

Advancing the GERD Care Pathway With Targeted and Timely Referrals

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The Need for an Innovative Approach to Chronic GERD

Gastroesophageal reflux disease (GERD) is a common, chronic, and debilitating esophageal condition that affects approximately 40% of adults in the United States,¹ and according to Raman Muthusamy, MD, MAS, professor of clinical medicine at the David Geffen School of Medicine at UCLA, in Los Angeles, many symptoms are often incompletely managed by the most commonly prescribed pharmacologic therapy for GERD: proton pump inhibitors (PPIs).¹ Not only do more than half of patients who take daily PPIs have refractory symptoms, they are associated with an increased risk for enteric infection, kidney disease, bone fractures, and micronutrient deficiencies.¹⁻⁵ In fact, for patients with symptomatic and confirmed GERD with predominant heartburn symptoms, the American Society for Gastrointestinal Endoscopy (ASGE) recommends “medical management, including PPIs at the lowest possible dose for the shortest possible period of time while initiating discussion about long-term management options.”⁶

Moreover, PPIs work by inhibiting acid production in the parietal cell of the stomach and thus do not address the structural deficiencies underlying the disease.⁷ “When you take a PPI, you’re neutralizing the acid content of the backwash that comes up from the stomach,” Dr Muthusamy said. “But PPIs don’t address the barrier. They don’t stop the liquid from washing up into the throat or even into the lungs, which can cause coughing or asthma or a sore throat.⁸⁻¹⁰ You’re not stopping the reflux with a PPI; you’re just making it less acidic.” Il Joon Paik, MD, the director of the Gastrointestinal Motility Lab at the University of Miami, in Florida, agrees: “PPIs don’t change—can’t change—the flow pattern.”

Traditional Surgical Options Are Not Ideal

Patients may be kept on PPI therapy because of concerns about traditional surgical methods for managing the anti-reflux barrier.¹¹ These surgeries are invasive; associated with potential postoperative complications, which may necessitate a revision; and suitable only for a narrow range of patients.¹²⁻¹⁴ “A common surgery for reflux is Nissen fundoplication,” Dr Muthusamy said.

“It’s a 360-degree fundoplication that’s been associated with a lot of risks.¹⁵ Patients sometimes have difficulty swallowing because of the tightness of the wrap, and difficulty burping, which leads to gas bloat.^{11,15} There are a lot of fears associated with these side effects.”

A Transformative Approach to GERD Management: TIF 2.0

Transoral incisionless fundoplication (TIF) 2.0 is a minimally invasive endoscopic outpatient procedure that reconstructs the gastroesophageal flap, addressing the root cause of reflux.^{13,16} A durable treatment option that fills the gap between PPI therapy and traditional anti-reflux surgeries, TIF 2.0 helps to elongate, strengthen, and tighten the lower esophageal sphincter by creating a 3-cm, 270-degree esophagogastric fundoplication (Figure 1).^{13,17-19} “A straightforward TIF 2.0 without surgery is an option for patients who have very small hiatal hernias—2 cm or less and a Hill grade classification of 2 or less—especially when they have reflux symptoms and proper esophageal peristalsis,” Dr Paik said.¹⁸ Patients with a hiatal hernia larger than 2 cm axially or a Hill grade of 3 or 4 may be eligible for the consecutive TIF 2.0 (cTIF) procedure, which consists of a hiatal hernia repair followed by a TIF procedure under a single anesthesia setting.^{6,11,13} Dr Paik’s approach is consistent with the 2024 ASGE guidelines on the diagnosis and management of GERD.⁶

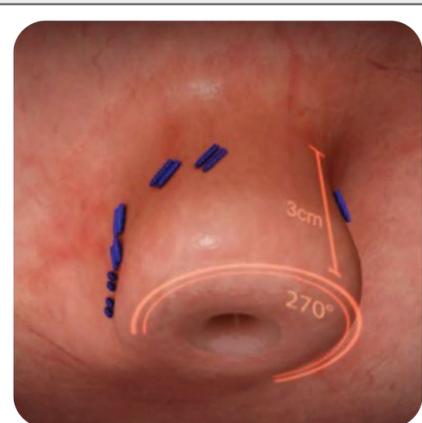


Figure 1. The transoral incisionless fundoplication 2.0 procedure addresses the root cause of GERD by reconstructing the gastroesophageal flap valve with up to a 3-cm, 270-degree esophagogastric fundoplication, depending on patient anatomy.

