the procedure, 84% of patients were satisfied with their results



Benefits of TIF

- Addresses the primary cause of GERD – anatomical defect
- No external skin incisions – no scarring
- No internal cutting or dissecting of the natural anatomy – more rapid recovery
- Fewer adverse events and complications than conventional laparoscopic surgery
- Does not limit future treatment options
- Can be revised if required

Indications
The TIF procedure, using the EsophyX device, may be right for you if:
- You are at least 18 years old.
- You have symptomatic chronic gastroesophageal reflux disease (GERD).
- You require and respond to pharmacological therapy.
- You have a hiatal hernia less than or equal to 2cm in size.
- You have a Body Mass Index (BMI) less than 35.

Your surgeon may have other criteria he or she uses to determine whether you are an appropriate candidate. Ask your surgeon to discuss those criteria with you.

Contraindications
The TIF procedure may not be right for you if:
- You have a bleeding disorder, chronic cough, stricture, severe esophagitis, esophageal diverticulae, an obstruction, a paraesophageal hernia, limited neck mobility, osteophytes of the spine, esophageal varices, esophageal infections or fungal disease, or esophageal stenosis.
- You have any kind of normal or abnormal esophageal anatomy which would prohibit insertion of the EsophyX device.
- You cannot adhere to the post-operative diet recommended for appropriate healing.
- You are under 18 years old.
- You have a hiatal hernia greater than 2cm in size.
- You have a BMI greater than 35.
- You are pregnant.

Your surgeon may have other criteria he or she uses to determine whether you are an appropriate candidate. Ask your surgeon to discuss those criteria with you.

Warnings/Precautions
While the TIF procedure is less invasive than conventional laparoscopic fundoplication and has an excellent safety profile, it is important to note that TIF is still a surgical procedure. All surgical procedures have risks. Therefore, it is important to understand the associated risks. Before you decide on a procedure, speak to your surgeon in detail about the risks and complications that may arise. Expected risks or discomforts anticipated as a result of an endoscopic procedure include:
- Pharyngolaryngeal pain (sore throat)
- Musculoskeletal pain (left shoulder pain)
- Temporary epigastric or abdominal pain which can be treated with standard pain medication
- Temporary dysphagia (difficulty swallowing) due to swelling
- Nausea or vomiting

These expected events occur in greater than 25% or more than 25 out of 100 people who have the TIF procedure. They are usually mild in severity and resolve themselves shortly after surgery. Infrequent risks or discomforts as a result of an endoscopic procedure include:
- Oral or dental injury
- Bleeding
- Bloating sensation
- Bruising

These infrequent events occur in 1-10%, or 1-10 out of 100 people who have the TIF procedure. They are usually mild in severity and resolve themselves shortly after surgery.

Rare risks as a result of an endoscopic procedure and of this particular procedure include:
- Esophageal perforation, laceration or tear
- Aspiration, hypoxia or achalasia
- Nerve damage
- Arrythmia (abnormal heartbeat)
- Pneumothorax, chest pain
- Pneumoabdomen
- Fistula
- Infection of the mediastinal space

These events occur in less than 1%, or less than 1 out of 100 people who have the TIF procedure.

Rarely, additional surgeries may be needed to repair an adverse event from the first procedure including: operation to repair an above-mentioned adverse event. These adverse events can be moderate to severe. Additional risks include:
- Reoperation after a failed procedure (insufficient symptom relief)
- Retraction and fastening of tissue other than gastric tissue

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