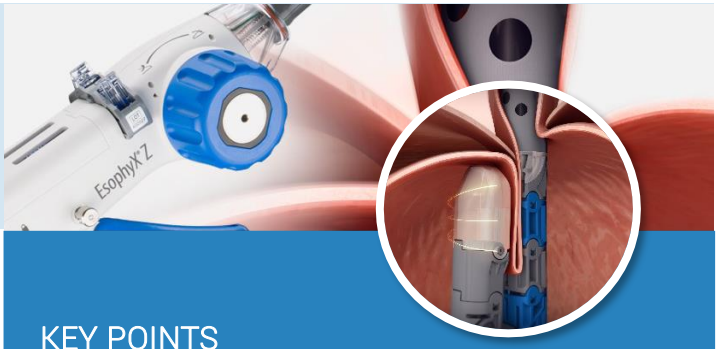
ABSTRACT

Transoral Incisionless Fundoplication vs. Sham Intervention to Control Chronic GERD: Transoral Incisionless Fundoplication (TIF 2.0) is effective in chronic PPI-dependent GERD patients when followed up for 6 months



BACKGROUND

Until recently only two therapeutic options have been available to control symptoms and esophagitis in chronic gastro-esophageal reflux disease (GERD), i.e. lifelong proton pump inhibitor (PPI) therapy or anti-reflux surgery. The Transoral Incisionless Fundoplication procedure (TIF 2.0) has been developed and found to offer a therapeutic alternative for these patients.

METHODS

Patients studied were objectively confirmed with GERD and persistent moderate to severe GERD symptoms and without PPI therapy. Of 121 screened patients, 44 were randomized with 22 patients in each group. Those allocated to TIF had the TIF 2.0 procedure completed during general anesthesia by the EsophyX device with SerosaFuse fasteners. The sham procedure consisted of upper GI endoscopy under general anesthesia. Neither the patient nor the assessor was aware of the patients' group affiliation. The primary effectiveness endpoint was the proportion of patients in clinical remission after 6-month follow-up. Secondary outcomes were: PPI consumption, esophageal acid exposure, reduction in Quality of Life in Reflux and Dyspepsia, and Gastrointestinal Symptom Rating Scale scores and healing of reflux esophagitis.

RESULTS

After 6 months 13/22 (59%) of the chronic GERD patients remained in clinical remission after the active intervention. Likewise, the secondary outcome measures were all in favor of the TIF 2.0 procedure. No safety issues were raised.

CONCLUSION

Transoral Incisionless Fundoplication (TIF 2.0) is effective in chronic PPI-dependent GERD patients when followed up for 6 months. Clinicaltrials.gov: CT01110811.

KEY POINTS

1. At 69% of the TIF group normalized esophageal acid exposure vs 20% of the sham group. Improvement in pH parameters remained stable at 3Y follow-up
2. A multi-center, double-blind, sham controlled randomized trial
3. 1:1 ratio TIF group (n=22) vs sham group (n=22)
4. Duration of study: 6 months
5. Objective of study was to gauge time to "treatment failure" during first 6 months after intervention
6. No safety issues were reported

B. Håkansson, E. Coron, M. Montgomery, J. Tack, G.B. Cadiere, R. Bischops, A. Rajan, A. Thorell, S. Bruley des Varannes, U. Arnelo, M. Lerhun, L. Lundell

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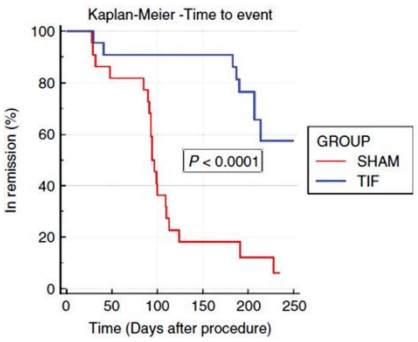
https://www.ncbi.nlm.nih.gov/pubmed/26463242



Time in clinical remission after either TIF procedure or sham intervention during the 6 months of follow-up

Reference: Håkansson B, et al; Aliment Pharmacol Ther. 2015 Dec; 42(11-12):1261-70

Learn more about the TIF® Procedure for Reflux

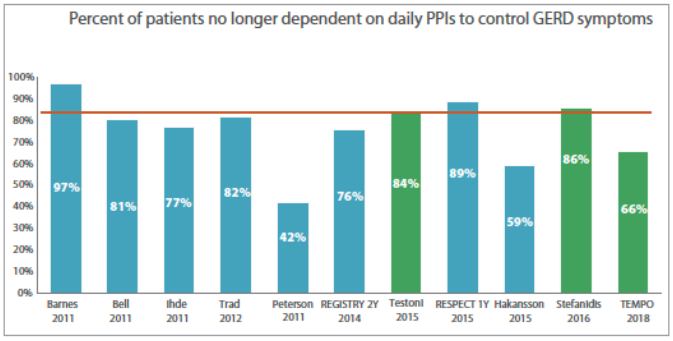
TIF® PROCEDURE FOR REFLUX

EndoGastric Solutions, Inc. 18109 NE 76th Street, Suite 100 Redmond, WA 98052 (425) 307-9200