GERD, gastroesophageal reflux disease. Based on references 13, 18, and 19.

Making the Case for TIF 2.0 and cTIF Referral

The efficacy of TIF 2.0 in alleviating GERD symptoms, including heartburn and regurgitation, has been demonstrated by research.^{17,20,21} “Clinical outcomes are quite good,” Dr Muthusamy said. “Randomized controlled trials show that about 80% of patients will have a good response, revealed by both subjective and objective parameters, like quality of life and pH testing.^{17,22} About 65% to 75% of patients will be able to come off their medications, which is pretty respectable. Some fraction will require pharmacologic therapy again, but by and large, patients are satisfied.”^{17,22} In fact, a 2015 trial found that 6 months after the TIF procedure, reflux esophagitis healed in 77% of patients diagnosed with the condition at screening,²³ and a 2018 trial with 5 years of follow-up for TIF 2.0 demonstrated an 80% reduction in atypical symptoms and improvements in the proportion of patients who no longer required daily PPIs (66%) and who achieved sustained regurgitation elimination (86%).¹⁷

More recent data further corroborate these results. A 2025 prospective multicenter cohort study enrolled 85 patients with a hiatal hernia less than 2 cm, a body mass index under 35 kg/m², and confirmed GERD with typical or atypical symptoms to undergo the TIF 2.0 procedure.²⁴ Outcomes were assessed at the last follow-up after the procedure within 12 months.²⁴ Compared with baseline, results showed a significant reduction in symptoms scores as assessed by the GERD Health-Related Quality of Life (31 vs 4) and the Reflux Symptom Index (14 vs 3) questionnaires and increases in the proportion of patients either not, or occasionally, taking PPIs (19% vs 80%) and exhibiting normal esophageal acid exposure time (14% vs 72%) (Figure 2).²⁴ There were no serious adverse events.²⁴

TIF 2.0 has also been shown to result in less dysphagia and gas bloat compared with traditional anti-reflux surgeries.^{11,13,15} In addition, TIF 2.0 is amenable to repeat procedures in a way that traditional surgery is not. “Doing a revision of a TIF 2.0 procedure is much more practical and straightforward than redoing a Nissen fundoplication,” Dr Muthusamy said.^{11,25,26} “That’s a major advantage because regardless of treatment approach, symptoms will return for a fraction of patients.”²⁷ According to Dr Paik, “Many times, we’re able to fix issues from other procedures with TIF 2.0. If there’s no re-herniation, we can repeat an endoscopic TIF 2.0 and tailor the valve to be a little tighter. With a Nissen, a patient often can’t have a second surgery. So, we’re avoiding a lot of potential problems because we have options now for tailoring the anti-reflux barrier.”^{18,28} Both physicians agreed that with timely referrals, patients may avoid surgery altogether. That is, patients who are referred for advanced treatment earlier in their disease state may need to have only the TIF 2.0 procedure and not the cTIF procedure.¹⁶

More Patients Could Benefit From Advanced GERD Treatment

Despite the availability of these safe and effective approaches to managing refractory GERD, many gastroenterologists are reluctant to refer patients for advanced GERD treatments, such as TIF 2.0 and cTIF.^{13,17,22,29} “Providers may not be aware that there are options outside

of Nissen fundoplication,” Dr Muthusamy noted.

Clinicians may also have a bias against advanced GERD treatments, such as the cTIF procedure based on previous unsuccessful endoscopic methods.²⁹ “A lot of gastroenterologists and surgeons won’t recommend a hiatal hernia repair for patients who have a very weak esophagus and so have issues with swallowing to begin with. That explains much of the referral hesitation,” Dr Paik said. “But the benefit of TIF 2.0 is that you can tailor the wrap based on the strength of the esophagus, so that it doesn’t become too restrictive. It enables you to create the optimal anti-reflux barrier.”¹⁸

