

RESPECT Randomized Controlled Trial Efficacy of Transoral Fundoplication vs Omeprazole for Treatment of Regurgitation



BACKGROUND

Transoral esophagogastric fundoplication (TF) can decrease or eliminate features of gastroesophageal reflux disease (GERD) in some patients whose symptoms persist despite proton pump inhibitor (PPI) therapy. We performed a prospective, sham-controlled trial to determine if TF reduced troublesome regurgitation to a greater extent than PPIs in patients with GERD.

METHODS

We screened 696 patients with troublesome regurgitation despite daily PPI use with 3 validated GERD specific symptom scales, on and off PPIs. Patients with GERD and hiatal hernias ≤ 2 cm were randomly assigned to groups that underwent TF and then received 6 months of placebo (n = 87), or sham surgery and 6 months of once- or twice-daily Omeprazole (controls, n = 42). Patients were blinded to therapy during follow-up period and reassessed at 2, 12, and 26 weeks. At 6 months, patients underwent 48-hour esophageal pH monitoring and esophagogastroduodenoscopy.

RESULTS

By intention-to-treat analysis, TF eliminated troublesome regurgitation in a larger proportion of patients (67%) than PPIs (45%) (P = 0.05). Control of esophageal pH improved after TF (P < .001), but not after sham surgery (mean 8.6% before and 8.9% after). Subjects from both groups who completed the protocol had similar reductions in GERD symptom scores. Severe complications were rare (3 subjects receiving TF and 1 receiving the sham surgery).

CONCLUSION

TF was an effective treatment for patients with GERD symptoms, particularly in those with persistent regurgitation despite PPI therapy, based on evaluation 6 months after the procedure.

KEY POINTS

1. Troublesome regurgitation was eliminated in 72% of TIF patients at >1Y.
2. Median heartburn score decreased from 17 to 5 at 6 months and to 3 at >1Y post-TIF.
3. Complete cessation of PPI therapy was achieved in 72% of TIF patients >1Y.
4. Normalized in 69% of patients.
5. A multi-center, randomized single-blind, controlled TIF/Placebo vs. Sham/PPIs trial.
6. 2:1 ratio TIF/Placebo group (n=80) vs. Sham/PPI group (n=40).
7. Compare safety and effectiveness of TIF vs. Sham/PPI's in patients with "troublesome symptoms" specifically regurgitation.
8. Duration of study: 6 months, 1 year w/crossover (abstract).

Hunter, JG,
Kahrilas, PJ
Bell, RC
Wilson, EB
Trad, KS
Dolan, JP

Perry, KA
Oelschlager, BK
Soper, NJ
Snyder, BE
Burch, MA

Melvin, WS
Reavis, KM
Turgeon, DG
Hungness, ES
Diggs, BS

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[https://www.gastrojournal.org/article/S0016-5085\(14\)01208-6/fulltext](https://www.gastrojournal.org/article/S0016-5085(14)01208-6/fulltext)

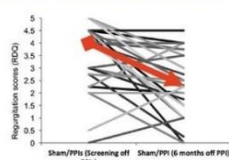
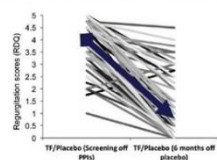
Learn more about the TIF® Procedure for Reflux



67% TIF/Placebo (off PPI)
elimination of regurgitation

p = 0.023

SHAM/High Dose PPI **45%**
elimination of regurgitation

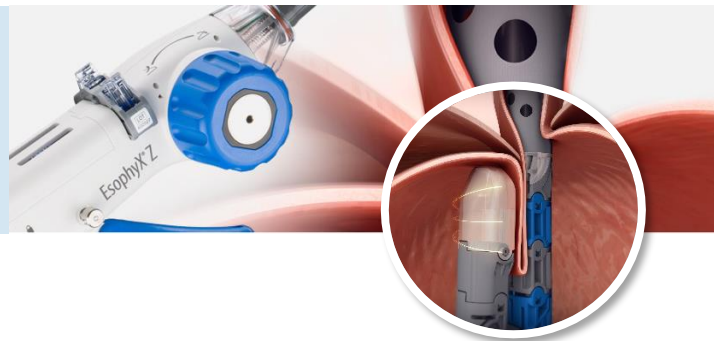


TIF procedure provided clinically significant greater reduction in regurgitation scores vs. the sham group using Reflux Disease Questionnaire (RDQ).

Reference: Hunter, et al. *Gastroenterology*. 2015 Feb;148(1):324-33.



Data Supports GERD Treatment Gap Option

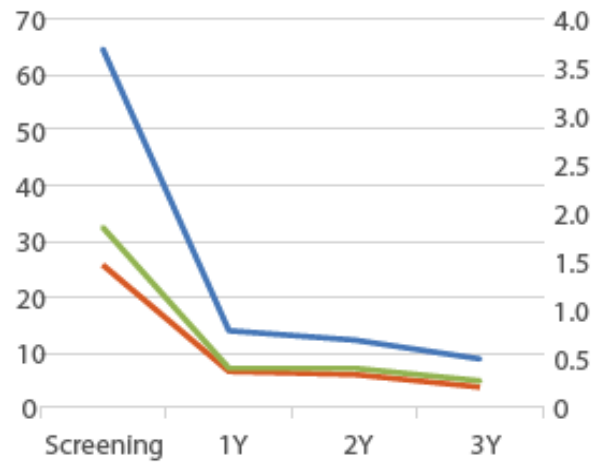


3 Year TIF Procedure Durability

In the randomized controlled trial TEMPO at three year follow-up⁷

- All symptom scores improved significantly after the TIF procedure as measured by validated questionnaires off PPIs
- No significant change between 1, 2 or 3 year follow-up points
- Number of TEMPO patients evaluated: 60 at 1 year, 55 at 2 year, 52 at 3 year

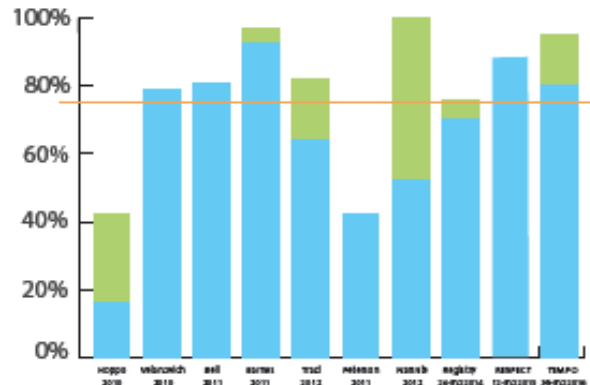
- RDQ – Reflux Disease Questionnaire (right-side axis)
- GERD-HRQL – GERD Health Related Quality of Life (left-side axis)
- RSI – Reflux Symptom Index (left-side axis)



75% of TIF Patients Off PPIs^{6-14,16}

- Weighted average % of patients completely off PPIs
- 75% completely off PPIs; 8% occasional use
- 10 studies; n=527 patients (weighted average follow-up at 13 mos.)

- Post-TIF PPI Use (Completely Off)
- Post-TIF PPI Use (Occasional)



82% of TIF Patients' Esophagitis Healed^{6,7,11,15}

- Weighted average % of patients esophagitis completely healed
- 82% completely healed; 4% improved
- 4 studies; n=82 patients (weighted average follow-up at 18 mos.)

- Completely Healed
- Improved 1 Grade