Data Supports GERD Treatment Gap Option

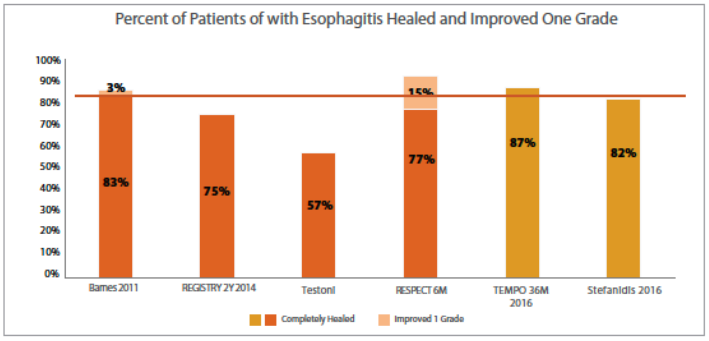
81% of TIF patients no longer use PPIs daily

84% Esophagitis healed or improved one grade



Weighted incidence is 81.41% across 11 studies with follow-up > 6mo in 568 patients

Weighted incidence is 78.35% across 3 studies follow-up > 59 mo in 120 patients

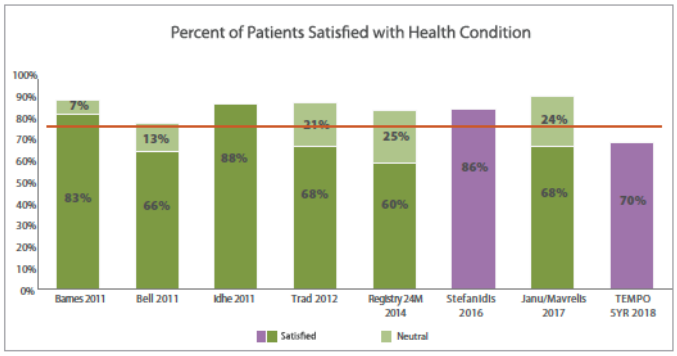


Weighted incidence is 80.25% across 6 studies follow-up > 6mo in 122 patients)

Weighted incidence is 83.94% across 2 studies follow-up > 36mo in 56 patients)

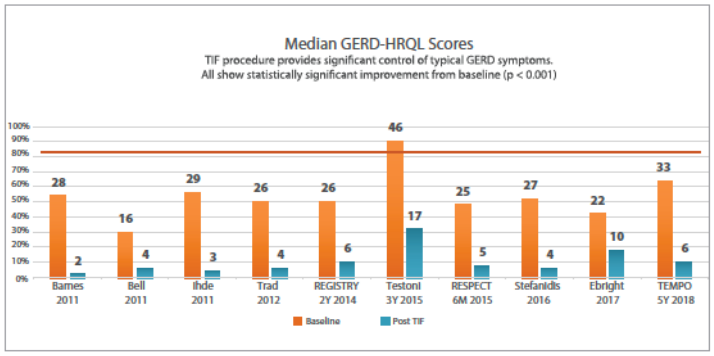
78% of TIF patients were satisfied with their health condition

81% Significantly improved quality of life scores



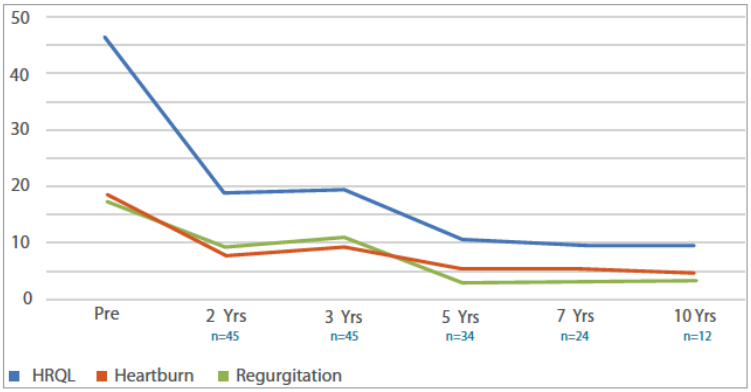
Weighted incidence is 73.1% across 8 studies follow-up > 6mo in 495 patients)

Weighted incidence is 78.4% across 2 studies follow-up > 59mo in 88 patients)



In the 10 studies where the follow-up was >=6 months, the weighted average percent reduction in the median score from the pre-study median baseline was 80.81%

TIF Procedure Delivers 10-Year Durability



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