A Wide Range of Candidates

Considering the large proportion of patients on PPIs who experience refractory GERD symptoms, it is likely that physicians have many patients in their practices who are appropriate for referral for these safe and effective procedures.^{1,13,17} According to Drs Muthusamy and Paik, many patients are unaware of these options. Appropriate patients include those who:

- are reliant on PPIs and continue to experience symptoms^{1,17,18,20,21};
 - have been using PPIs for more than 1 year²;
 - have concerns about the long-term use of PPIs²; and
 - experience significantly diminished quality of life.¹⁷
- Clinicians can better identify appropriate candidates for TIF 2.0 and cTIF by considering relevant ICD-10 codes, including³⁰:
- K21.0 GERD with esophagitis
 - K21.9 GERD without esophagitis
 - K30 functional dyspepsia
 - R10.13 epigastric pain
 - K44.9 diaphragmatic hernia without obstruction or gangrene
 - R12 heartburn

“Five years ago, the University of Miami system was doing fewer than 12 hiatal hernia repairs per year,” Dr Paik said. “We’re doing around 300 procedures now, and 90% of our surgeries are cTIF. The ability to tailor the anti-reflux barrier is a huge benefit.”

Referral Best Practices

DR PAIK

“I perform an esophageal reflux evaluation for patients with chronic GERD who are experiencing symptoms. I recommend esophageal manometry and some type of reflux testing for patients, like 24-hour pH monitoring or the wireless pH capsule. Based on those studies and looking at pathologic acid reflux and the extent and duration of reflux, and also at esophageal function, we discuss the cases in our Multidisciplinary Reflux Program; then, I perform the TIF 2.0 or cTIF. Those are first candidates for considering these treatments, especially if they’re interested in having the procedure. For other patients, we need to understand end-organ damage and carefully consider concerns of reflux causing aspiration, especially with large hiatal hernias. We also consider patients with dysphagia secondary to obstructive hiatal hernias. We pay special attention to those patients who can end up with lung damage and pulmonary dysfunction due to reflux.”

DR MUTHUSAMY

“I start off with a consultation where I answer questions and review the workup, procedure, recovery, and long-term results. If the patient wants to proceed, we complete the workup and continue with scheduling. A multidisciplinary approach is important, so that patients get the best menu of approaches. There are complex situations, so we have a case conference where we present the more challenging cases together. We get

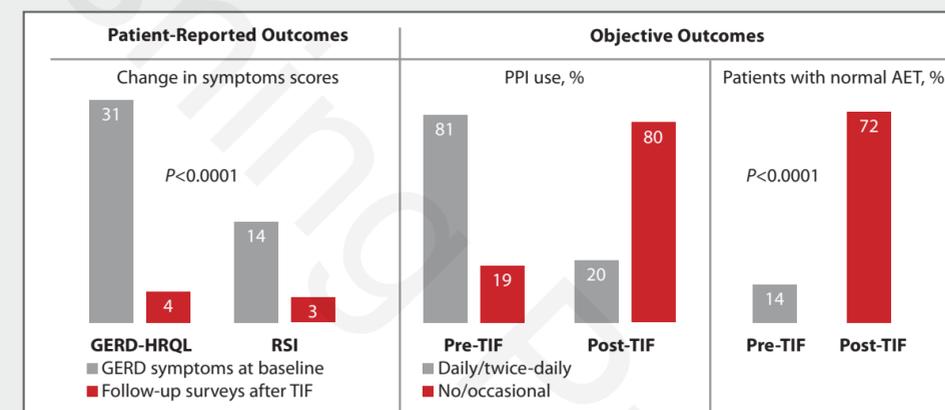


Figure 2. The TIF 2.0 procedure resulted in significant improvements in symptom scores, PPI use, and normal esophageal AET.

AET, acid exposure time; GERD, gastroesophageal reflux disease; HRQL, health-related quality of life; PPI, proton pump inhibitor; RSI, Reflux Symptom Index; TIF, transoral incisionless fundoplication.

Reprinted from *Gastrointest Endosc*, 101(1), Canto MI, Diehl DL, Parker B, et al, Outcomes of transoral incisionless fundoplication (TIF 2.0): a prospective multicenter cohort study in academic and community gastroenterology and surgery practices (with video), 90-102, 2025, with permission from Elsevier.

Based on reference 24.

opinions from gastroenterologists, motility experts, and surgeons. We try to tailor treatment and provide the best option for each patient.”

Conclusion

The TIF 2.0 and cTIF procedures are durable treatment options for appropriate patients with GERD who require and respond to PPI therapy, that address some of the deficiencies of traditional anti-reflux surgeries.^{13,16-18} These are effective options with few side effects and are appropriate for a broad range of patients.^{13,17,22} Drs Muthusamy and Paik emphasize the importance of increasing awareness of the clinical benefits of these advanced procedures to overcome referral resistance and improve the health and quality of life of more patients.^{17,20,21,23,29} In fact, Dr Muthusamy sees a shift already underway. “It’s clear there has been increased demand for TIF 2.0,” he said.

References

1. Delshad SD, et al. *Gastroenterology*. 2020;158(5):1250-1261.
2. Lehalt WB, et al. *Fed Pract*. 2017;34(2):19-23.
3. Lazarus B, et al. *JAMA Intern Med*. 2016;176(2):238-246.
4. Khalili H, et al. *BMJ*. 2012;304:e372.
5. Lam JR, et al. *JAMA*. 2013;310(22):2435-2442.
6. Desai M, et al. *Gastrointest Endosc*. 2024 Dec 17: S0016-5107(24)03559-4.
7. Ahmed A, et al. Proton pump inhibitors (PPI). In: *StatPearls* [internet]. 2023.
8. Wu J, et al. *Front Physiol*. 2022;20:13:1005404.
9. Ates F, et al. *Gastroenterol Hepatol (N Y)*. 2014;10(11):729-736.
10. Richter JE. *Eur J Gastroenterol Hepatol*. 2004;16(9):837-845.
11. Jaruvongvanich VK, et al. *Endosc Int Open*. 2023;11(1): E11-E18.
12. Perry KA. *J Am Coll Surg*. 2021;232(3):318-319.
13. Janu P, et al. *Surg Innov*. 2019;26(6):675-686.
14. Celasin H, et al. *Medicine (Baltimore)*. 2017;96(1):e5779.
15. Nguyen NT, et al. *Surg Endosc*. 2021;35(6):3214-3220.
16. Ihde GM. *Therap Adv Gastroenterol*. 2020; 21:13: 1756284820924206.
17. Trad KS, et al. *Surg Innov*. 2018;25(2):149-157.
18. Bazerbachi F, et al. *Gastrointest Endosc*. 2019;90(3):370-383.
19. Aslam N, et al. *Frontline Gastroenterol*. 2023;14(3):249-257.
20. Haseeb M, et al. *Gastrointest Endosc*. 2023;97(3):394-406.
21. Testoni S, et al. *Endosc Int Open*. 2021;9(2):E239-E246.
22. Trad KS, et al. *Surg Endosc*. 2017;31(6):2498-2508.
23. Hunter JG, et al. *Gastroenterology*. 2015;148(2):324-333.
24. Canto MI, et al. *Gastrointest Endosc*. 2025;101(1):90-102.
25. Furnée EJB, et al. *J Gastrointest Surg*. 2009;13(8):1539-1549.
26. Bell RCW, et al. *Surg Endosc*. 2015;29(7):1746-1752.
27. Robinson B, et al. *Surg Endosc*. 2015;29(9):2520-2524.
28. Ghosh G, et al. *Surg Endosc*. 2023;37(5):3701-3709.
29. Fass R. *Gastroenterol Hepatol (N Y)*. 2017;13(1):50-52.
30. EndoGastric Solutions. Reimbursement codes. Accessed February 27, 2025. www.endogastricsolutions.com/providers/support/reimbursement-coding-for-tif-procedure-with-esophyx-device/

Disclosures: Dr Muthusamy has received research support from CDx Diagnostics. He is a consultant to and/or has received honoraria from Boston Scientific, Castle Biosciences, Medtronic, and Pentax Medical. He has stock options in Capsovision. Dr Paik reported no relevant financial disclosures.

Merit Medical defines the term “cTIF” as a consecutive transoral incisionless fundoplication, which consists of a hiatal hernia repair followed by a transoral incisionless fundoplication procedure under a single anesthesia setting.